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Dossier zur Nutzenbewertung gemäß § 35a SGB V

Abrocitinib (Cibinqo®)

Pfizer Europe MA EEIG
als örtlicher Vertreter des Zulassungsinhabers
Pfizer Europe MA EEIG

Modul 4 A

Behandlung von mittelschwerer bis schwerer atopischer Dermatitis bei Jugendlichen ab einem Alter von 12 Jahren, die für eine systemische Therapie infrage kommen

Medizinischer Nutzen und medizinischer Zusatznutzen, Patient:innengruppen mit therapeutisch bedeutsamem Zusatznutzen

Stand: 18.04.2024

Anhang 4-G: Zusatzanalysen

Responderanalysen JADE DARE (Woche 26)

Proportion of Subjects Achieving EASI Response >= 75% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Age group (<40, >=40)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: <40	Baseline, N	230	247
	Week 26, N	230	247
	Number of Subjects with observed Case, N1 (%)	185 (80.4)	220 (89.1)
	Number of Subjects with NRI, N2 (%)	45 (19.6)	27 (10.9)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	154 (67.0)	179 (72.5)
	95% CI	(60.9, 73.0)	(66.9, 78.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9239	
	95% CI	(0.8203, 1.0406)	
	Two-sided P-value	0.1923	
Age (years) group: >=40	Baseline, N	132	118
	Week 26, N	132	118
	Number of Subjects with observed Case, N1 (%)	116 (87.9)	104 (88.1)
	Number of Subjects with NRI, N2 (%)	16 (12.1)	14 (11.9)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving EASI Response >= 75% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Age group (<40, >=40)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: >=40	Responders, n (%)	100 (75.8)	82 (69.5)
	95% CI	(68.4, 83.1)	(61.2, 77.8)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0902	
	95% CI	(0.9349, 1.2712)	
	Two-sided P-value	0.2707	
	P-value of interaction	0.0951	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
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P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving EASI Response >= 75% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Sex

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Sex: Male	Baseline, N	193	204
	Week 26, N	193	204
	Number of Subjects with observed Case, N1 (%)	169 (87.6)	180 (88.2)
	Number of Subjects with NRI, N2 (%)	24 (12.4)	24 (11.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	137 (71.0)	134 (65.7)
	95% CI	(64.6, 77.4)	(59.2, 72.2)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0807	
	95% CI	(0.9451, 1.2357)	
	Two-sided P-value	0.2568	
Sex: Female	Baseline, N	169	161
	Week 26, N	169	161
	Number of Subjects with observed Case, N1 (%)	132 (78.1)	144 (89.4)
	Number of Subjects with NRI, N2 (%)	37 (21.9)	17 (10.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
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Proportion of Subjects Achieving EASI Response >= 75% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Sex

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Sex: Female	Responders, n (%)	117 (69.2)	127 (78.9)
	95% CI	(62.3, 76.2)	(72.6, 85.2)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.8776	
	95% CI	(0.7719, 0.9979)	
	Two-sided P-value	0.0464	
	P-value of interaction	0.0280	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving EASI Response >= 75% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Region of enrollment: US/Canada/Australia	Baseline, N	177	195
	Week 26, N	177	195
	Number of Subjects with observed Case, N1 (%)	142 (80.2)	169 (86.7)
	Number of Subjects with NRI, N2 (%)	35 (19.8)	26 (13.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	118 (66.7)	136 (69.7)
	95% CI	(59.7, 73.6)	(63.3, 76.2)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9559	
	95% CI	(0.8316, 1.0987)	
	Two-sided P-value	0.5255	
Region of enrollment: Europe	Baseline, N	150	132
	Week 26, N	150	132
	Number of Subjects with observed Case, N1 (%)	130 (86.7)	122 (92.4)
	Number of Subjects with NRI, N2 (%)	20 (13.3)	10 (7.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving EASI Response >= 75% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Region of enrollment: Europe	Responders, n (%)	111 (74.0)	94 (71.2)
	95% CI	(67.0, 81.0)	(63.5, 78.9)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0391	
	95% CI	(0.8997, 1.2002)	
	Two-sided P-value	0.6014	
Region of enrollment: Asia	Baseline, N	17	19
	Week 26, N	17	19
	Number of Subjects with observed Case, N1 (%)	15 (88.2)	18 (94.7)
	Number of Subjects with NRI, N2 (%)	2 (11.8)	1 (5.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	11 (64.7)	16 (84.2)
	95% CI	(42.0, 87.4)	(67.8, 100.0)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving EASI Response >= 75% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.7684	
	95% CI	(0.5143, 1.1480)	
	Two-sided P-value	0.1983	
Region of enrollment: Latin America	Baseline, N	18	19
	Week 26, N	18	19
	Number of Subjects with observed Case, N1 (%)	14 (77.8)	15 (78.9)
	Number of Subjects with NRI, N2 (%)	4 (22.2)	4 (21.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	14 (77.8)	15 (78.9)
	95% CI	(58.6, 97.0)	(60.6, 97.3)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9852	
	95% CI	(0.7020, 1.3827)	
	Two-sided P-value	0.9312	
	P-value of interaction	0.5379	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving EASI Response >= 75% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Baseline disease severity

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline disease severity: Moderate	Baseline, N	216	220
	Week 26, N	216	220
	Number of Subjects with observed Case, N1 (%)	178 (82.4)	195 (88.6)
	Number of Subjects with NRI, N2 (%)	38 (17.6)	25 (11.4)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	159 (73.6)	160 (72.7)
	95% CI	(67.7, 79.5)	(66.8, 78.6)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0122	
	95% CI	(0.9034, 1.1340)	
	Two-sided P-value	0.8350	
Baseline disease severity: Severe	Baseline, N	146	145
	Week 26, N	146	145
	Number of Subjects with observed Case, N1 (%)	123 (84.2)	129 (89.0)
	Number of Subjects with NRI, N2 (%)	23 (15.8)	16 (11.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving EASI Response >= 75% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Baseline disease severity

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline disease severity: Severe	Responders, n (%)	95 (65.1)	101 (69.7)
	95% CI	(57.3, 72.8)	(62.2, 77.1)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9342	
	95% CI	(0.7959, 1.0965)	
	Two-sided P-value	0.4047	
	P-value of interaction	0.4236	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
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P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving EASI Response >= 90% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Age group (<40, >=40)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: <40	Baseline, N	230	247
	Week 26, N	230	247
	Number of Subjects with observed Case, N1 (%)	185 (80.4)	220 (89.1)
	Number of Subjects with NRI, N2 (%)	45 (19.6)	27 (10.9)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	114 (49.6)	113 (45.7)
	95% CI	(43.1, 56.0)	(39.5, 52.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0834	
	95% CI	(0.8975, 1.3078)	
	Two-sided P-value	0.4042	
Age (years) group: >=40	Baseline, N	132	118
	Week 26, N	132	118
	Number of Subjects with observed Case, N1 (%)	116 (87.9)	104 (88.1)
	Number of Subjects with NRI, N2 (%)	16 (12.1)	14 (11.9)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
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Proportion of Subjects Achieving EASI Response >= 90% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Age group (<40, >=40)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: >=40	Responders, n (%)	76 (57.6)	59 (50.0)
	95% CI	(49.1, 66.0)	(41.0, 59.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1515	
	95% CI	(0.9127, 1.4527)	
	Two-sided P-value	0.2341	
	P-value of interaction	0.6895	

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P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving EASI Response >= 90% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Sex

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Sex: Male	Baseline, N	193	204
	Week 26, N	193	204
	Number of Subjects with observed Case, N1 (%)	169 (87.6)	180 (88.2)
	Number of Subjects with NRI, N2 (%)	24 (12.4)	24 (11.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	95 (49.2)	83 (40.7)
	95% CI	(42.2, 56.3)	(33.9, 47.4)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.2098	
	95% CI	(0.9718, 1.5061)	
	Two-sided P-value	0.0883	
Sex: Female	Baseline, N	169	161
	Week 26, N	169	161
	Number of Subjects with observed Case, N1 (%)	132 (78.1)	144 (89.4)
	Number of Subjects with NRI, N2 (%)	37 (21.9)	17 (10.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
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Proportion of Subjects Achieving EASI Response >= 90% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Sex

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Sex: Female	Responders, n (%)	95 (56.2)	89 (55.3)
	95% CI	(48.7, 63.7)	(47.6, 63.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0169	
	95% CI	(0.8389, 1.2326)	
	Two-sided P-value	0.8645	
	P-value of interaction	0.2428	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving EASI Response >= 90% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Region of enrollment: US/Canada/Australia	Baseline, N	177	195
	Week 26, N	177	195
	Number of Subjects with observed Case, N1 (%)	142 (80.2)	169 (86.7)
	Number of Subjects with NRI, N2 (%)	35 (19.8)	26 (13.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	88 (49.7)	89 (45.6)
	95% CI	(42.4, 57.1)	(38.6, 52.6)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0893	
	95% CI	(0.8802, 1.3480)	
	Two-sided P-value	0.4314	
Region of enrollment: Europe	Baseline, N	150	132
	Week 26, N	150	132
	Number of Subjects with observed Case, N1 (%)	130 (86.7)	122 (92.4)
	Number of Subjects with NRI, N2 (%)	20 (13.3)	10 (7.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving EASI Response >= 90% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Region of enrollment: Europe	Responders, n (%)	83 (55.3)	60 (45.5)
	95% CI	(47.4, 63.3)	(37.0, 53.9)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.2173	
	95% CI	(0.9616, 1.5410)	
	Two-sided P-value	0.1021	
Region of enrollment: Asia	Baseline, N	17	19
	Week 26, N	17	19
	Number of Subjects with observed Case, N1 (%)	15 (88.2)	18 (94.7)
	Number of Subjects with NRI, N2 (%)	2 (11.8)	1 (5.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	6 (35.3)	10 (52.6)
	95% CI	(12.6, 58.0)	(30.2, 75.1)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving EASI Response >= 90% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.6706	
	95% CI	(0.3098, 1.4515)	
	Two-sided P-value	0.3104	
Region of enrollment: Latin America	Baseline, N	18	19
	Week 26, N	18	19
	Number of Subjects with observed Case, N1 (%)	14 (77.8)	15 (78.9)
	Number of Subjects with NRI, N2 (%)	4 (22.2)	4 (21.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	13 (72.2)	13 (68.4)
	95% CI	(51.5, 92.9)	(47.5, 89.3)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0556	
	95% CI	(0.6944, 1.6046)	
	Two-sided P-value	0.8002	
	P-value of interaction	0.5107	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving EASI Response >= 90% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Baseline disease severity

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline disease severity: Moderate	Baseline, N	216	220
	Week 26, N	216	220
	Number of Subjects with observed Case, N1 (%)	178 (82.4)	195 (88.6)
	Number of Subjects with NRI, N2 (%)	38 (17.6)	25 (11.4)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	119 (55.1)	104 (47.3)
	95% CI	(48.5, 61.7)	(40.7, 53.9)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1654	
	95% CI	(0.9692, 1.4013)	
	Two-sided P-value	0.1036	
Baseline disease severity: Severe	Baseline, N	146	145
	Week 26, N	146	145
	Number of Subjects with observed Case, N1 (%)	123 (84.2)	129 (89.0)
	Number of Subjects with NRI, N2 (%)	23 (15.8)	16 (11.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving EASI Response >= 90% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Baseline disease severity

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline disease severity: Severe	Responders, n (%)	71 (48.6)	68 (46.9)
	95% CI	(40.5, 56.7)	(38.8, 55.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0370	
	95% CI	(0.8154, 1.3188)	
	Two-sided P-value	0.7673	
	P-value of interaction	0.4499	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; EASI = eczema area and severity index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Binary Outcome Analysis: EASI-100 response at week 26 - Full Analysis Set Safety Population
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Week 26									
Full Analysis Set Safety Population	362	79 (21.8%) (17.7%, 26.4%)	365	50 (13.7%) (10.3%, 17.7%)	1.76 (1.19, 2.60)	1.59 (1.15, 2.20)	8.1% (2.6%, 13.7%)	0.0041+*	--
Baseline Disease Severity									
Week 26									
Moderate baseline disease (IGA=3)	216	52 (24.1%) (18.5%, 30.3%)	220	31 (14.1%) (9.8%, 19.4%)	1.93 (1.18, 3.16)	1.71 (1.14, 2.56)	10.0% (2.7%, 17.3%)	0.0102*	0.3916
Severe baseline disease (IGA=4)	146	27 (18.5%) (12.6%, 25.8%)	145	19 (13.1%) (8.1%, 19.7%)	1.50 (0.79, 2.85)	1.41 (0.82, 2.42)	5.4% (-3.0%, 13.7%)	0.2607	
Gender									
Week 26									
Male	193	43 (22.3%) (16.6%, 28.8%)	204	22 (10.8%) (6.9%, 15.9%)	2.37 (1.36, 4.14)	2.07 (1.29, 3.32)	11.5% (4.2%, 18.7%)	0.0026*	0.2046
Female	169	36 (21.3%) (15.4%, 28.3%)	161	28 (17.4%) (11.9%, 24.1%)	1.29 (0.74, 2.23)	1.22 (0.79, 1.91)	3.9% (-4.6%, 12.4%)	0.4049	

Notes:
Number of subjects: Full Analysis Set Safety Population
Analysis on overall population is calculated based on stratified CMH (Cochran-Mantel-Haenszel) models, for OR, RR, and RD, stratified by by disease activity (moderate, severe) at enrollment.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: EASI-100 response at week 26 - Full Analysis Set Safety Population
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Region									
Week 26									
US/Canada/Australia	177	46 (26.0%) (19.7%, 33.1%)	195	18 (9.2%) (5.6%, 14.2%)	3.45 (1.91, 6.23)	2.82 (1.70, 4.67)	16.8% (9.1%, 24.4%)	<0.0001*	0.0057*
Europe	150	26 (17.3%) (11.6%, 24.4%)	132	21 (15.9%) (10.1%, 23.3%)	1.11 (0.59, 2.08)	1.09 (0.64, 1.84)	1.4% (-7.3%, 10.1%)	0.8730	
Asia	17	1 (5.9%) (0.1%, 28.7%)	19	5 (26.3%) (9.1%, 51.2%)	0.18 (0.02, 1.68)	0.22 (0.03, 1.73)	-20.4% (-43.2%, 2.3%)	0.1821	
Latin America	18	6 (33.3%) (13.3%, 59.0%)	19	6 (31.6%) (12.6%, 56.6%)	1.08 (0.27, 4.29)	1.06 (0.42, 2.68)	1.8% (-28.4%, 31.9%)	1.0000	
Age Subgroup									
Week 26									
<40 years	230	41 (17.8%) (13.1%, 23.4%)	247	31 (12.6%) (8.7%, 17.3%)	1.51 (0.91, 2.51)	1.42 (0.92, 2.18)	5.3% (-1.2%, 11.7%)	0.1247	0.1947
>=40 years	132	38 (28.8%) (21.2%, 37.3%)	118	19 (16.1%) (10.0%, 24.0%)	2.11 (1.13, 3.91)	1.79 (1.09, 2.92)	12.7% (2.5%, 22.9%)	0.0231*	

Notes:
Number of subjects: Full Analysis Set Safety Population
Analysis on overall population is calculated based on stratified CMH (Cochran-Mantel-Haenszel) models, for OR, RR, and RD, stratified by by disease activity (moderate, severe) at enrollment.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.

Proportion of Subjects Achieving Peak Pruritus Numerical Rating Scale (PP-NRS4) Response >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI)
(Protocol B7451050)

Age group (<40, >=40)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: <40	Baseline, N	227	246
	Week 26, N	227	246
	Number of Subjects with observed Case, N1 (%)	195 (85.9)	221 (89.8)
	Number of Subjects with NRI, N2 (%)	32 (14.1)	25 (10.2)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	142 (62.6)	152 (61.8)
	95% CI	(56.3, 68.9)	(55.7, 67.9)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0124	
	95% CI	(0.8796, 1.1653)	
	Two-sided P-value	0.8636	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Peak Pruritus Numerical Rating Scale (PP-NRS4) Response >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI)
(Protocol B7451050)

Age group (<40, >=40)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: >=40	Baseline, N	130	118
	Week 26, N	130	118
	Number of Subjects with observed Case, N1 (%)	116 (89.2)	106 (89.8)
	Number of Subjects with NRI, N2 (%)	14 (10.8)	12 (10.2)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	99 (76.2)	77 (65.3)
	95% CI	(68.8, 83.5)	(56.7, 73.8)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1670	
	95% CI	(0.9914, 1.3737)	
	Two-sided P-value	0.0634	
	P-value of interaction	0.1958	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Peak Pruritus Numerical Rating Scale (PP-NRS4) Response >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI)
(Protocol B7451050)

Sex

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Sex: Male	Baseline, N	191	204
	Week 26, N	191	204
	Number of Subjects with observed Case, N1 (%)	174 (91.1)	183 (89.7)
	Number of Subjects with NRI, N2 (%)	17 (8.9)	21 (10.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	127 (66.5)	119 (58.3)
	95% CI	(59.8, 73.2)	(51.6, 65.1)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1399	
	95% CI	(0.9776, 1.3291)	
	Two-sided P-value	0.0948	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Peak Pruritus Numerical Rating Scale (PP-NRS4) Response >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI)
(Protocol B7451050)

Sex

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Sex: Female	Baseline, N	166	160
	Week 26, N	166	160
	Number of Subjects with observed Case, N1 (%)	137 (82.5)	144 (90.0)
	Number of Subjects with NRI, N2 (%)	29 (17.5)	16 (10.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	114 (68.7)	110 (68.8)
	95% CI	(61.6, 75.7)	(61.6, 75.9)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9989	
	95% CI	(0.8628, 1.1565)	
	Two-sided P-value	0.9883	
	P-value of interaction	0.2229	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Peak Pruritus Numerical Rating Scale (PP-NRS4) Response >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI)
(Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Region of enrollment: US/Canada/Australia	Baseline, N	174	195
	Week 26, N	174	195
	Number of Subjects with observed Case, N1 (%)	147 (84.5)	172 (88.2)
	Number of Subjects with NRI, N2 (%)	27 (15.5)	23 (11.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	122 (70.1)	120 (61.5)
	95% CI	(63.3, 76.9)	(54.7, 68.4)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1394	
	95% CI	(0.9832, 1.3203)	
	Two-sided P-value	0.0827	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Peak Pruritus Numerical Rating Scale (PP-NRS4) Response >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI)
(Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Region of enrollment: Europe	Baseline, N	148	131
	Week 26, N	148	131
	Number of Subjects with observed Case, N1 (%)	133 (89.9)	122 (93.1)
	Number of Subjects with NRI, N2 (%)	15 (10.1)	9 (6.9)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	99 (66.9)	84 (64.1)
	95% CI	(59.3, 74.5)	(55.9, 72.3)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0432	
	95% CI	(0.8792, 1.2378)	
	Two-sided P-value	0.6280	
Region of enrollment: Asia	Baseline, N	17	19
	Week 26, N	17	19
	Number of Subjects with observed Case, N1 (%)	16 (94.1)	18 (94.7)
	Number of Subjects with NRI, N2 (%)	1 (5.9)	1 (5.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Peak Pruritus Numerical Rating Scale (PP-NRS4) Response >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI)
(Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Region of enrollment: Asia	Responders, n (%)	7 (41.2)	14 (73.7)
	95% CI	(17.8, 64.6)	(53.9, 93.5)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.5588	
	95% CI	(0.2981, 1.0477)	
	Two-sided P-value	0.0696	
Region of enrollment: Latin America	Baseline, N	18	19
	Week 26, N	18	19
	Number of Subjects with observed Case, N1 (%)	15 (83.3)	15 (78.9)
	Number of Subjects with NRI, N2 (%)	3 (16.7)	4 (21.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	13 (72.2)	11 (57.9)
	95% CI	(51.5, 92.9)	(35.7, 80.1)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Peak Pruritus Numerical Rating Scale (PP-NRS4) Response >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI)
(Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.2475	
	95% CI	(0.7729, 2.0133)	
	Two-sided P-value	0.3653	
	P-value of interaction	0.1556	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Peak Pruritus Numerical Rating Scale (PP-NRS4) Response >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI)
(Protocol B7451050)

Baseline disease severity

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline disease severity: Moderate	Baseline, N	213	219
	Week 26, N	213	219
	Number of Subjects with observed Case, N1 (%)	182 (85.4)	196 (89.5)
	Number of Subjects with NRI, N2 (%)	31 (14.6)	23 (10.5)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	139 (65.3)	132 (60.3)
	95% CI	(58.9, 71.7)	(53.8, 66.8)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0827	
	95% CI	(0.9361, 1.2522)	
	Two-sided P-value	0.2844	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving Peak Pruritus Numerical Rating Scale (PP-NRS4) Response >= 4 Points Improvement from Baseline at Week 26 by Subgroup - (FAS with Baseline >= 4, NRI)
(Protocol B7451050)

Baseline disease severity

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline disease severity: Severe	Baseline, N	144	145
	Week 26, N	144	145
	Number of Subjects with observed Case, N1 (%)	129 (89.6)	131 (90.3)
	Number of Subjects with NRI, N2 (%)	15 (10.4)	14 (9.7)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	102 (70.8)	97 (66.9)
	95% CI	(63.4, 78.3)	(59.2, 74.6)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0588	
	95% CI	(0.9066, 1.2366)	
	Two-sided P-value	0.4703	
	P-value of interaction	0.8374	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Binary Outcome Analysis: Achieving 0-1 in PP-NRS total score at week 26 - Full Analysis Set Safety Population
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Week 26									
Full Analysis Set Safety Population	362	139 (38.4%) (33.4%, 43.6%)	365	114 (31.2%) (26.5%, 36.3%)	1.37 (1.01, 1.86)	1.23 (1.01, 1.50)	7.2% (0.3%, 14.1%)	0.0425+*	--
Baseline Disease Severity									
Week 26									
Moderate baseline disease (IGA=3)	216	82 (38.0%) (31.5%, 44.8%)	220	73 (33.2%) (27.0%, 39.8%)	1.23 (0.83, 1.83)	1.14 (0.89, 1.47)	4.8% (-4.2%, 13.8%)	0.3178	0.4227
Severe baseline disease (IGA=4)	146	57 (39.0%) (31.1%, 47.5%)	145	41 (28.3%) (21.1%, 36.3%)	1.62 (0.99, 2.65)	1.38 (0.99, 1.92)	10.8% (-0.0%, 21.6%)	0.0628	
Gender									
Week 26									
Male	193	73 (37.8%) (31.0%, 45.1%)	204	53 (26.0%) (20.1%, 32.6%)	1.73 (1.13, 2.66)	1.46 (1.09, 1.95)	11.8% (2.7%, 21.0%)	0.0131*	0.1628
Female	169	66 (39.1%) (31.7%, 46.8%)	161	61 (37.9%) (30.4%, 45.9%)	1.05 (0.67, 1.64)	1.03 (0.78, 1.35)	1.2% (-9.3%, 11.7%)	0.9099	

Notes:
Number of subjects: Full Analysis Set Safety Population
Analysis on overall population is calculated based on stratified CMH (Cochran-Mantel-Haenszel) models, for OR, RR, and RD, stratified by by disease activity (moderate, severe) at enrollment.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Achieving 0-1 in PP-NRS total score at week 26 - Full Analysis Set Safety Population
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Region									
Week 26									
US/Canada/Australia	177	70 (39.5%) (32.3%, 47.2%)	195	59 (30.3%) (23.9%, 37.2%)	1.51 (0.98, 2.32)	1.31 (0.99, 1.73)	9.3% (-0.4%, 19.0%)	0.0644	0.3786
Europe	150	61 (40.7%) (32.7%, 49.0%)	132	43 (32.6%) (24.7%, 41.3%)	1.42 (0.87, 2.31)	1.25 (0.91, 1.71)	8.1% (-3.1%, 19.3%)	0.1749	
Asia	17	3 (17.6%) (3.8%, 43.4%)	19	6 (31.6%) (12.6%, 56.6%)	0.46 (0.10, 2.25)	0.56 (0.16, 1.90)	-13.9% (-41.6%, 13.7%)	0.4513	
Latin America	18	5 (27.8%) (9.7%, 53.5%)	19	6 (31.6%) (12.6%, 56.6%)	0.83 (0.20, 3.43)	0.88 (0.32, 2.38)	-3.8% (-33.2%, 25.6%)	1.0000	
Age Subgroup									
Week 26									
<40 years	230	79 (34.3%) (28.2%, 40.9%)	247	80 (32.4%) (26.6%, 38.6%)	1.09 (0.75, 1.60)	1.06 (0.82, 1.37)	2.0% (-6.5%, 10.4%)	0.6977	0.0437*
>=40 years	132	60 (45.5%) (36.8%, 54.3%)	118	34 (28.8%) (20.8%, 37.9%)	2.06 (1.22, 3.48)	1.58 (1.12, 2.22)	16.6% (4.9%, 28.4%)	0.0088*	

Notes:
Number of subjects: Full Analysis Set Safety Population
Analysis on overall population is calculated based on stratified CMH (Cochran-Mantel-Haenszel) models, for OR, RR, and RD, stratified by by disease activity (moderate, severe) at enrollment.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.

Proportion of Subjects with DLQI < 2 Response at Week 26 by Subgroup (FAS with Baseline >= 2, NRI)
(Protocol B7451050)

Age group (<40, >=40)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: <40	Baseline, N	227	243
	Week 26, N	227	243
	Number of Subjects with observed Case, N1 (%)	184 (81.1)	216 (88.9)
	Number of Subjects with NRI, N2 (%)	43 (18.9)	27 (11.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	75 (33.0)	77 (31.7)
	95% CI	(26.9, 39.2)	(25.8, 37.5)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0427	
	95% CI	(0.8028, 1.3543)	
	Two-sided P-value	0.7541	
Age (years) group: >=40	Baseline, N	131	118
	Week 26, N	131	118
	Number of Subjects with observed Case, N1 (%)	116 (88.5)	105 (89.0)
	Number of Subjects with NRI, N2 (%)	15 (11.5)	13 (11.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with DLQI < 2 Response at Week 26 by Subgroup (FAS with Baseline >= 2, NRI)
(Protocol B7451050)

Age group (<40, >=40)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: >=40	Responders, n (%)	62 (47.3)	37 (31.4)
	95% CI	(38.8, 55.9)	(23.0, 39.7)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.5094	
	95% CI	(1.0935, 2.0835)	
	Two-sided P-value	0.0123	
	P-value of interaction	0.0807	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with DLQI < 2 Response at Week 26 by Subgroup (FAS with Baseline >= 2, NRI)
(Protocol B7451050)

Sex

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Sex: Male	Baseline, N	191	201
	Week 26, N	191	201
	Number of Subjects with observed Case, N1 (%)	168 (88.0)	178 (88.6)
	Number of Subjects with NRI, N2 (%)	23 (12.0)	23 (11.4)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	70 (36.6)	64 (31.8)
	95% CI	(29.8, 43.5)	(25.4, 38.3)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1510	
	95% CI	(0.8742, 1.5155)	
	Two-sided P-value	0.3163	
Sex: Female	Baseline, N	167	160
	Week 26, N	167	160
	Number of Subjects with observed Case, N1 (%)	132 (79.0)	143 (89.4)
	Number of Subjects with NRI, N2 (%)	35 (21.0)	17 (10.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with DLQI < 2 Response at Week 26 by Subgroup (FAS with Baseline >= 2, NRI)
(Protocol B7451050)

Sex

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Sex: Female	Responders, n (%)	67 (40.1)	50 (31.3)
	95% CI	(32.7, 47.6)	(24.1, 38.4)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.2838	
	95% CI	(0.9556, 1.7247)	
	Two-sided P-value	0.0972	
	P-value of interaction	0.5958	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with DLQI < 2 Response at Week 26 by Subgroup (FAS with Baseline >= 2, NRI)
(Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Region of enrollment: US/Canada/Australia	Baseline, N	174	191
	Week 26, N	174	191
	Number of Subjects with observed Case, N1 (%)	142 (81.6)	166 (86.9)
	Number of Subjects with NRI, N2 (%)	32 (18.4)	25 (13.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	68 (39.1)	62 (32.5)
	95% CI	(31.8, 46.3)	(25.8, 39.1)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.2039	
	95% CI	(0.9134, 1.5868)	
	Two-sided P-value	0.1878	
Region of enrollment: Europe	Baseline, N	150	132
	Week 26, N	150	132
	Number of Subjects with observed Case, N1 (%)	129 (86.0)	122 (92.4)
	Number of Subjects with NRI, N2 (%)	21 (14.0)	10 (7.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with DLQI < 2 Response at Week 26 by Subgroup (FAS with Baseline >= 2, NRI)
(Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Region of enrollment: Europe	Responders, n (%)	56 (37.3)	40 (30.3)
	95% CI	(29.6, 45.1)	(22.5, 38.1)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.2320	
	95% CI	(0.8843, 1.7163)	
	Two-sided P-value	0.2174	
Region of enrollment: Asia	Baseline, N	16	19
	Week 26, N	16	19
	Number of Subjects with observed Case, N1 (%)	15 (93.8)	18 (94.7)
	Number of Subjects with NRI, N2 (%)	1 (6.3)	1 (5.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	7 (43.8)	5 (26.3)
	95% CI	(19.4, 68.1)	(6.5, 46.1)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with DLQI < 2 Response at Week 26 by Subgroup (FAS with Baseline >= 2, NRI)
(Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.6625	
	95% CI	(0.6525, 4.2360)	
	Two-sided P-value	0.2868	
Region of enrollment: Latin America	Baseline, N	18	19
	Week 26, N	18	19
	Number of Subjects with observed Case, N1 (%)	14 (77.8)	15 (78.9)
	Number of Subjects with NRI, N2 (%)	4 (22.2)	4 (21.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	6 (33.3)	7 (36.8)
	95% CI	(11.6, 55.1)	(15.2, 58.5)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9048	
	95% CI	(0.3755, 2.1801)	
	Two-sided P-value	0.8235	
	P-value of interaction	0.8316	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with DLQI < 2 Response at Week 26 by Subgroup (FAS with Baseline >= 2, NRI)
(Protocol B7451050)

Baseline disease severity

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline disease severity: Moderate	Baseline, N	212	217
	Week 26, N	212	217
	Number of Subjects with observed Case, N1 (%)	175 (82.5)	192 (88.5)
	Number of Subjects with NRI, N2 (%)	37 (17.5)	25 (11.5)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	81 (38.2)	72 (33.2)
	95% CI	(31.7, 44.7)	(26.9, 39.4)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1515	
	95% CI	(0.8925, 1.4858)	
	Two-sided P-value	0.2779	
Baseline disease severity: Severe	Baseline, N	146	144
	Week 26, N	146	144
	Number of Subjects with observed Case, N1 (%)	125 (85.6)	129 (89.6)
	Number of Subjects with NRI, N2 (%)	21 (14.4)	15 (10.4)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects with DLQI < 2 Response at Week 26 by Subgroup (FAS with Baseline >= 2, NRI)
(Protocol B7451050)

Baseline disease severity

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline disease severity: Severe	Responders, n (%)	56 (38.4)	42 (29.2)
	95% CI	(30.5, 46.2)	(21.7, 36.6)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.3151	
	95% CI	(0.9481, 1.8241)	
	Two-sided P-value	0.1009	
	P-value of interaction	0.5303	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; DLQI = Dermatology Life Quality Index; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated by using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving POEM Total Score < 3 Response at Week 26 by Subgroup - (FAS with Baseline >= 3, NRI)
(Protocol B7451050)

Age group (<40, >=40)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: <40	Baseline, N	226	246
	Week 26, N	226	246
	Number of Subjects with observed Case, N1 (%)	182 (80.5)	217 (88.2)
	Number of Subjects with NRI, N2 (%)	44 (19.5)	29 (11.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	56 (24.8)	47 (19.1)
	95% CI	(19.2, 30.4)	(14.2, 24.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.2969	
	95% CI	(0.9203, 1.8278)	
	Two-sided P-value	0.1375	
Age (years) group: >=40	Baseline, N	132	117
	Week 26, N	132	117
	Number of Subjects with observed Case, N1 (%)	117 (88.6)	103 (88.0)
	Number of Subjects with NRI, N2 (%)	15 (11.4)	14 (12.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving POEM Total Score < 3 Response at Week 26 by Subgroup - (FAS with Baseline >= 3, NRI)
(Protocol B7451050)

Age group (<40, >=40)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: >=40	Responders, n (%)	50 (37.9)	22 (18.8)
	95% CI	(29.6, 46.2)	(11.7, 25.9)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	2.0145	
	95% CI	(1.3035, 3.1133)	
	Two-sided P-value	0.0016	
	P-value of interaction	0.1194	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving POEM Total Score < 3 Response at Week 26 by Subgroup - (FAS with Baseline >= 3, NRI)
(Protocol B7451050)

Sex

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Sex: Male	Baseline, N	190	202
	Week 26, N	190	202
	Number of Subjects with observed Case, N1 (%)	167 (87.9)	178 (88.1)
	Number of Subjects with NRI, N2 (%)	23 (12.1)	24 (11.9)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	54 (28.4)	34 (16.8)
	95% CI	(22.0, 34.8)	(11.7, 22.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.6885	
	95% CI	(1.1540, 2.4707)	
	Two-sided P-value	0.0070	
Sex: Female	Baseline, N	168	161
	Week 26, N	168	161
	Number of Subjects with observed Case, N1 (%)	132 (78.6)	142 (88.2)
	Number of Subjects with NRI, N2 (%)	36 (21.4)	19 (11.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving POEM Total Score < 3 Response at Week 26 by Subgroup - (FAS with Baseline >= 3, NRI)
(Protocol B7451050)

Sex

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Sex: Female	Responders, n (%)	52 (31.0)	35 (21.7)
	95% CI	(24.0, 37.9)	(15.4, 28.1)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.4238	
	95% CI	(0.9835, 2.0613)	
	Two-sided P-value	0.0613	
	P-value of interaction	0.5289	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving POEM Total Score < 3 Response at Week 26 by Subgroup - (FAS with Baseline >= 3, NRI)
(Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Region of enrollment: US/Canada/Australia	Baseline, N	177	193
	Week 26, N	177	193
	Number of Subjects with observed Case, N1 (%)	144 (81.4)	166 (86.0)
	Number of Subjects with NRI, N2 (%)	33 (18.6)	27 (14.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	51 (28.8)	37 (19.2)
	95% CI	(22.1, 35.5)	(13.6, 24.7)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.5030	
	95% CI	(1.0373, 2.1778)	
	Two-sided P-value	0.0313	
Region of enrollment: Europe	Baseline, N	150	132
	Week 26, N	150	132
	Number of Subjects with observed Case, N1 (%)	129 (86.0)	121 (91.7)
	Number of Subjects with NRI, N2 (%)	21 (14.0)	11 (8.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving POEM Total Score < 3 Response at Week 26 by Subgroup - (FAS with Baseline >= 3, NRI)
(Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Region of enrollment: Europe	Responders, n (%)	45 (30.0)	23 (17.4)
	95% CI	(22.7, 37.3)	(11.0, 23.9)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.7217	
	95% CI	(1.1038, 2.6857)	
	Two-sided P-value	0.0166	
Region of enrollment: Asia	Baseline, N	14	19
	Week 26, N	14	19
	Number of Subjects with observed Case, N1 (%)	13 (92.9)	18 (94.7)
	Number of Subjects with NRI, N2 (%)	1 (7.1)	1 (5.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	4 (28.6)	6 (31.6)
	95% CI	(4.9, 52.2)	(10.7, 52.5)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving POEM Total Score < 3 Response at Week 26 by Subgroup - (FAS with Baseline >= 3, NRI)
(Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9048	
	95% CI	(0.3134, 2.6120)	
	Two-sided P-value	0.8532	
Region of enrollment: Latin America	Baseline, N	17	19
	Week 26, N	17	19
	Number of Subjects with observed Case, N1 (%)	13 (76.5)	15 (78.9)
	Number of Subjects with NRI, N2 (%)	4 (23.5)	4 (21.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	6 (35.3)	3 (15.8)
	95% CI	(12.6, 58.0)	(0.0, 32.2)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	2.2353	
	95% CI	(0.6588, 7.5843)	
	Two-sided P-value	0.1969	
	P-value of interaction	0.6651	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving POEM Total Score < 3 Response at Week 26 by Subgroup - (FAS with Baseline >= 3, NRI)
(Protocol B7451050)

Baseline disease severity

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline disease severity: Moderate	Baseline, N	213	219
	Week 26, N	213	219
	Number of Subjects with observed Case, N1 (%)	175 (82.2)	193 (88.1)
	Number of Subjects with NRI, N2 (%)	38 (17.8)	26 (11.9)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	65 (30.5)	41 (18.7)
	95% CI	(24.3, 36.7)	(13.6, 23.9)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.6300	
	95% CI	(1.1575, 2.2955)	
	Two-sided P-value	0.0052	
Baseline disease severity: Severe	Baseline, N	145	144
	Week 26, N	145	144
	Number of Subjects with observed Case, N1 (%)	124 (85.5)	127 (88.2)
	Number of Subjects with NRI, N2 (%)	21 (14.5)	17 (11.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving POEM Total Score < 3 Response at Week 26 by Subgroup - (FAS with Baseline >= 3, NRI)
(Protocol B7451050)

Baseline disease severity

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline disease severity: Severe	Responders, n (%)	41 (28.3)	28 (19.4)
	95% CI	(20.9, 35.6)	(13.0, 25.9)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.4542	
	95% CI	(0.9540, 2.2167)	
	Two-sided P-value	0.0817	
	P-value of interaction	0.6804	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; POEM = patient-oriented eczema measure; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Binary Outcome Analysis: Achieving 0 in POEM total score at week 26 - Full Analysis Set Safety Population
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Week 26									
Full Analysis Set Safety Population	359	49 (13.6%) (10.3%, 17.6%)	365	26 (7.1%) (4.7%, 10.3%)	2.06 (1.25, 3.40)	1.92 (1.22, 3.01)	6.5% (2.1%, 10.9%)	0.0040+*	--
Baseline Disease Severity									
Week 26									
Moderate baseline disease (IGA=3)	214	29 (13.6%) (9.3%, 18.9%)	220	15 (6.8%) (3.9%, 11.0%)	2.14 (1.11, 4.12)	1.99 (1.10, 3.60)	6.7% (1.1%, 12.4%)	0.0254*	0.9166
Severe baseline disease (IGA=4)	145	20 (13.8%) (8.6%, 20.5%)	145	11 (7.6%) (3.8%, 13.2%)	1.95 (0.90, 4.23)	1.82 (0.90, 3.66)	6.2% (-0.9%, 13.3%)	0.1274	
Gender									
Week 26									
Male	191	26 (13.6%) (9.1%, 19.3%)	204	11 (5.4%) (2.7%, 9.4%)	2.76 (1.33, 5.77)	2.52 (1.28, 4.97)	8.2% (2.5%, 14.0%)	0.0056*	0.4235
Female	168	23 (13.7%) (8.9%, 19.8%)	161	15 (9.3%) (5.3%, 14.9%)	1.54 (0.77, 3.08)	1.47 (0.80, 2.71)	4.4% (-2.5%, 11.2%)	0.2314	

Notes:
Number of subjects: Full Analysis Set Safety Population
Number of subjects: Full Analysis Set Safety Population, excluding subjects with baseline POEM 0.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Achieving 0 in POEM total score at week 26 - Full Analysis Set Safety Population
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Region									
Week 26									
US/Canada/Australia	177	27 (15.3%) (10.3%, 21.4%)	195	16 (8.2%) (4.8%, 13.0%)	2.01 (1.05, 3.88)	1.86 (1.04, 3.33)	7.0% (0.5%, 13.6%)	0.0360*	0.9211
Europe	150	17 (11.3%) (6.7%, 17.5%)	132	7 (5.3%) (2.2%, 10.6%)	2.28 (0.92, 5.69)	2.14 (0.91, 4.99)	6.0% (-0.3%, 12.4%)	0.0874	
Asia	15	2 (13.3%) (1.7%, 40.5%)	19	2 (10.5%) (1.3%, 33.1%)	1.31 (0.16, 10.56)	1.27 (0.20, 7.97)	2.8% (-19.2%, 24.9%)	1.0000	
Latin America	17	3 (17.6%) (3.8%, 43.4%)	19	1 (5.3%) (0.1%, 26.0%)	3.86 (0.36, 41.20)	3.35 (0.38, 29.26)	12.4% (-8.3%, 33.1%)	0.3255	
Age Subgroup									
Week 26									
<40 years	227	22 (9.7%) (6.2%, 14.3%)	247	19 (7.7%) (4.7%, 11.8%)	1.29 (0.68, 2.45)	1.26 (0.70, 2.27)	2.0% (-3.1%, 7.1%)	0.5137	0.0094*
>=40 years	132	27 (20.5%) (13.9%, 28.3%)	118	7 (5.9%) (2.4%, 11.8%)	4.08 (1.70, 9.76)	3.45 (1.56, 7.62)	14.5% (6.4%, 22.6%)	0.0008*	

Notes:
Number of subjects: Full Analysis Set Safety Population
Number of subjects: Full Analysis Set Safety Population, excluding subjects with baseline POEM 0.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.

Proportion of Subjects Achieving SCORAD Response >= 75% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Age group (<40, >=40)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: <40	Baseline, N	230	247
	Week 26, N	230	247
	Number of Subjects with observed Case, N1 (%)	183 (79.6)	219 (88.7)
	Number of Subjects with NRI, N2 (%)	47 (20.4)	28 (11.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	89 (38.7)	91 (36.8)
	95% CI	(32.4, 45.0)	(30.8, 42.9)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0503	
	95% CI	(0.8341, 1.3226)	
	Two-sided P-value	0.6764	
Age (years) group: >=40	Baseline, N	132	118
	Week 26, N	132	118
	Number of Subjects with observed Case, N1 (%)	117 (88.6)	104 (88.1)
	Number of Subjects with NRI, N2 (%)	15 (11.4)	14 (11.9)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD Response >= 75% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Age group (<40, >=40)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: >=40	Responders, n (%)	63 (47.7)	42 (35.6)
	95% CI	(39.2, 56.2)	(27.0, 44.2)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.3409	
	95% CI	(0.9921, 1.8124)	
	Two-sided P-value	0.0564	
	P-value of interaction	0.2069	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD Response >= 75% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Sex

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Sex: Male	Baseline, N	193	204
	Week 26, N	193	204
	Number of Subjects with observed Case, N1 (%)	168 (87.0)	180 (88.2)
	Number of Subjects with NRI, N2 (%)	25 (13.0)	24 (11.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	77 (39.9)	61 (29.9)
	95% CI	(33.0, 46.8)	(23.6, 36.2)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.3342	
	95% CI	(1.0162, 1.7518)	
	Two-sided P-value	0.0379	
Sex: Female	Baseline, N	169	161
	Week 26, N	169	161
	Number of Subjects with observed Case, N1 (%)	132 (78.1)	143 (88.8)
	Number of Subjects with NRI, N2 (%)	37 (21.9)	18 (11.2)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD Response >= 75% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Sex

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Sex: Female	Responders, n (%)	75 (44.4)	72 (44.7)
	95% CI	(36.9, 51.9)	(37.0, 52.4)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9924	
	95% CI	(0.7800, 1.2625)	
	Two-sided P-value	0.9502	
	P-value of interaction	0.1104	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD Response >= 75% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Region of enrollment: US/Canada/Australia	Baseline, N	177	195
	Week 26, N	177	195
	Number of Subjects with observed Case, N1 (%)	141 (79.7)	168 (86.2)
	Number of Subjects with NRI, N2 (%)	36 (20.3)	27 (13.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	75 (42.4)	65 (33.3)
	95% CI	(35.1, 49.7)	(26.7, 39.9)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.2712	
	95% CI	(0.9777, 1.6528)	
	Two-sided P-value	0.0732	
Region of enrollment: Europe	Baseline, N	150	132
	Week 26, N	150	132
	Number of Subjects with observed Case, N1 (%)	130 (86.7)	122 (92.4)
	Number of Subjects with NRI, N2 (%)	20 (13.3)	10 (7.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD Response >= 75% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Region of enrollment: Europe	Responders, n (%)	61 (40.7)	47 (35.6)
	95% CI	(32.8, 48.5)	(27.4, 43.8)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.1421	
	95% CI	(0.8461, 1.5417)	
	Two-sided P-value	0.3853	
Region of enrollment: Asia	Baseline, N	17	19
	Week 26, N	17	19
	Number of Subjects with observed Case, N1 (%)	15 (88.2)	18 (94.7)
	Number of Subjects with NRI, N2 (%)	2 (11.8)	1 (5.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	4 (23.5)	9 (47.4)
	95% CI	(3.4, 43.7)	(24.9, 69.8)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD Response >= 75% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.4967	
	95% CI	(0.1866, 1.3226)	
	Two-sided P-value	0.1614	
Region of enrollment: Latin America	Baseline, N	18	19
	Week 26, N	18	19
	Number of Subjects with observed Case, N1 (%)	14 (77.8)	15 (78.9)
	Number of Subjects with NRI, N2 (%)	4 (22.2)	4 (21.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	12 (66.7)	12 (63.2)
	95% CI	(44.9, 88.4)	(41.5, 84.8)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.0556	
	95% CI	(0.6571, 1.6956)	
	Two-sided P-value	0.8231	
	P-value of interaction	0.3197	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD Response >= 75% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Baseline disease severity

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline disease severity: Moderate	Baseline, N	216	220
	Week 26, N	216	220
	Number of Subjects with observed Case, N1 (%)	176 (81.5)	194 (88.2)
	Number of Subjects with NRI, N2 (%)	40 (18.5)	26 (11.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	92 (42.6)	71 (32.3)
	95% CI	(36.0, 49.2)	(26.1, 38.5)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.3198	
	95% CI	(1.0318, 1.6882)	
	Two-sided P-value	0.0272	
Baseline disease severity: Severe	Baseline, N	146	145
	Week 26, N	146	145
	Number of Subjects with observed Case, N1 (%)	124 (84.9)	129 (89.0)
	Number of Subjects with NRI, N2 (%)	22 (15.1)	16 (11.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD Response >= 75% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Baseline disease severity

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline disease severity: Severe	Responders, n (%)	60 (41.1)	62 (42.8)
	95% CI	(33.1, 49.1)	(34.7, 50.8)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.9611	
	95% CI	(0.7333, 1.2597)	
	Two-sided P-value	0.7738	
	P-value of interaction	0.0893	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD Response >= 90% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Age group (<40, >=40)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: <40	Baseline, N	230	247
	Week 26, N	230	247
	Number of Subjects with observed Case, N1 (%)	183 (79.6)	219 (88.7)
	Number of Subjects with NRI, N2 (%)	47 (20.4)	28 (11.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	42 (18.3)	32 (13.0)
	95% CI	(13.3, 23.3)	(8.8, 17.1)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.4095	
	95% CI	(0.9230, 2.1525)	
	Two-sided P-value	0.1121	
Age (years) group: >=40	Baseline, N	132	118
	Week 26, N	132	118
	Number of Subjects with observed Case, N1 (%)	117 (88.6)	104 (88.1)
	Number of Subjects with NRI, N2 (%)	15 (11.4)	14 (11.9)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD Response >= 90% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Age group (<40, >=40)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Age (years) group: >=40	Responders, n (%)	38 (28.8)	20 (16.9)
	95% CI	(21.1, 36.5)	(10.2, 23.7)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.6985	
	95% CI	(1.0498, 2.7480)	
	Two-sided P-value	0.0309	
	P-value of interaction	0.5685	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD Response >= 90% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Sex

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Sex: Male	Baseline, N	193	204
	Week 26, N	193	204
	Number of Subjects with observed Case, N1 (%)	168 (87.0)	180 (88.2)
	Number of Subjects with NRI, N2 (%)	25 (13.0)	24 (11.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	43 (22.3)	23 (11.3)
	95% CI	(16.4, 28.2)	(6.9, 15.6)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.9761	
	95% CI	(1.2394, 3.1507)	
	Two-sided P-value	0.0042	
Sex: Female	Baseline, N	169	161
	Week 26, N	169	161
	Number of Subjects with observed Case, N1 (%)	132 (78.1)	143 (88.8)
	Number of Subjects with NRI, N2 (%)	37 (21.9)	18 (11.2)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD Response >= 90% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Sex

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Sex: Female	Responders, n (%)	37 (21.9)	29 (18.0)
	95% CI	(15.7, 28.1)	(12.1, 23.9)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.2155	
	95% CI	(0.7863, 1.8789)	
	Two-sided P-value	0.3799	
	P-value of interaction	0.1356	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD Response >= 90% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Region of enrollment: US/Canada/Australia	Baseline, N	177	195
	Week 26, N	177	195
	Number of Subjects with observed Case, N1 (%)	141 (79.7)	168 (86.2)
	Number of Subjects with NRI, N2 (%)	36 (20.3)	27 (13.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	44 (24.9)	22 (11.3)
	95% CI	(18.5, 31.2)	(6.8, 15.7)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	2.2034	
	95% CI	(1.3777, 3.5240)	
	Two-sided P-value	0.0010	
Region of enrollment: Europe	Baseline, N	150	132
	Week 26, N	150	132
	Number of Subjects with observed Case, N1 (%)	130 (86.7)	122 (92.4)
	Number of Subjects with NRI, N2 (%)	20 (13.3)	10 (7.6)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD Response >= 90% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Region of enrollment: Europe	Responders, n (%)	27 (18.0)	19 (14.4)
	95% CI	(11.9, 24.1)	(8.4, 20.4)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.2505	
	95% CI	(0.7300, 2.1422)	
	Two-sided P-value	0.4156	
Region of enrollment: Asia	Baseline, N	17	19
	Week 26, N	17	19
	Number of Subjects with observed Case, N1 (%)	15 (88.2)	18 (94.7)
	Number of Subjects with NRI, N2 (%)	2 (11.8)	1 (5.3)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	1 (5.9)	4 (21.1)
	95% CI	(0.0, 17.1)	(2.7, 39.4)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD Response >= 90% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Region

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	0.2794	
	95% CI	(0.0345, 2.2620)	
	Two-sided P-value	0.2321	
Region of enrollment: Latin America	Baseline, N	18	19
	Week 26, N	18	19
	Number of Subjects with observed Case, N1 (%)	14 (77.8)	15 (78.9)
	Number of Subjects with NRI, N2 (%)	4 (22.2)	4 (21.1)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	8 (44.4)	7 (36.8)
	95% CI	(21.5, 67.4)	(15.2, 58.5)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.2063	
	95% CI	(0.5512, 2.6400)	
	Two-sided P-value	0.6387	
	P-value of interaction	0.1251	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD Response >= 90% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Baseline disease severity

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline disease severity: Moderate	Baseline, N	216	220
	Week 26, N	216	220
	Number of Subjects with observed Case, N1 (%)	176 (81.5)	194 (88.2)
	Number of Subjects with NRI, N2 (%)	40 (18.5)	26 (11.8)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0
	Responders, n (%)	50 (23.1)	30 (13.6)
	95% CI	(17.5, 28.8)	(9.1, 18.2)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.6975	
	95% CI	(1.1245, 2.5626)	
	Two-sided P-value	0.0118	
Baseline disease severity: Severe	Baseline, N	146	145
	Week 26, N	146	145
	Number of Subjects with observed Case, N1 (%)	124 (84.9)	129 (89.0)
	Number of Subjects with NRI, N2 (%)	22 (15.1)	16 (11.0)
	Number of Subjects Missing Cases without NRI, N3 (%)	0	0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Proportion of Subjects Achieving SCORAD Response >= 90% Improvement from Baseline at Week 26 by Subgroup - (FAS, NRI)
(Protocol B7451050)

Baseline disease severity

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Baseline disease severity: Severe	Responders, n (%)	30 (20.5)	22 (15.2)
	95% CI	(14.0, 27.1)	(9.3, 21.0)
	Abrocitinib vs Dupilumab Response Ratio		
	Estimate	1.3543	
	95% CI	(0.8215, 2.2325)	
	Two-sided P-value	0.2344	
	P-value of interaction	0.4942	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; CMH = Cochran-Mantel-Haenszel; SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set at the specified visit; n (%) = number of subjects with response (percentage based on N); NRI = non-responder imputation.
CI for the response rate was based on normal approximation (or the Clopper-Pearson exact method when there were 0 or 100% responders); Response ratio was calculated using wald method without stratification.
A log regression model was used to provide two sided Wald p-value for testing subgroup and treatment interaction. 0.5 was added to the empty cells.
P-value of interaction was based on a type3 Wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment * subgroup category) are zero.

Binary Outcome Analysis: SCORAD-100 response at week 26 - Full Analysis Set Safety Population
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Week 26									
Full Analysis Set Safety Population	362	37 (10.2%) (7.3%, 13.8%)	365	22 (6.0%) (3.8%, 9.0%)	1.77 (1.03, 3.07)	1.70 (1.02, 2.82)	4.2% (0.2%, 8.2%)	0.0384+*	--
Baseline Disease Severity									
Week 26									
Moderate baseline disease (IGA=3)	216	25 (11.6%) (7.6%, 16.6%)	220	12 (5.5%) (2.8%, 9.3%)	2.27 (1.11, 4.64)	2.12 (1.09, 4.11)	6.1% (0.9%, 11.3%)	0.0253*	0.2397
Severe baseline disease (IGA=4)	146	12 (8.2%) (4.3%, 13.9%)	145	10 (6.9%) (3.4%, 12.3%)	1.21 (0.51, 2.89)	1.19 (0.53, 2.67)	1.3% (-4.7%, 7.4%)	0.8251	
Gender									
Week 26									
Male	193	21 (10.9%) (6.9%, 16.2%)	204	9 (4.4%) (2.0%, 8.2%)	2.65 (1.18, 5.93)	2.47 (1.16, 5.25)	6.5% (1.2%, 11.7%)	0.0213*	0.2219
Female	169	16 (9.5%) (5.5%, 14.9%)	161	13 (8.1%) (4.4%, 13.4%)	1.19 (0.55, 2.56)	1.17 (0.58, 2.36)	1.4% (-4.7%, 7.5%)	0.7007	

Notes:
Number of subjects: Full Analysis Set Safety Population
Analysis on overall population is calculated based on stratified CMH (Cochran-Mantel-Haenszel) models, for OR, RR, and RD, stratified by by disease activity (moderate, severe) at enrollment.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: SCORAD-100 response at week 26 - Full Analysis Set Safety Population
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Region									
Week 26									
US/Canada/Australia	177	15 (8.5%) (4.8%, 13.6%)	195	7 (3.6%) (1.5%, 7.3%)	2.49 (0.99, 6.25)	2.36 (0.99, 5.66)	4.9% (0.0%, 9.7%)	0.0504	0.2424
Europe	150	17 (11.3%) (6.7%, 17.5%)	132	9 (6.8%) (3.2%, 12.5%)	1.75 (0.75, 4.06)	1.66 (0.77, 3.60)	4.5% (-2.1%, 11.2%)	0.2199	
Asia	17	0 (0.0%)	19	3 (15.8%) (3.4%, 39.6%)	0.13 (0.01, 2.81)	0.16 (0.01, 2.87)	-14.7% (-33.0%, 3.6%)	0.2310	
Latin America	18	5 (27.8%) (9.7%, 53.5%)	19	3 (15.8%) (3.4%, 39.6%)	2.05 (0.41, 10.24)	1.76 (0.49, 6.31)	12.0% (-14.4%, 38.4%)	0.4470	
Age Subgroup									
Week 26									
<40 years	230	19 (8.3%) (5.0%, 12.6%)	247	14 (5.7%) (3.1%, 9.3%)	1.50 (0.73, 3.06)	1.46 (0.75, 2.84)	2.6% (-2.0%, 7.2%)	0.2836	0.3246
>=40 years	132	18 (13.6%) (8.3%, 20.7%)	118	8 (6.8%) (3.0%, 12.9%)	2.17 (0.91, 5.20)	2.01 (0.91, 4.45)	6.9% (-0.5%, 14.3%)	0.0969	

Notes:
Number of subjects: Full Analysis Set Safety Population
Analysis on overall population is calculated based on stratified CMH (Cochran-Mantel-Haenszel) models, for OR, RR, and RD, stratified by by disease activity (moderate, severe) at enrollment.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: EQ-5D VAS 15-point improvement at week 26 - Full Analysis Set Safety Population
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Week 26									
Full Analysis Set Safety Population	302	119 (39.4%) (33.9%, 45.2%)	309	136 (44.0%) (38.4%, 49.7%)	0.82 (0.60, 1.14)	0.89 (0.74, 1.08)	-4.7% (-12.5%, 3.1%)	0.2380+	--
Baseline Disease Severity									
Week 26									
Moderate baseline disease (IGA=3)	177	59 (33.3%) (26.4%, 40.8%)	184	78 (42.4%) (35.2%, 49.9%)	0.68 (0.44, 1.04)	0.79 (0.60, 1.03)	-9.1% (-19.0%, 0.9%)	0.0832	0.2250
Severe baseline disease (IGA=4)	125	60 (48.0%) (39.0%, 57.1%)	125	58 (46.4%) (37.4%, 55.5%)	1.07 (0.65, 1.75)	1.03 (0.80, 1.34)	1.6% (-10.8%, 14.0%)	0.8992	
Gender									
Week 26									
Male	161	57 (35.4%) (28.0%, 43.3%)	172	65 (37.8%) (30.5%, 45.5%)	0.90 (0.58, 1.41)	0.94 (0.71, 1.24)	-2.4% (-12.7%, 8.0%)	0.7329	0.4258
Female	141	62 (44.0%) (35.6%, 52.6%)	137	71 (51.8%) (43.1%, 60.4%)	0.73 (0.46, 1.17)	0.85 (0.66, 1.09)	-7.9% (-19.6%, 3.9%)	0.2298	

Notes:
Number of subjects: Full Analysis Set Safety Population
Number of subjects: Full Analysis Set Safety Population, excluding subjects with baseline EQ5D-VAS >85.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: EQ-5D VAS 15-point improvement at week 26 - Full Analysis Set Safety Population
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Region									
Week 26									
US/Canada/Australia	138	45 (32.6%) (24.9%, 41.1%)	155	61 (39.4%) (31.6%, 47.5%)	0.75 (0.46, 1.21)	0.83 (0.61, 1.13)	-6.7% (-17.7%, 4.2%)	0.2731	0.6191
Europe	131	61 (46.6%) (37.8%, 55.5%)	119	59 (49.6%) (40.3%, 58.9%)	0.89 (0.54, 1.46)	0.94 (0.73, 1.22)	-3.0% (-15.4%, 9.4%)	0.7040	
Asia	16	4 (25.0%) (7.3%, 52.4%)	19	9 (47.4%) (24.4%, 71.1%)	0.37 (0.09, 1.57)	0.53 (0.20, 1.40)	-22.4% (-53.3%, 8.5%)	0.2928	
Latin America	17	9 (52.9%) (27.8%, 77.0%)	16	7 (43.8%) (19.8%, 70.1%)	1.45 (0.37, 5.70)	1.21 (0.59, 2.47)	9.2% (-24.8%, 43.2%)	0.7319	
Age Subgroup									
Week 26									
<40 years	198	80 (40.4%) (33.5%, 47.6%)	209	91 (43.5%) (36.7%, 50.6%)	0.88 (0.59, 1.30)	0.93 (0.74, 1.17)	-3.1% (-12.7%, 6.4%)	0.5475	0.6106
>=40 years	104	39 (37.5%) (28.2%, 47.5%)	100	45 (45.0%) (35.0%, 55.3%)	0.73 (0.42, 1.28)	0.83 (0.60, 1.16)	-7.5% (-21.0%, 6.0%)	0.3199	

Notes:
Number of subjects: Full Analysis Set Safety Population
Number of subjects: Full Analysis Set Safety Population, excluding subjects with baseline EQ5D-VAS >85.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events-Total mortality at 26 weeks (TEAE leading to death) - Safety Set
JADE DARE (PF-04965842) - 2023 datacut

No adverse events of this type occurred

Proportion of Subjects with Treatment-Emergent Adverse Events (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set
(Protocol B7451050)

			Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term			
Overall	Overall	N	362	365
		n (%)	264 (72.9)	237 (64.9)
		95% CI[a]	(68.35, 77.51)	(60.04, 69.83)
		Relative Risk (95% CI)[a]	1.12 (1.02, 1.24)	
		P-value	0.0203	
		Odds Ratio (95% CI)[a]	1.45 (1.06, 2.00)	
		P-value	0.0201	
		Risk Difference% (95% CI)[a]	8.00 (1.29, 14.70)	
		P-value	0.0194	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR or OR can't be calculated.
a. Results calculated with normal approximation.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 23SEP2021 (23:43)
Output File: ./nda1_cdisc/B7451050_GBA/adae_prop_2_e

Proportion of Subjects with Treatment-Emergent Serious Adverse Events (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set
(Protocol B7451050)

			Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term			
Overall	Overall	N	362	365
		n (%)	6 (1.7)	5 (1.4)
		95% CI[a]	(0.34, 2.97)	(0.18, 2.56)
		Relative Risk (95% CI)[a]	1.21 (0.37, 3.93)	
		P-value	0.7512	
		Odds Ratio (95% CI)[a]	1.21 (0.37, 4.01)	
		P-value	0.7511	
		Risk Difference% (95% CI)[a]	0.29 (-1.49, 2.06)	
		P-value	0.7509	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR or OR can't be calculated.
a. Results calculated with normal approximation.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 23SEP2021 (23:43)
Output File: ./nda1_cdisc/B7451050_GBA/adae_prop_5_e

Proportion of Subjects with Treatment-Emergent Severe Adverse Events (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set (Protocol B7451050)

			Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term			
Overall	Overall	N	362	365
		n (%)	10 (2.8)	8 (2.2)
		95% CI[a]	(1.07, 4.45)	(0.69, 3.69)
		Relative Risk (95% CI)[a]	1.26 (0.50, 3.16)	
		P-value	0.6214	
		Odds Ratio (95% CI)[a]	1.27 (0.49, 3.25)	
		P-value	0.6213	
		Risk Difference% (95% CI)[a]	0.57 (-1.69, 2.83)	
		P-value	0.6206	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR or OR can't be calculated.
a. Results calculated with normal approximation.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 23SEP2021 (23:43)
Output File: ./nda1_cdisc/B7451050_GBA/adae_prop_6_e

Proportion of Subjects with Non-Severe Treatment-Emergent Adverse Events (All Causalities) - Safety Analysis Set
(Protocol B7451050)

			Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term			
Overall	Overall	N	362	365
		n (%)	267 (73.8)	237 (64.9)
		95% CI[a]	(69.22, 78.29)	(60.04, 69.83)
		Relative Risk (95% CI)[a]	1.14 (1.03, 1.25)	
		P-value	0.0102	
		Odds Ratio (95% CI)[a]	1.52 (1.10, 2.09)	
		P-value	0.0101	
		Risk Difference% (95% CI)[a]	8.83 (2.15, 15.50)	
		P-value	0.0095	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR or OR can't be calculated.
a. Results calculated with normal approximation.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 23SEP2021 (23:43)
Output File: ./nda1_cdisc/B7451050_GBA/adae_prop_10

Proportion of Subjects with Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Age (years) group: <40	Overall	Overall	N	230	247
			n (%)	174 (75.7)	162 (65.6)
			95% CI[a]	(70.11, 81.20)	(59.66, 71.51)
			Relative Risk (95% CI)[a]	1.15 (1.03, 1.30)	
			P-value	0.0162	
Age (years) group: >=40	Overall	Overall	N	132	118
			n (%)	94 (71.2)	77 (65.3)
			95% CI[a]	(63.49, 78.94)	(56.66, 73.85)
			Relative Risk (95% CI)[a]	1.09 (0.92, 1.29)	
			P-value	0.3154	
			Test for interaction[b]	0.5042	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Sex

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Sex: Male	Overall	Overall	N	193	204
			n (%)	141 (73.1)	128 (62.7)
			95% CI[a]	(66.80, 79.32)	(56.11, 69.38)
			Relative Risk (95% CI)[a]	1.16 (1.02, 1.33)	
			P-value	0.0284	
Sex: Female	Overall	Overall	N	169	161
			n (%)	127 (75.1)	111 (68.9)
			95% CI[a]	(68.63, 81.66)	(61.80, 76.09)
			Relative Risk (95% CI)[a]	1.09 (0.95, 1.25)	
			P-value	0.2115	
			Test for interaction[b]	0.6631	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Region of enrollment: US/Canada/Australia	Overall	Overall	N	177	195
			n (%)	133 (75.1)	130 (66.7)
			95% CI[a]	(68.77, 81.51)	(60.05, 73.28)
			Relative Risk (95% CI)[a]	1.13 (0.99, 1.28)	
			P-value	0.0723	
Region of enrollment: Europe	Overall	Overall	N	150	132
			n (%)	111 (74.0)	90 (68.2)
			95% CI[a]	(66.98, 81.02)	(60.24, 76.13)
			Relative Risk (95% CI)[a]	1.09 (0.93, 1.26)	
			P-value	0.2855	
Region of enrollment: Asia	Overall	Overall	N	17	19
			n (%)	12 (70.6)	10 (52.6)
			95% CI[a]	(48.93, 92.25)	(30.18, 75.08)
			Relative Risk (95% CI)[a]	1.34 (0.79, 2.27)	
			P-value	0.2736	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:29)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_2_1

Proportion of Subjects with Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Region of enrollment: Latin America	Overall	Overall	N	18	19
			n (%)	12 (66.7)	9 (47.4)
			95% CI[a]	(44.89, 88.44)	(24.92, 69.82)
			Relative Risk (95% CI)[a]	1.41 (0.79, 2.50)	
			P-value	0.2446	
			Test for interaction[b]	0.9036	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:29)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_2_1

Proportion of Subjects with Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Baseline disease severity: Moderate	Overall	Overall	N	216	220
			n (%)	162 (75.0)	148 (67.3)
			95% CI[a]	(69.23, 80.77)	(61.07, 73.47)
			Relative Risk (95% CI)[a]	1.11 (0.99, 1.26)	
			P-value	0.0760	
Baseline disease severity: Severe	Overall	Overall	N	146	145
			n (%)	106 (72.6)	91 (62.8)
			95% CI[a]	(65.37, 79.84)	(54.89, 70.63)
			Relative Risk (95% CI)[a]	1.16 (0.99, 1.36)	
			P-value	0.0746	
			Test for interaction[b]	0.8701	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:29)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_2_1

Proportion of Subjects with Treatment-Emergent Adverse Events by Subgroup (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Age (years) group: <40	Overall	Overall	N	230	247
			n (%)	170 (73.9)	161 (65.2)
			95% CI[a]	(68.24, 79.59)	(59.24, 71.12)
			Relative Risk (95% CI)[a]	1.13 (1.01, 1.28)	
			P-value	0.0387	
Age (years) group: >=40	Overall	Overall	N	132	118
			n (%)	94 (71.2)	76 (64.4)
			95% CI[a]	(63.49, 78.94)	(55.77, 73.05)
			Relative Risk (95% CI)[a]	1.11 (0.93, 1.31)	
			P-value	0.2538	
			Test for interaction[b]	0.7420	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events by Subgroup (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set
(Protocol B7451050)

Sex

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Sex: Male	Overall	Overall	N	193	204
			n (%)	138 (71.5)	126 (61.8)
			95% CI[a]	(65.13, 77.87)	(55.10, 68.43)
			Relative Risk (95% CI)[a]	1.16 (1.01, 1.33)	
			P-value	0.0404	
Sex: Female	Overall	Overall	N	169	161
			n (%)	126 (74.6)	111 (68.9)
			95% CI[a]	(67.99, 81.12)	(61.80, 76.09)
			Relative Risk (95% CI)[a]	1.08 (0.94, 1.24)	
			P-value	0.2595	
			Test for interaction[b]	0.6783	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events by Subgroup (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Region of enrollment: US/Canada/Australia	Overall	Overall	N	177	195
			n (%)	132 (74.6)	129 (66.2)
			95% CI[a]	(68.16, 80.99)	(59.51, 72.80)
			Relative Risk (95% CI)[a]	1.13 (0.99, 1.29)	
			P-value	0.0756	
Region of enrollment: Europe	Overall	Overall	N	150	132
			n (%)	109 (72.7)	89 (67.4)
			95% CI[a]	(65.53, 79.80)	(59.43, 75.42)
			Relative Risk (95% CI)[a]	1.08 (0.92, 1.26)	
			P-value	0.3404	
Region of enrollment: Asia	Overall	Overall	N	17	19
			n (%)	11 (64.7)	10 (52.6)
			95% CI[a]	(41.99, 87.42)	(30.18, 75.08)
			Relative Risk (95% CI)[a]	1.23 (0.71, 2.14)	
			P-value	0.4637	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_2_e

Proportion of Subjects with Treatment-Emergent Adverse Events by Subgroup (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Region of enrollment: Latin America	Overall	Overall	N	18	19
			n (%)	12 (66.7)	9 (47.4)
			95% CI[a]	(44.89, 88.44)	(24.92, 69.82)
			Relative Risk (95% CI)[a]	1.41 (0.79, 2.50)	
			P-value	0.2446	
			Test for interaction[b]	0.9209	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_2_e

Proportion of Subjects with Treatment-Emergent Adverse Events by Subgroup (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Baseline disease severity: Moderate	Overall	Overall	N	216	220
			n (%)	161 (74.5)	147 (66.8)
			95% CI[a]	(68.73, 80.35)	(60.60, 73.04)
			Relative Risk (95% CI)[a]	1.12 (0.99, 1.26)	
			P-value	0.0777	
Baseline disease severity: Severe	Overall	Overall	N	146	145
			n (%)	103 (70.5)	90 (62.1)
			95% CI[a]	(63.15, 77.94)	(54.17, 69.97)
			Relative Risk (95% CI)[a]	1.14 (0.96, 1.34)	
			P-value	0.1279	
			Test for interaction[b]	0.9582	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_2_e

Proportion of Subjects with Treatment-Emergent Serious Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Age (years) group: <40	Overall	Overall	N	230	247
			n (%)	3 (1.3)	4 (1.6)
			95% CI[a]	(0.00, 2.77)	(0.05, 3.19)
			Relative Risk (95% CI)[a]	0.81 (0.18, 3.56)	
			P-value	0.7754	
Age (years) group: >=40	Overall	Overall	N	132	118
			n (%)	3 (2.3)	2 (1.7)
			95% CI[a]	(0.00, 4.82)	(0.00, 4.02)
			Relative Risk (95% CI)[a]	1.34 (0.23, 7.89)	
			P-value	0.7456	
			Test for interaction[b]	0.6669	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Serious Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Sex

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Sex: Male	Overall	Overall	N	193	204
			n (%)	4 (2.1)	4 (2.0)
			95% CI[a]	(0.06, 4.08)	(0.06, 3.86)
			Relative Risk (95% CI)[a]	1.06 (0.27, 4.17)	
			P-value	0.9369	
Sex: Female	Overall	Overall	N	169	161
			n (%)	2 (1.2)	2 (1.2)
			95% CI[a]	(0.00, 2.81)	(0.00, 2.95)
			Relative Risk (95% CI)[a]	0.95 (0.14, 6.68)	
			P-value	0.9611	
			Test for interaction[b]	0.9268	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Serious Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Region of enrollment: US/Canada/Australia	Overall	Overall	N	177	195
			n (%)	2 (1.1)	3 (1.5)
			95% CI[a]	(0.00, 2.69)	(0.00, 3.27)
			Relative Risk (95% CI)[a]	0.73 (0.12, 4.34)	
			P-value	0.7336	
Region of enrollment: Europe	Overall	Overall	N	150	132
			n (%)	4 (2.7)	3 (2.3)
			95% CI[a]	(0.09, 5.24)	(0.00, 4.82)
			Relative Risk (95% CI)[a]	1.17 (0.27, 5.15)	
			P-value	0.8322	
Region of enrollment: Asia	Overall	Overall	N	17	19
			n (%)	0	0
Region of enrollment: Latin America	Overall	Overall	N	18	19
			n (%)	0	0
			Test for interaction[b]	0.9862	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_5

Proportion of Subjects with Treatment-Emergent Serious Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Baseline disease severity: Moderate	Overall	Overall	N	216	220
			n (%)	5 (2.3)	5 (2.3)
			95% CI[a]	(0.31, 4.32)	(0.30, 4.24)
			Relative Risk (95% CI)[a]	1.02 (0.30, 3.47)	
			P-value	0.9766	
Baseline disease severity: Severe	Overall	Overall	N	146	145
			n (%)	1 (0.7)	1 (0.7)
			95% CI[a]	(0.00, 2.02)	(0.00, 2.04)
			Relative Risk (95% CI)[a]	0.99 (0.06, 15.73)	
			P-value	0.9961	
			Test for interaction[b]	0.9783	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_5

Proportion of Subjects with Treatment-Emergent Serious Adverse Events by Subgroup (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Age (years) group: <40	Overall	Overall	N	230	247
			n (%)	3 (1.3)	4 (1.6)
			95% CI[a]	(0.00, 2.77)	(0.05, 3.19)
			Relative Risk (95% CI)[a]	0.81 (0.18, 3.56)	
			P-value	0.7754	
Age (years) group: >=40	Overall	Overall	N	132	118
			n (%)	3 (2.3)	1 (0.8)
			95% CI[a]	(0.00, 4.82)	(0.00, 2.50)
			Relative Risk (95% CI)[a]	2.68 (0.28, 25.43)	
			P-value	0.3901	
			Test for interaction[b]	0.3599	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Serious Adverse Events by Subgroup (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set
(Protocol B7451050)

Sex

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Sex: Male	Overall	Overall	N	193	204
			n (%)	4 (2.1)	3 (1.5)
			95% CI[a]	(0.06, 4.08)	(0.00, 3.12)
			Relative Risk (95% CI)[a]	1.41 (0.32, 6.22)	
			P-value	0.6504	
Sex: Female	Overall	Overall	N	169	161
			n (%)	2 (1.2)	2 (1.2)
			95% CI[a]	(0.00, 2.81)	(0.00, 2.95)
			Relative Risk (95% CI)[a]	0.95 (0.14, 6.68)	
			P-value	0.9611	
			Test for interaction[b]	0.7121	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Serious Adverse Events by Subgroup (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Region of enrollment: US/Canada/Australia	Overall	Overall	N	177	195
			n (%)	2 (1.1)	3 (1.5)
			95% CI[a]	(0.00, 2.69)	(0.00, 3.27)
			Relative Risk (95% CI)[a]	0.73 (0.12, 4.34)	
			P-value	0.7336	
Region of enrollment: Europe	Overall	Overall	N	150	132
			n (%)	4 (2.7)	2 (1.5)
			95% CI[a]	(0.09, 5.24)	(0.00, 3.60)
			Relative Risk (95% CI)[a]	1.76 (0.33, 9.45)	
			P-value	0.5099	
Region of enrollment: Asia	Overall	Overall	N	17	19
			n (%)	0	0
Region of enrollment: Latin America	Overall	Overall	N	18	19
			n (%)	0	0
			Test for interaction[b]	0.9031	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_5_e

Proportion of Subjects with Treatment-Emergent Serious Adverse Events by Subgroup (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Baseline disease severity: Moderate	Overall	Overall	N	216	220
			n (%)	5 (2.3)	5 (2.3)
			95% CI[a]	(0.31, 4.32)	(0.30, 4.24)
			Relative Risk (95% CI)[a]	1.02 (0.30, 3.47)	
			P-value	0.9766	
Baseline disease severity: Severe	Overall	Overall	N	146	145
			n (%)	1 (0.7)	0
			95% CI[a]	(0.00, 2.02)	(0.00, 2.51)
			Relative Risk (95% CI)[a]	1.99 (0.07, 58.95)	
			P-value	0.6898	
			Test for interaction[b]	0.8593	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_5_e

Proportion of Subjects with Treatment-Emergent Severe Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Age (years) group: <40	Overall	Overall	N	230	247
			n (%)	6 (2.6)	6 (2.4)
			95% CI[a]	(0.55, 4.67)	(0.51, 4.35)
			Relative Risk (95% CI)[a]	1.07 (0.35, 3.28)	
			P-value	0.9004	
Age (years) group: >=40	Overall	Overall	N	132	118
			n (%)	5 (3.8)	2 (1.7)
			95% CI[a]	(0.53, 7.04)	(0.00, 4.02)
			Relative Risk (95% CI)[a]	2.23 (0.44, 11.30)	
			P-value	0.3309	
			Test for interaction[b]	0.4442	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Severe Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Sex

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Sex: Male	Overall	Overall	N	193	204
			n (%)	6 (3.1)	2 (1.0)
			95% CI[a]	(0.66, 5.56)	(0.00, 2.33)
			Relative Risk (95% CI)[a]	3.17 (0.65, 15.52)	
			P-value	0.1544	
Sex: Female	Overall	Overall	N	169	161
			n (%)	5 (3.0)	6 (3.7)
			95% CI[a]	(0.40, 5.51)	(0.80, 6.65)
			Relative Risk (95% CI)[a]	0.79 (0.25, 2.55)	
			P-value	0.6983	
			Test for interaction[b]	0.2392	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Severe Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Region of enrollment: US/Canada/Australia	Overall	Overall	N	177	195
			n (%)	5 (2.8)	6 (3.1)
			95% CI[a]	(0.38, 5.27)	(0.65, 5.50)
			Relative Risk (95% CI)[a]	0.92 (0.29, 2.96)	
			P-value	0.8861	
Region of enrollment: Europe	Overall	Overall	N	150	132
			n (%)	5 (3.3)	2 (1.5)
			95% CI[a]	(0.46, 6.21)	(0.00, 3.60)
			Relative Risk (95% CI)[a]	2.20 (0.43, 11.15)	
			P-value	0.3410	
Region of enrollment: Asia	Overall	Overall	N	17	19
			n (%)	1 (5.9)	0
			95% CI[a]	(0.00, 17.07)	(0.00, 17.65)
			Relative Risk (95% CI)[a]	2.29 (0.08, 64.21)	
			P-value	0.6252	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Severe Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Region of enrollment: Latin America	Overall	Overall	N	18	19
			n (%)	0	0
			Test for interaction[b]	0.8432	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_6

Proportion of Subjects with Treatment-Emergent Severe Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Baseline disease severity: Moderate	Overall	Overall	N	216	220
			n (%)	5 (2.3)	5 (2.3)
			95% CI[a]	(0.31, 4.32)	(0.30, 4.24)
			Relative Risk (95% CI)[a]	1.02 (0.30, 3.47)	
			P-value	0.9766	
Baseline disease severity: Severe	Overall	Overall	N	146	145
			n (%)	6 (4.1)	3 (2.1)
			95% CI[a]	(0.89, 7.33)	(0.00, 4.39)
			Relative Risk (95% CI)[a]	1.99 (0.51, 7.79)	
			P-value	0.3250	
			Test for interaction[b]	0.4201	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_6

Proportion of Subjects with Treatment-Emergent Severe Adverse Events by Subgroup (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Age (years) group: <40	Overall	Overall	N	230	247
			n (%)	5 (2.2)	6 (2.4)
			95% CI[a]	(0.29, 4.06)	(0.51, 4.35)
			Relative Risk (95% CI)[a]	0.89 (0.28, 2.89)	
			P-value	0.8529	
Age (years) group: >=40	Overall	Overall	N	132	118
			n (%)	5 (3.8)	2 (1.7)
			95% CI[a]	(0.53, 7.04)	(0.00, 4.02)
			Relative Risk (95% CI)[a]	2.23 (0.44, 11.30)	
			P-value	0.3309	
			Test for interaction[b]	0.3408	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_6_e

Proportion of Subjects with Treatment-Emergent Severe Adverse Events by Subgroup (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set
(Protocol B7451050)

Sex

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Sex: Male	Overall	Overall	N	193	204
			n (%)	6 (3.1)	2 (1.0)
			95% CI[a]	(0.66, 5.56)	(0.00, 2.33)
			Relative Risk (95% CI)[a]	3.17 (0.65, 15.52)	
			P-value	0.1544	
Sex: Female	Overall	Overall	N	169	161
			n (%)	4 (2.4)	6 (3.7)
			95% CI[a]	(0.07, 4.66)	(0.80, 6.65)
			Relative Risk (95% CI)[a]	0.64 (0.18, 2.21)	
			P-value	0.4754	
			Test for interaction[b]	0.1439	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_6_e

Proportion of Subjects with Treatment-Emergent Severe Adverse Events by Subgroup (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Region of enrollment: US/Canada/Australia	Overall	Overall	N	177	195
			n (%)	5 (2.8)	6 (3.1)
			95% CI[a]	(0.38, 5.27)	(0.65, 5.50)
			Relative Risk (95% CI)[a]	0.92 (0.29, 2.96)	
			P-value	0.8861	
Region of enrollment: Europe	Overall	Overall	N	150	132
			n (%)	5 (3.3)	2 (1.5)
			95% CI[a]	(0.46, 6.21)	(0.00, 3.60)
			Relative Risk (95% CI)[a]	2.20 (0.43, 11.15)	
			P-value	0.3410	
Region of enrollment: Asia	Overall	Overall	N	17	19
			n (%)	0	0
Region of enrollment: Latin America	Overall	Overall	N	18	19
			n (%)	0	0
			Test for interaction[b]	0.8759	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_6_e

Proportion of Subjects with Treatment-Emergent Severe Adverse Events by Subgroup (Excluding Adverse Events Related to AD, All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Baseline disease severity: Moderate	Overall	Overall	N	216	220
			n (%)	5 (2.3)	5 (2.3)
			95% CI[a]	(0.31, 4.32)	(0.30, 4.24)
			Relative Risk (95% CI)[a]	1.02 (0.30, 3.47)	
			P-value	0.9766	
Baseline disease severity: Severe	Overall	Overall	N	146	145
			n (%)	5 (3.4)	3 (2.1)
			95% CI[a]	(0.47, 6.37)	(0.00, 4.39)
			Relative Risk (95% CI)[a]	1.66 (0.40, 6.80)	
			P-value	0.4845	
			Test for interaction[b]	0.5825	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_6_e

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
Overall	Overall	Age (years) group: <40	N	230	247
			n (%)	129 (56.1)	87 (35.2)
			95% CI[a]	(49.67, 62.50)	(29.27, 41.18)
			Relative Risk (95% CI)[a]	1.59 (1.30, 1.95)	
			P-value	<.0001	
		Age (years) group: >=40	N	132	118
			n (%)	68 (51.5)	42 (35.6)
			95% CI[a]	(42.99, 60.04)	(26.95, 44.23)
			Relative Risk (95% CI)[a]	1.45 (1.08, 1.94)	
			P-value	0.0136	
			Test for interaction[b]	0.4642	
Gastrointestinal disorders	Overall	Age (years) group: <40	N	230	247
			n (%)	53 (23.0)	7 (2.8)
			95% CI[a]	(17.60, 28.49)	(0.76, 4.90)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
			Relative Risk (95% CI)[a]	8.13 (3.77, 17.52)	
			P-value	<.0001	
		Age (years) group: >=40	N	132	118
			n (%)	17 (12.9)	4 (3.4)
			95% CI[a]	(7.16, 18.59)	(0.12, 6.66)
			Relative Risk (95% CI)[a]	3.80 (1.32, 10.97)	
			P-value	0.0136	
			Test for interaction[b]	0.0148	
	Nausea	Age (years) group: <40	N	230	247
			n (%)	53 (23.0)	5 (2.0)
			95% CI[a]	(17.60, 28.49)	(0.27, 3.78)
			Relative Risk (95% CI)[a]	11.38 (4.63, 27.98)	
			P-value	<.0001	
		Age (years) group: >=40	N	132	118
			n (%)	17 (12.9)	3 (2.5)
			95% CI[a]	(7.16, 18.59)	(0.00, 5.38)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
			Relative Risk (95% CI)[a]	5.07 (1.52, 16.85)	
			P-value	0.0082	
			Test for interaction[b]	0.0132	
	Vomiting	Age (years) group: <40	N	230	247
			n (%)	9 (3.9)	4 (1.6)
			95% CI[a]	(1.41, 6.42)	(0.05, 3.19)
			Relative Risk (95% CI)[a]	2.42 (0.75, 7.74)	
			P-value	0.1374	
		Age (years) group: >=40	N	132	118
			n (%)	2 (1.5)	2 (1.7)
			95% CI[a]	(0.00, 3.60)	(0.00, 4.02)
			Relative Risk (95% CI)[a]	0.89 (0.13, 6.25)	
			P-value	0.9100	
			Test for interaction[b]	0.2587	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
General disorders and administration site conditions	Overall	Age (years) group: <40	N	230	247
			n (%)	3 (1.3)	3 (1.2)
			95% CI[a]	(0.00, 2.77)	(0.00, 2.58)
			Relative Risk (95% CI)[a]	1.07 (0.22, 5.27)	
			P-value	0.9300	
		Age (years) group: >=40	N	132	118
			n (%)	7 (5.3)	2 (1.7)
			95% CI[a]	(1.48, 9.13)	(0.00, 4.02)
			Relative Risk (95% CI)[a]	3.13 (0.66, 14.77)	
			P-value	0.1497	
			Test for interaction[b]	0.1610	
	Fatigue	Age (years) group: <40	N	230	247
			n (%)	3 (1.3)	3 (1.2)
			95% CI[a]	(0.00, 2.77)	(0.00, 2.58)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
			Relative Risk (95% CI)[a]	1.07 (0.22, 5.27)	
			P-value	0.9300	
		Age (years) group: >=40	N	132	118
			n (%)	7 (5.3)	2 (1.7)
			95% CI[a]	(1.48, 9.13)	(0.00, 4.02)
			Relative Risk (95% CI)[a]	3.13 (0.66, 14.77)	
			P-value	0.1497	
			Test for interaction[b]	0.1610	
Infections and infestations	Overall	Age (years) group: <40	N	230	247
			n (%)	44 (19.1)	48 (19.4)
			95% CI[a]	(14.05, 24.21)	(14.50, 24.37)
			Relative Risk (95% CI)[a]	0.98 (0.68, 1.42)	
			P-value	0.9333	
		Age (years) group: >=40	N	132	118
			n (%)	24 (18.2)	28 (23.7)
			95% CI[a]	(11.60, 24.76)	(16.05, 31.40)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
			Relative Risk (95% CI)[a]	0.77 (0.47, 1.24)	
			P-value	0.2823	
			Test for interaction[b]	0.4034	
	COVID-19	Age (years) group: <40	N	230	247
			n (%)	9 (3.9)	9 (3.6)
			95% CI[a]	(1.41, 6.42)	(1.31, 5.98)
			Relative Risk (95% CI)[a]	1.07 (0.43, 2.66)	
			P-value	0.8774	
		Age (years) group: >=40	N	132	118
			n (%)	6 (4.5)	3 (2.5)
			95% CI[a]	(0.99, 8.10)	(0.00, 5.38)
			Relative Risk (95% CI)[a]	1.79 (0.46, 6.99)	
			P-value	0.4036	
			Test for interaction[b]	0.5518	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
	Conjunctivitis	Age (years) group: <40	N	230	247
			n (%)	4 (1.7)	20 (8.1)
			95% CI[a]	(0.05, 3.43)	(4.70, 11.50)
			Relative Risk (95% CI)[a]	0.21 (0.07, 0.62)	
			P-value	0.0044	
		Age (years) group: >=40	N	132	118
			n (%)	4 (3.0)	15 (12.7)
			95% CI[a]	(0.11, 5.95)	(6.70, 18.72)
			Relative Risk (95% CI)[a]	0.24 (0.08, 0.70)	
			P-value	0.0089	
			Test for interaction[b]	0.3803	
	Folliculitis	Age (years) group: <40	N	230	247
			n (%)	7 (3.0)	2 (0.8)
			95% CI[a]	(0.82, 5.26)	(0.00, 1.93)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
			Relative Risk (95% CI)[a]	3.76 (0.79, 17.91)	
			P-value	0.0965	
		Age (years) group: >=40	N	132	118
			n (%)	5 (3.8)	1 (0.8)
			95% CI[a]	(0.53, 7.04)	(0.00, 2.50)
			Relative Risk (95% CI)[a]	4.47 (0.53, 37.71)	
			P-value	0.1688	
			Test for interaction[b]	0.7526	
	Herpes simplex	Age (years) group: <40	N	230	247
			n (%)	9 (3.9)	3 (1.2)
			95% CI[a]	(1.41, 6.42)	(0.00, 2.58)
			Relative Risk (95% CI)[a]	3.22 (0.88, 11.75)	
			P-value	0.0764	
		Age (years) group: >=40	N	132	118
			n (%)	3 (2.3)	2 (1.7)
			95% CI[a]	(0.00, 4.82)	(0.00, 4.02)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
			Relative Risk (95% CI)[a]	1.34 (0.23, 7.89)	
			P-value	0.7456	
			Test for interaction[b]	0.3522	
	Nasopharyngitis	Age (years) group: <40	N	230	247
			n (%)	11 (4.8)	10 (4.0)
			95% CI[a]	(2.02, 7.54)	(1.59, 6.51)
			Relative Risk (95% CI)[a]	1.18 (0.51, 2.73)	
			P-value	0.6965	
		Age (years) group: >=40	N	132	118
			n (%)	3 (2.3)	2 (1.7)
			95% CI[a]	(0.00, 4.82)	(0.00, 4.02)
			Relative Risk (95% CI)[a]	1.34 (0.23, 7.89)	
			P-value	0.7456	
			Test for interaction[b]	0.9467	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
	Oral herpes	Age (years) group: <40	N	230	247
			n (%)	7 (3.0)	7 (2.8)
			95% CI[a]	(0.82, 5.26)	(0.76, 4.90)
			Relative Risk (95% CI)[a]	1.07 (0.38, 3.01)	
			P-value	0.8923	
		Age (years) group: >=40	N	132	118
			n (%)	2 (1.5)	8 (6.8)
			95% CI[a]	(0.00, 3.60)	(2.24, 11.32)
			Relative Risk (95% CI)[a]	0.22 (0.05, 1.03)	
			P-value	0.0548	
			Test for interaction[b]	0.0692	
	Upper respiratory tract infection	Age (years) group: <40	N	230	247
			n (%)	6 (2.6)	7 (2.8)
			95% CI[a]	(0.55, 4.67)	(0.76, 4.90)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
			Relative Risk (95% CI)[a]	0.92 (0.31, 2.70)	
			P-value	0.8800	
		Age (years) group: >=40	N	132	118
			n (%)	4 (3.0)	2 (1.7)
			95% CI[a]	(0.11, 5.95)	(0.00, 4.02)
			Relative Risk (95% CI)[a]	1.79 (0.33, 9.58)	
			P-value	0.4976	
			Test for interaction[b]	0.5198	
Investigations	Overall	Age (years) group: <40	N	230	247
			n (%)	22 (9.6)	19 (7.7)
			95% CI[a]	(5.76, 13.37)	(4.37, 11.02)
			Relative Risk (95% CI)[a]	1.24 (0.69, 2.24)	
			P-value	0.4668	
		Age (years) group: >=40	N	132	118
			n (%)	16 (12.1)	7 (5.9)
			95% CI[a]	(6.55, 17.69)	(1.67, 10.19)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
			Relative Risk (95% CI)[a]	2.04 (0.87, 4.79)	
			P-value	0.1005	
			Test for interaction[b]	0.3293	
	Blood creatine phosphokinase increased	Age (years) group: <40	N	230	247
			n (%)	5 (2.2)	10 (4.0)
			95% CI[a]	(0.29, 4.06)	(1.59, 6.51)
			Relative Risk (95% CI)[a]	0.54 (0.19, 1.55)	
			P-value	0.2495	
		Age (years) group: >=40	N	132	118
			n (%)	9 (6.8)	3 (2.5)
			95% CI[a]	(2.52, 11.12)	(0.00, 5.38)
			Relative Risk (95% CI)[a]	2.68 (0.74, 9.67)	
			P-value	0.1318	
			Test for interaction[b]	0.0468	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
	Natural killer cell count decreased	Age (years) group: <40	N	230	247
			n (%)	7 (3.0)	0
			95% CI[a]	(0.82, 5.26)	(0.00, 1.48)
			Relative Risk (95% CI)[a]	15.07 (0.86, 263.98)	
			P-value	0.0634	
		Age (years) group: >=40	N	132	118
			n (%)	3 (2.3)	0
			95% CI[a]	(0.00, 4.82)	(0.00, 3.08)
			Relative Risk (95% CI)[a]	5.39 (0.27, 106.43)	
			P-value	0.2687	
			Test for interaction[b]	0.5919	
	SARS-CoV-2 test positive	Age (years) group: <40	N	230	247
			n (%)	10 (4.3)	9 (3.6)
			95% CI[a]	(1.71, 6.98)	(1.31, 5.98)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
			Relative Risk (95% CI)[a]	1.19 (0.49, 2.88)	
			P-value	0.6948	
		Age (years) group: >=40	N	132	118
			n (%)	5 (3.8)	4 (3.4)
			95% CI[a]	(0.53, 7.04)	(0.12, 6.66)
			Relative Risk (95% CI)[a]	1.12 (0.31, 4.06)	
			P-value	0.8662	
			Test for interaction[b]	0.9170	
Nervous system disorders	Overall	Age (years) group: <40	N	230	247
			n (%)	33 (14.3)	18 (7.3)
			95% CI[a]	(9.82, 18.88)	(4.05, 10.53)
			Relative Risk (95% CI)[a]	1.97 (1.14, 3.40)	
			P-value	0.0149	
		Age (years) group: >=40	N	132	118
			n (%)	22 (16.7)	9 (7.6)
			95% CI[a]	(10.31, 23.02)	(2.84, 12.42)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
			Relative Risk (95% CI)[a]	2.19 (1.05, 4.56)	
			P-value	0.0370	
			Test for interaction[b]	0.6772	
	Dizziness	Age (years) group: <40	N	230	247
			n (%)	6 (2.6)	1 (0.4)
			95% CI[a]	(0.55, 4.67)	(0.00, 1.20)
			Relative Risk (95% CI)[a]	6.44 (0.78, 53.11)	
			P-value	0.0834	
		Age (years) group: >=40	N	132	118
			n (%)	4 (3.0)	3 (2.5)
			95% CI[a]	(0.11, 5.95)	(0.00, 5.38)
			Relative Risk (95% CI)[a]	1.19 (0.27, 5.22)	
			P-value	0.8157	
			Test for interaction[b]	0.4751	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
	Headache	Age (years) group: <40	N	230	247
			n (%)	28 (12.2)	17 (6.9)
			95% CI[a]	(7.95, 16.40)	(3.73, 10.04)
			Relative Risk (95% CI)[a]	1.77 (1.00, 3.14)	
			P-value	0.0520	
		Age (years) group: >=40	N	132	118
			n (%)	19 (14.4)	7 (5.9)
			95% CI[a]	(8.41, 20.38)	(1.67, 10.19)
			Relative Risk (95% CI)[a]	2.43 (1.06, 5.57)	
			P-value	0.0364	
			Test for interaction[b]	0.4922	
Skin and subcutaneous tissue disorders	Overall	Age (years) group: <40	N	230	247
			n (%)	47 (20.4)	19 (7.7)
			95% CI[a]	(15.22, 25.65)	(4.37, 11.02)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
			Relative Risk (95% CI)[a]	2.66 (1.61, 4.39)	
			P-value	0.0001	
		Age (years) group: >=40	N	132	118
			n (%)	14 (10.6)	4 (3.4)
			95% CI[a]	(5.35, 15.86)	(0.12, 6.66)
			Relative Risk (95% CI)[a]	3.13 (1.06, 9.24)	
			P-value	0.0390	
			Test for interaction[b]	0.1683	
	Acne	Age (years) group: <40	N	230	247
			n (%)	33 (14.3)	10 (4.0)
			95% CI[a]	(9.82, 18.88)	(1.59, 6.51)
			Relative Risk (95% CI)[a]	3.54 (1.79, 7.03)	
			P-value	0.0003	
		Age (years) group: >=40	N	132	118
			n (%)	13 (9.8)	0
			95% CI[a]	(4.77, 14.93)	(0.00, 3.08)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
			Relative Risk (95% CI)[a]	23.34 (1.40, 389.13)	
			P-value	0.0282	
			Test for interaction[b]	0.7370	
	Dermatitis atopic	Age (years) group: <40	N	230	247
			n (%)	16 (7.0)	10 (4.0)
			95% CI[a]	(3.67, 10.24)	(1.59, 6.51)
			Relative Risk (95% CI)[a]	1.72 (0.80, 3.71)	
			P-value	0.1679	
		Age (years) group: >=40	N	132	118
			n (%)	1 (0.8)	4 (3.4)
			95% CI[a]	(0.00, 2.24)	(0.12, 6.66)
			Relative Risk (95% CI)[a]	0.22 (0.03, 1.97)	
			P-value	0.1774	
			Test for interaction[b]	0.0481	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Sex

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
Overall	Overall	Sex: Male	N	193	204
			n (%)	100 (51.8)	68 (33.3)
			95% CI[a]	(44.76, 58.86)	(26.86, 39.80)
			Relative Risk (95% CI)[a]	1.55 (1.23, 1.97)	
			P-value	0.0003	
		Sex: Female	N	169	161
			n (%)	97 (57.4)	61 (37.9)
			95% CI[a]	(49.94, 64.85)	(30.39, 45.38)
			Relative Risk (95% CI)[a]	1.51 (1.20, 1.92)	
			P-value	0.0006	
			Test for interaction[b]	0.7096	
Gastrointestinal disorders	Overall	Sex: Male	N	193	204
			n (%)	21 (10.9)	4 (2.0)
			95% CI[a]	(6.49, 15.27)	(0.06, 3.86)
			Relative Risk (95% CI)[a]	5.55 (1.94, 15.87)	
			P-value	0.0014	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Sex

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
		Sex: Female	N	169	161
			n (%)	49 (29.0)	7 (4.3)
			95% CI[a]	(22.15, 35.83)	(1.20, 7.50)
			Relative Risk (95% CI)[a]	6.67 (3.11, 14.29)	
			P-value	<.0001	
			Test for interaction[b]	0.0005	
	Nausea	Sex: Male	N	193	204
			n (%)	21 (10.9)	2 (1.0)
			95% CI[a]	(6.49, 15.27)	(0.00, 2.33)
			Relative Risk (95% CI)[a]	11.10 (2.64, 46.70)	
			P-value	0.0010	
		Sex: Female	N	169	161
			n (%)	49 (29.0)	6 (3.7)
			95% CI[a]	(22.15, 35.83)	(0.80, 6.65)
			Relative Risk (95% CI)[a]	7.78 (3.43, 17.66)	
			P-value	<.0001	
			Test for interaction[b]	0.0006	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Sex

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
	Vomiting	Sex: Male	N	193	204
			n (%)	2 (1.0)	3 (1.5)
			95% CI[a]	(0.00, 2.46)	(0.00, 3.12)
			Relative Risk (95% CI)[a]	0.70 (0.12, 4.17)	
			P-value	0.6997	
		Sex: Female	N	169	161
			n (%)	9 (5.3)	3 (1.9)
			95% CI[a]	(1.94, 8.71)	(0.00, 3.95)
			Relative Risk (95% CI)[a]	2.86 (0.79, 10.37)	
			P-value	0.1102	
			Test for interaction[b]	0.0936	
General disorders and administration site conditions	Overall	Sex: Male	N	193	204
			n (%)	3 (1.6)	3 (1.5)
			95% CI[a]	(0.00, 3.30)	(0.00, 3.12)
			Relative Risk (95% CI)[a]	1.06 (0.22, 5.17)	
			P-value	0.9455	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Sex

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
		Sex: Female	N	169	161
			n (%)	7 (4.1)	2 (1.2)
			95% CI[a]	(1.14, 7.15)	(0.00, 2.95)
			Relative Risk (95% CI)[a]	3.33 (0.70, 15.81)	
			P-value	0.1294	
			Test for interaction[b]	0.1904	
	Fatigue	Sex: Male	N	193	204
			n (%)	3 (1.6)	3 (1.5)
			95% CI[a]	(0.00, 3.30)	(0.00, 3.12)
			Relative Risk (95% CI)[a]	1.06 (0.22, 5.17)	
			P-value	0.9455	
		Sex: Female	N	169	161
			n (%)	7 (4.1)	2 (1.2)
			95% CI[a]	(1.14, 7.15)	(0.00, 2.95)
			Relative Risk (95% CI)[a]	3.33 (0.70, 15.81)	
			P-value	0.1294	
			Test for interaction[b]	0.1904	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Sex

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
Infections and infestations	Overall	Sex: Male	N	193	204
			n (%)	40 (20.7)	41 (20.1)
			95% CI[a]	(15.01, 26.44)	(14.60, 25.60)
			Relative Risk (95% CI)[a]	1.03 (0.70, 1.52)	
			P-value	0.8768	
		Sex: Female	N	169	161
			n (%)	28 (16.6)	35 (21.7)
			95% CI[a]	(10.96, 22.17)	(15.37, 28.11)
			Relative Risk (95% CI)[a]	0.76 (0.49, 1.19)	
			P-value	0.2343	
			Test for interaction[b]	0.3320	
	COVID-19	Sex: Male	N	193	204
			n (%)	7 (3.6)	5 (2.5)
			95% CI[a]	(0.99, 6.26)	(0.33, 4.57)
			Relative Risk (95% CI)[a]	1.48 (0.48, 4.58)	
			P-value	0.4969	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Sex

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
		Sex: Female	N	169	161
			n (%)	8 (4.7)	7 (4.3)
			95% CI[a]	(1.53, 7.94)	(1.20, 7.50)
			Relative Risk (95% CI)[a]	1.09 (0.40, 2.93)	
			P-value	0.8665	
			Test for interaction[b]	0.7869	
	Conjunctivitis	Sex: Male	N	193	204
			n (%)	7 (3.6)	20 (9.8)
			95% CI[a]	(0.99, 6.26)	(5.72, 13.88)
			Relative Risk (95% CI)[a]	0.37 (0.16, 0.86)	
			P-value	0.0200	
		Sex: Female	N	169	161
			n (%)	1 (0.6)	15 (9.3)
			95% CI[a]	(0.00, 1.75)	(4.83, 13.81)
			Relative Risk (95% CI)[a]	0.06 (0.01, 0.48)	
			P-value	0.0073	
			Test for interaction[b]	0.4937	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
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Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Sex

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
	Folliculitis	Sex: Male	N	193	204
			n (%)	10 (5.2)	2 (1.0)
			95% CI[a]	(2.05, 8.31)	(0.00, 2.33)
			Relative Risk (95% CI)[a]	5.28 (1.17, 23.81)	
			P-value	0.0302	
		Sex: Female	N	169	161
			n (%)	2 (1.2)	1 (0.6)
			95% CI[a]	(0.00, 2.81)	(0.00, 1.83)
			Relative Risk (95% CI)[a]	1.91 (0.17, 20.81)	
			P-value	0.5972	
			Test for interaction[b]	0.0729	
	Herpes simplex	Sex: Male	N	193	204
			n (%)	8 (4.1)	2 (1.0)
			95% CI[a]	(1.33, 6.96)	(0.00, 2.33)
			Relative Risk (95% CI)[a]	4.23 (0.91, 19.66)	
			P-value	0.0660	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Sex

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
		Sex: Female	N	169	161
			n (%)	4 (2.4)	3 (1.9)
			95% CI[a]	(0.07, 4.66)	(0.00, 3.95)
			Relative Risk (95% CI)[a]	1.27 (0.29, 5.59)	
			P-value	0.7516	
			Test for interaction[b]	0.2368	
	Nasopharyngitis	Sex: Male	N	193	204
			n (%)	7 (3.6)	7 (3.4)
			95% CI[a]	(0.99, 6.26)	(0.93, 5.93)
			Relative Risk (95% CI)[a]	1.06 (0.38, 2.96)	
			P-value	0.9159	
		Sex: Female	N	169	161
			n (%)	7 (4.1)	5 (3.1)
			95% CI[a]	(1.14, 7.15)	(0.43, 5.79)
			Relative Risk (95% CI)[a]	1.33 (0.43, 4.12)	
			P-value	0.6165	
			Test for interaction[b]	0.7611	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Sex

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
	Oral herpes	Sex: Male	N	193	204
			n (%)	3 (1.6)	7 (3.4)
			95% CI[a]	(0.00, 3.30)	(0.93, 5.93)
			Relative Risk (95% CI)[a]	0.45 (0.12, 1.73)	
			P-value	0.2461	
		Sex: Female	N	169	161
			n (%)	6 (3.6)	8 (5.0)
			95% CI[a]	(0.76, 6.34)	(1.61, 8.33)
			Relative Risk (95% CI)[a]	0.71 (0.25, 2.01)	
			P-value	0.5249	
			Test for interaction[b]	0.8754	
	Upper respiratory tract infection	Sex: Male	N	193	204
			n (%)	6 (3.1)	3 (1.5)
			95% CI[a]	(0.66, 5.56)	(0.00, 3.12)
			Relative Risk (95% CI)[a]	2.11 (0.54, 8.33)	
			P-value	0.2849	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Sex

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
		Sex: Female	N	169	161
			n (%)	4 (2.4)	6 (3.7)
			95% CI[a]	(0.07, 4.66)	(0.80, 6.65)
			Relative Risk (95% CI)[a]	0.64 (0.18, 2.21)	
			P-value	0.4754	
			Test for interaction[b]	0.2174	
Investigations	Overall	Sex: Male	N	193	204
			n (%)	21 (10.9)	12 (5.9)
			95% CI[a]	(6.49, 15.27)	(2.65, 9.11)
			Relative Risk (95% CI)[a]	1.85 (0.94, 3.66)	
			P-value	0.0769	
		Sex: Female	N	169	161
			n (%)	17 (10.1)	14 (8.7)
			95% CI[a]	(5.52, 14.59)	(4.34, 13.05)
			Relative Risk (95% CI)[a]	1.16 (0.59, 2.27)	
			P-value	0.6717	
			Test for interaction[b]	0.3986	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Sex

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
	Blood creatine phosphokinase increased	Sex: Male	N	193	204
			n (%)	9 (4.7)	7 (3.4)
			95% CI[a]	(1.69, 7.64)	(0.93, 5.93)
			Relative Risk (95% CI)[a]	1.36 (0.52, 3.58)	
			P-value	0.5345	
		Sex: Female	N	169	161
			n (%)	5 (3.0)	6 (3.7)
			95% CI[a]	(0.40, 5.51)	(0.80, 6.65)
			Relative Risk (95% CI)[a]	0.79 (0.25, 2.55)	
			P-value	0.6983	
			Test for interaction[b]	0.4755	
	Natural killer cell count decreased	Sex: Male	N	193	204
			n (%)	5 (2.6)	0
			95% CI[a]	(0.35, 4.83)	(0.00, 1.79)
			Relative Risk (95% CI)[a]	10.60 (0.58, 192.65)	
			P-value	0.1107	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Sex

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
		Sex: Female	N	169	161
			n (%)	5 (3.0)	0
			95% CI[a]	(0.40, 5.51)	(0.00, 2.27)
			Relative Risk (95% CI)[a]	9.56 (0.53, 173.52)	
			P-value	0.1270	
			Test for interaction[b]	0.8670	
	SARS-CoV-2 test positive	Sex: Male	N	193	204
			n (%)	7 (3.6)	5 (2.5)
			95% CI[a]	(0.99, 6.26)	(0.33, 4.57)
			Relative Risk (95% CI)[a]	1.48 (0.48, 4.58)	
			P-value	0.4969	
		Sex: Female	N	169	161
			n (%)	8 (4.7)	8 (5.0)
			95% CI[a]	(1.53, 7.94)	(1.61, 8.33)
			Relative Risk (95% CI)[a]	0.95 (0.37, 2.48)	
			P-value	0.9208	
			Test for interaction[b]	0.6334	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Sex

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
Nervous system disorders	Overall	Sex: Male	N	193	204
			n (%)	28 (14.5)	12 (5.9)
			95% CI[a]	(9.54, 19.48)	(2.65, 9.11)
			Relative Risk (95% CI)[a]	2.47 (1.29, 4.71)	
			P-value	0.0062	
		Sex: Female	N	169	161
			n (%)	27 (16.0)	15 (9.3)
			95% CI[a]	(10.45, 21.50)	(4.83, 13.81)
			Relative Risk (95% CI)[a]	1.71 (0.95, 3.10)	
			P-value	0.0747	
			Test for interaction[b]	0.7148	
	Dizziness	Sex: Male	N	193	204
			n (%)	4 (2.1)	2 (1.0)
			95% CI[a]	(0.06, 4.08)	(0.00, 2.33)
			Relative Risk (95% CI)[a]	2.11 (0.39, 11.41)	
			P-value	0.3842	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Sex

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
		Sex: Female	N	169	161
			n (%)	6 (3.6)	2 (1.2)
			95% CI[a]	(0.76, 6.34)	(0.00, 2.95)
			Relative Risk (95% CI)[a]	2.86 (0.59, 13.95)	
			P-value	0.1943	
			Test for interaction[b]	0.5557	
	Headache	Sex: Male	N	193	204
			n (%)	24 (12.4)	10 (4.9)
			95% CI[a]	(7.78, 17.09)	(1.94, 7.86)
			Relative Risk (95% CI)[a]	2.54 (1.25, 5.16)	
			P-value	0.0103	
		Sex: Female	N	169	161
			n (%)	23 (13.6)	14 (8.7)
			95% CI[a]	(8.44, 18.78)	(4.34, 13.05)
			Relative Risk (95% CI)[a]	1.57 (0.83, 2.93)	
			P-value	0.1623	
			Test for interaction[b]	0.5872	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Sex

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
Skin and subcutaneous tissue disorders	Overall	Sex: Male	N	193	204
			n (%)	34 (17.6)	12 (5.9)
			95% CI[a]	(12.24, 22.99)	(2.65, 9.11)
			Relative Risk (95% CI)[a]	2.99 (1.60, 5.61)	
			P-value	0.0006	
		Sex: Female	N	169	161
			n (%)	27 (16.0)	11 (6.8)
			95% CI[a]	(10.45, 21.50)	(2.94, 10.73)
			Relative Risk (95% CI)[a]	2.34 (1.20, 4.56)	
			P-value	0.0126	
			Test for interaction[b]	0.5853	
	Acne	Sex: Male	N	193	204
			n (%)	24 (12.4)	4 (2.0)
			95% CI[a]	(7.78, 17.09)	(0.06, 3.86)
			Relative Risk (95% CI)[a]	6.34 (2.24, 17.94)	
			P-value	0.0005	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Sex

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
		Sex: Female	N	169	161
			n (%)	22 (13.0)	6 (3.7)
			95% CI[a]	(7.94, 18.09)	(0.80, 6.65)
			Relative Risk (95% CI)[a]	3.49 (1.45, 8.39)	
			P-value	0.0052	
			Test for interaction[b]	0.7950	
	Dermatitis atopic	Sex: Male	N	193	204
			n (%)	11 (5.7)	8 (3.9)
			95% CI[a]	(2.43, 8.97)	(1.26, 6.59)
			Relative Risk (95% CI)[a]	1.45 (0.60, 3.54)	
			P-value	0.4099	
		Sex: Female	N	169	161
			n (%)	6 (3.6)	6 (3.7)
			95% CI[a]	(0.76, 6.34)	(0.80, 6.65)
			Relative Risk (95% CI)[a]	0.95 (0.31, 2.89)	
			P-value	0.9318	
			Test for interaction[b]	0.5105	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
Overall	Overall	Region of enrollment: US/Canada/Australia	N	177	195
			n (%)	92 (52.0)	68 (34.9)
			95% CI[a]	(44.62, 59.34)	(28.18, 41.56)
			Relative Risk (95% CI)[a]	1.49 (1.17, 1.89)	
			P-value	0.0010	
		Region of enrollment: Europe	N	150	132
			n (%)	90 (60.0)	55 (41.7)
			95% CI[a]	(52.16, 67.84)	(33.26, 50.08)
			Relative Risk (95% CI)[a]	1.44 (1.13, 1.83)	
			P-value	0.0030	
		Region of enrollment: Asia	N	17	19
			n (%)	9 (52.9)	4 (21.1)
			95% CI[a]	(29.21, 76.67)	(2.72, 39.38)
			Relative Risk (95% CI)[a]	2.51 (0.94, 6.70)	
			P-value	0.0650	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
		Region of enrollment: Latin America	N	18	19
			n (%)	6 (33.3)	2 (10.5)
			95% CI[a]	(11.56, 55.11)	(0.00, 24.33)
			Relative Risk (95% CI)[a]	3.17 (0.73, 13.70)	
			P-value	0.1230	
			Test for interaction[b]	0.8773	
Gastrointestinal disorders	Overall	Region of enrollment: US/Canada/Australia	N	177	195
			n (%)	39 (22.0)	6 (3.1)
			95% CI[a]	(15.93, 28.14)	(0.65, 5.50)
			Relative Risk (95% CI)[a]	7.16 (3.11, 16.51)	
			P-value	<.0001	
		Region of enrollment: Europe	N	150	132
			n (%)	30 (20.0)	5 (3.8)
			95% CI[a]	(13.60, 26.40)	(0.53, 7.04)
			Relative Risk (95% CI)[a]	5.28 (2.11, 13.21)	
			P-value	0.0004	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
		Region of enrollment: Asia	N	17	19
			n (%)	1 (5.9)	0
			95% CI[a]	(0.00, 17.07)	(0.00, 17.65)
			Relative Risk (95% CI)[a]	2.29 (0.08, 64.21)	
			P-value	0.6252	
		Region of enrollment: Latin America	N	18	19
			n (%)	0	0
			Test for interaction[b]	0.0039	
	Nausea	Region of enrollment: US/Canada/Australia	N	177	195
			n (%)	39 (22.0)	4 (2.1)
			95% CI[a]	(15.93, 28.14)	(0.06, 4.04)
			Relative Risk (95% CI)[a]	10.74 (3.92, 29.45)	
			P-value	<.0001	
		Region of enrollment: Europe	N	150	132
			n (%)	30 (20.0)	4 (3.0)
			95% CI[a]	(13.60, 26.40)	(0.11, 5.95)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
			Relative Risk (95% CI)[a]	6.60 (2.39, 18.24)	
			P-value	0.0003	
		Region of enrollment: Asia	N	17	19
			n (%)	1 (5.9)	0
			95% CI[a]	(0.00, 17.07)	(0.00, 17.65)
			Relative Risk (95% CI)[a]	2.29 (0.08, 64.21)	
			P-value	0.6252	
		Region of enrollment: Latin America	N	18	19
			n (%)	0	0
			Test for interaction[b]	0.0019	
	Vomiting	Region of enrollment: US/Canada/Australia	N	177	195
			n (%)	7 (4.0)	3 (1.5)
			95% CI[a]	(1.08, 6.83)	(0.00, 3.27)
			Relative Risk (95% CI)[a]	2.57 (0.68, 9.79)	
			P-value	0.1664	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
		Region of enrollment: Europe	N	150	132
			n (%)	4 (2.7)	3 (2.3)
			95% CI[a]	(0.09, 5.24)	(0.00, 4.82)
			Relative Risk (95% CI)[a]	1.17 (0.27, 5.15)	
			P-value	0.8322	
		Region of enrollment: Asia	N	17	19
			n (%)	0	0
		Region of enrollment: Latin America	N	18	19
			n (%)	0	0
			Test for interaction[b]	0.8619	
General disorders and administration site conditions	Overall	Region of enrollment: US/Canada/Australia	N	177	195
			n (%)	6 (3.4)	2 (1.0)
			95% CI[a]	(0.72, 6.06)	(0.00, 2.44)
			Relative Risk (95% CI)[a]	3.31 (0.68, 16.16)	
			P-value	0.1399	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
		Region of enrollment: Europe	N	150	132
			n (%)	4 (2.7)	3 (2.3)
			95% CI[a]	(0.09, 5.24)	(0.00, 4.82)
			Relative Risk (95% CI)[a]	1.17 (0.27, 5.15)	
			P-value	0.8322	
		Region of enrollment: Asia	N	17	19
			n (%)	0	0
		Region of enrollment: Latin America	N	18	19
			n (%)	0	0
			Test for interaction[b]	0.8540	
	Fatigue	Region of enrollment: US/Canada/Australia	N	177	195
			n (%)	6 (3.4)	2 (1.0)
			95% CI[a]	(0.72, 6.06)	(0.00, 2.44)
			Relative Risk (95% CI)[a]	3.31 (0.68, 16.16)	
			P-value	0.1399	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
		Region of enrollment: Europe	N	150	132
			n (%)	4 (2.7)	3 (2.3)
			95% CI[a]	(0.09, 5.24)	(0.00, 4.82)
			Relative Risk (95% CI)[a]	1.17 (0.27, 5.15)	
			P-value	0.8322	
		Region of enrollment: Asia	N	17	19
			n (%)	0	0
		Region of enrollment: Latin America	N	18	19
			n (%)	0	0
			Test for interaction[b]	0.8540	
Infections and infestations	Overall	Region of enrollment: US/Canada/Australia	N	177	195
			n (%)	24 (13.6)	38 (19.5)
			95% CI[a]	(8.52, 18.60)	(13.93, 25.05)
			Relative Risk (95% CI)[a]	0.70 (0.44, 1.11)	
			P-value	0.1294	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
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Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
		Region of enrollment: Europe	N	150	132
			n (%)	41 (27.3)	36 (27.3)
			95% CI[a]	(20.20, 34.47)	(19.68, 34.87)
			Relative Risk (95% CI)[a]	1.00 (0.68, 1.47)	
			P-value	0.9909	
		Region of enrollment: Asia	N	17	19
			n (%)	2 (11.8)	1 (5.3)
			95% CI[a]	(0.00, 27.08)	(0.00, 15.30)
			Relative Risk (95% CI)[a]	2.24 (0.22, 22.51)	
			P-value	0.4948	
		Region of enrollment: Latin America	N	18	19
			n (%)	1 (5.6)	1 (5.3)
			95% CI[a]	(0.00, 16.14)	(0.00, 15.30)
			Relative Risk (95% CI)[a]	1.06 (0.07, 15.64)	
			P-value	0.9686	
			Test for interaction[b]	0.5531	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
	COVID-19	Region of enrollment: US/Canada/Australia	N	177	195
			n (%)	4 (2.3)	4 (2.1)
			95% CI[a]	(0.07, 4.45)	(0.06, 4.04)
			Relative Risk (95% CI)[a]	1.10 (0.28, 4.34)	
			P-value	0.8899	
		Region of enrollment: Europe	N	150	132
			n (%)	11 (7.3)	7 (5.3)
			95% CI[a]	(3.16, 11.51)	(1.48, 9.13)
			Relative Risk (95% CI)[a]	1.38 (0.55, 3.46)	
			P-value	0.4890	
		Region of enrollment: Asia	N	17	19
			n (%)	0	0
		Region of enrollment: Latin America	N	18	19
			n (%)	0	1 (5.3)
			95% CI[a]	(0.00, 18.53)	(0.00, 15.30)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
			Relative Risk (95% CI)[a]	0.51 (0.02, 14.40)	
			P-value	0.6952	
			Test for interaction[b]	0.9070	
	Conjunctivitis	Region of enrollment: US/Canada/Australia	N	177	195
			n (%)	4 (2.3)	18 (9.2)
			95% CI[a]	(0.07, 4.45)	(5.17, 13.29)
			Relative Risk (95% CI)[a]	0.24 (0.08, 0.71)	
			P-value	0.0095	
		Region of enrollment: Europe	N	150	132
			n (%)	3 (2.0)	16 (12.1)
			95% CI[a]	(0.00, 4.24)	(6.55, 17.69)
			Relative Risk (95% CI)[a]	0.17 (0.05, 0.55)	
			P-value	0.0035	
		Region of enrollment: Asia	N	17	19
			n (%)	1 (5.9)	1 (5.3)
			95% CI[a]	(0.00, 17.07)	(0.00, 15.30)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
			Relative Risk (95% CI)[a]	1.12 (0.08, 16.52)	
			P-value	0.9355	
		Region of enrollment: Latin America	N	18	19
			n (%)	0	0
			Test for interaction[b]	0.2628	
	Folliculitis	Region of enrollment: US/Canada/Australia	N	177	195
			n (%)	5 (2.8)	3 (1.5)
			95% CI[a]	(0.38, 5.27)	(0.00, 3.27)
			Relative Risk (95% CI)[a]	1.84 (0.45, 7.57)	
			P-value	0.4006	
		Region of enrollment: Europe	N	150	132
			n (%)	5 (3.3)	0
			95% CI[a]	(0.46, 6.21)	(0.00, 2.76)
			Relative Risk (95% CI)[a]	8.83 (0.49, 160.17)	
			P-value	0.1406	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
		Region of enrollment: Asia	N	17	19
			n (%)	2 (11.8)	0
			95% CI[a]	(0.00, 27.08)	(0.00, 17.65)
			Relative Risk (95% CI)[a]	4.59 (0.22, 94.96)	
			P-value	0.3244	
		Region of enrollment: Latin America	N	18	19
			n (%)	0	0
			Test for interaction[b]	0.7124	
	Herpes simplex	Region of enrollment: US/Canada/Australia	N	177	195
			n (%)	3 (1.7)	1 (0.5)
			95% CI[a]	(0.00, 3.60)	(0.00, 1.52)
			Relative Risk (95% CI)[a]	3.31 (0.35, 31.48)	
			P-value	0.2986	
		Region of enrollment: Europe	N	150	132
			n (%)	9 (6.0)	4 (3.0)
			95% CI[a]	(2.20, 9.80)	(0.11, 5.95)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
			Relative Risk (95% CI)[a]	1.98 (0.62, 6.28)	
			P-value	0.2461	
		Region of enrollment: Asia	N	17	19
			n (%)	0	0
		Region of enrollment: Latin America	N	18	19
			n (%)	0	0
			Test for interaction[b]	0.9031	
	Nasopharyngitis	Region of enrollment: US/Canada/Australia	N	177	195
			n (%)	2 (1.1)	4 (2.1)
			95% CI[a]	(0.00, 2.69)	(0.06, 4.04)
			Relative Risk (95% CI)[a]	0.55 (0.10, 2.97)	
			P-value	0.4880	
		Region of enrollment: Europe	N	150	132
			n (%)	11 (7.3)	8 (6.1)
			95% CI[a]	(3.16, 11.51)	(1.99, 10.13)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
			Relative Risk (95% CI)[a]	1.21 (0.50, 2.92)	
			P-value	0.6712	
		Region of enrollment: Asia	N	17	19
			n (%)	0	0
		Region of enrollment: Latin America	N	18	19
			n (%)	1 (5.6)	0
			95% CI[a]	(0.00, 16.14)	(0.00, 17.65)
			Relative Risk (95% CI)[a]	2.17 (0.08, 60.76)	
			P-value	0.6494	
			Test for interaction[b]	0.8600	
	Oral herpes	Region of enrollment: US/Canada/Australia	N	177	195
			n (%)	1 (0.6)	5 (2.6)
			95% CI[a]	(0.00, 1.67)	(0.35, 4.78)
			Relative Risk (95% CI)[a]	0.22 (0.03, 1.87)	
			P-value	0.1654	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
		Region of enrollment: Europe	N	150	132
			n (%)	8 (5.3)	10 (7.6)
			95% CI[a]	(1.74, 8.93)	(3.06, 12.09)
			Relative Risk (95% CI)[a]	0.70 (0.29, 1.73)	
			P-value	0.4446	
		Region of enrollment: Asia	N	17	19
			n (%)	0	0
		Region of enrollment: Latin America	N	18	19
			n (%)	0	0
			Test for interaction[b]	0.9522	
	Upper respiratory tract infection	Region of enrollment: US/Canada/Australia	N	177	195
			n (%)	7 (4.0)	6 (3.1)
			95% CI[a]	(1.08, 6.83)	(0.65, 5.50)
			Relative Risk (95% CI)[a]	1.29 (0.44, 3.75)	
			P-value	0.6461	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
		Region of enrollment: Europe	N	150	132
			n (%)	3 (2.0)	3 (2.3)
			95% CI[a]	(0.00, 4.24)	(0.00, 4.82)
			Relative Risk (95% CI)[a]	0.88 (0.18, 4.29)	
			P-value	0.8742	
		Region of enrollment: Asia	N	17	19
			n (%)	0	0
		Region of enrollment: Latin America	N	18	19
			n (%)	0	0
			Test for interaction[b]	0.9776	
Investigations	Overall	Region of enrollment: US/Canada/Australia	N	177	195
			n (%)	12 (6.8)	13 (6.7)
			95% CI[a]	(3.08, 10.48)	(3.17, 10.17)
			Relative Risk (95% CI)[a]	1.02 (0.48, 2.17)	
			P-value	0.9653	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
		Region of enrollment: Europe	N	150	132
			n (%)	23 (15.3)	11 (8.3)
			95% CI[a]	(9.57, 21.10)	(3.62, 13.05)
			Relative Risk (95% CI)[a]	1.84 (0.93, 3.63)	
			P-value	0.0785	
		Region of enrollment: Asia	N	17	19
			n (%)	0	0
		Region of enrollment: Latin America	N	18	19
			n (%)	3 (16.7)	2 (10.5)
			95% CI[a]	(0.00, 33.88)	(0.00, 24.33)
			Relative Risk (95% CI)[a]	1.58 (0.30, 8.40)	
			P-value	0.5894	
			Test for interaction[b]	0.4656	
	Blood creatine phosphokinase increased	Region of enrollment: US/Canada/Australia	N	177	195
			n (%)	8 (4.5)	8 (4.1)
			95% CI[a]	(1.46, 7.58)	(1.32, 6.89)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
			Relative Risk (95% CI)[a]	1.10 (0.42, 2.87)	
			P-value	0.8430	
		Region of enrollment: Europe	N	150	132
			n (%)	4 (2.7)	4 (3.0)
			95% CI[a]	(0.09, 5.24)	(0.11, 5.95)
			Relative Risk (95% CI)[a]	0.88 (0.22, 3.45)	
			P-value	0.8545	
		Region of enrollment: Asia	N	17	19
			n (%)	0	0
		Region of enrollment: Latin America	N	18	19
			n (%)	2 (11.1)	1 (5.3)
			95% CI[a]	(0.00, 25.63)	(0.00, 15.30)
			Relative Risk (95% CI)[a]	2.11 (0.21, 21.32)	
			P-value	0.5265	
			Test for interaction[b]	0.9243	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
	Natural killer cell count decreased	Region of enrollment: US/Canada/Australia	N	177	195
			n (%)	0	0
		Region of enrollment: Europe	N	150	132
			n (%)	10 (6.7)	0
			95% CI[a]	(2.67, 10.66)	(0.00, 2.76)
			Relative Risk (95% CI)[a]	17.67 (1.04, 299.56)	
			P-value	0.0468	
		Region of enrollment: Asia	N	17	19
			n (%)	0	0
		Region of enrollment: Latin America	N	18	19
			n (%)	0	0
			Test for interaction[b]	NE	
	SARS-CoV-2 test positive	Region of enrollment: US/Canada/Australia	N	177	195
			n (%)	4 (2.3)	5 (2.6)
			95% CI[a]	(0.07, 4.45)	(0.35, 4.78)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
			Relative Risk (95% CI)[a]	0.88 (0.24, 3.23)	
			P-value	0.8489	
		Region of enrollment: Europe	N	150	132
			n (%)	10 (6.7)	7 (5.3)
			95% CI[a]	(2.67, 10.66)	(1.48, 9.13)
			Relative Risk (95% CI)[a]	1.26 (0.49, 3.21)	
			P-value	0.6322	
		Region of enrollment: Asia	N	17	19
			n (%)	0	0
		Region of enrollment: Latin America	N	18	19
			n (%)	1 (5.6)	1 (5.3)
			95% CI[a]	(0.00, 16.14)	(0.00, 15.30)
			Relative Risk (95% CI)[a]	1.06 (0.07, 15.64)	
			P-value	0.9686	
			Test for interaction[b]	0.9659	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
Nervous system disorders	Overall	Region of enrollment: US/Canada/Australia	N	177	195
			n (%)	24 (13.6)	13 (6.7)
			95% CI[a]	(8.52, 18.60)	(3.17, 10.17)
			Relative Risk (95% CI)[a]	2.03 (1.07, 3.87)	
			P-value	0.0306	
		Region of enrollment: Europe	N	150	132
			n (%)	27 (18.0)	12 (9.1)
			95% CI[a]	(11.85, 24.15)	(4.19, 14.00)
			Relative Risk (95% CI)[a]	1.98 (1.05, 3.75)	
			P-value	0.0360	
		Region of enrollment: Asia	N	17	19
			n (%)	2 (11.8)	2 (10.5)
			95% CI[a]	(0.00, 27.08)	(0.00, 24.33)
			Relative Risk (95% CI)[a]	1.12 (0.18, 7.09)	
			P-value	0.9061	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
		Region of enrollment: Latin America	N	18	19
			n (%)	2 (11.1)	0
			95% CI[a]	(0.00, 25.63)	(0.00, 17.65)
			Relative Risk (95% CI)[a]	4.33 (0.21, 89.87)	
			P-value	0.3432	
			Test for interaction[b]	0.9048	
	Dizziness	Region of enrollment: US/Canada/Australia	N	177	195
			n (%)	4 (2.3)	1 (0.5)
			95% CI[a]	(0.07, 4.45)	(0.00, 1.52)
			Relative Risk (95% CI)[a]	4.41 (0.50, 39.06)	
			P-value	0.1828	
		Region of enrollment: Europe	N	150	132
			n (%)	6 (4.0)	3 (2.3)
			95% CI[a]	(0.86, 7.14)	(0.00, 4.82)
			Relative Risk (95% CI)[a]	1.76 (0.45, 6.90)	
			P-value	0.4173	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
		Region of enrollment: Asia	N	17	19
			n (%)	0	0
		Region of enrollment: Latin America	N	18	19
			n (%)	0	0
			Test for interaction[b]	0.9848	
	Headache	Region of enrollment: US/Canada/Australia	N	177	195
			n (%)	21 (11.9)	12 (6.2)
			95% CI[a]	(7.10, 16.63)	(2.78, 9.53)
			Relative Risk (95% CI)[a]	1.93 (0.98, 3.80)	
			P-value	0.0583	
		Region of enrollment: Europe	N	150	132
			n (%)	22 (14.7)	10 (7.6)
			95% CI[a]	(9.01, 20.33)	(3.06, 12.09)
			Relative Risk (95% CI)[a]	1.94 (0.95, 3.94)	
			P-value	0.0682	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
		Region of enrollment: Asia	N	17	19
			n (%)	2 (11.8)	2 (10.5)
			95% CI[a]	(0.00, 27.08)	(0.00, 24.33)
			Relative Risk (95% CI)[a]	1.12 (0.18, 7.09)	
			P-value	0.9061	
		Region of enrollment: Latin America	N	18	19
			n (%)	2 (11.1)	0
			95% CI[a]	(0.00, 25.63)	(0.00, 17.65)
			Relative Risk (95% CI)[a]	4.33 (0.21, 89.87)	
			P-value	0.3432	
			Test for interaction[b]	0.9443	
Skin and subcutaneous tissue disorders	Overall	Region of enrollment: US/Canada/Australia	N	177	195
			n (%)	34 (19.2)	14 (7.2)
			95% CI[a]	(13.41, 25.01)	(3.56, 10.80)
			Relative Risk (95% CI)[a]	2.68 (1.49, 4.82)	
			P-value	0.0010	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
		Region of enrollment: Europe	N	150	132
			n (%)	21 (14.0)	7 (5.3)
			95% CI[a]	(8.45, 19.55)	(1.48, 9.13)
			Relative Risk (95% CI)[a]	2.64 (1.16, 6.01)	
			P-value	0.0208	
		Region of enrollment: Asia	N	17	19
			n (%)	5 (29.4)	2 (10.5)
			95% CI[a]	(7.75, 51.07)	(0.00, 24.33)
			Relative Risk (95% CI)[a]	2.79 (0.62, 12.57)	
			P-value	0.1805	
		Region of enrollment: Latin America	N	18	19
			n (%)	1 (5.6)	0
			95% CI[a]	(0.00, 16.14)	(0.00, 17.65)
			Relative Risk (95% CI)[a]	2.17 (0.08, 60.76)	
			P-value	0.6494	
			Test for interaction[b]	0.4840	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
	Acne	Region of enrollment: US/Canada/Australia	N	177	195
			n (%)	29 (16.4)	7 (3.6)
			95% CI[a]	(10.93, 21.84)	(0.98, 6.20)
			Relative Risk (95% CI)[a]	4.56 (2.05, 10.16)	
			P-value	0.0002	
		Region of enrollment: Europe	N	150	132
			n (%)	13 (8.7)	1 (0.8)
			95% CI[a]	(4.16, 13.17)	(0.00, 2.24)
			Relative Risk (95% CI)[a]	11.44 (1.52, 86.28)	
			P-value	0.0181	
		Region of enrollment: Asia	N	17	19
			n (%)	4 (23.5)	2 (10.5)
			95% CI[a]	(3.37, 43.69)	(0.00, 24.33)
			Relative Risk (95% CI)[a]	2.24 (0.47, 10.70)	
			P-value	0.3141	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
		Region of enrollment: Latin America	N	18	19
			n (%)	0	0
			Test for interaction[b]	0.1633	
	Dermatitis atopic	Region of enrollment: US/Canada/Australia	N	177	195
			n (%)	5 (2.8)	8 (4.1)
			95% CI[a]	(0.38, 5.27)	(1.32, 6.89)
			Relative Risk (95% CI)[a]	0.69 (0.23, 2.07)	
			P-value	0.5056	
		Region of enrollment: Europe	N	150	132
			n (%)	9 (6.0)	6 (4.5)
			95% CI[a]	(2.20, 9.80)	(0.99, 8.10)
			Relative Risk (95% CI)[a]	1.32 (0.48, 3.61)	
			P-value	0.5886	
		Region of enrollment: Asia	N	17	19
			n (%)	2 (11.8)	0
			95% CI[a]	(0.00, 27.08)	(0.00, 17.65)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
			Relative Risk (95% CI)[a]	4.59 (0.22, 94.96)	
			P-value	0.3244	
		Region of enrollment: Latin America	N	18	19
			n (%)	1 (5.6)	0
			95% CI[a]	(0.00, 16.14)	(0.00, 17.65)
			Relative Risk (95% CI)[a]	2.17 (0.08, 60.76)	
			P-value	0.6494	
			Test for interaction[b]	0.5650	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
Overall	Overall	Baseline disease severity: Moderate	N	216	220
			n (%)	121 (56.0)	76 (34.5)
			95% CI[a]	(49.40, 62.64)	(28.26, 40.83)
			Relative Risk (95% CI)[a]	1.62 (1.31, 2.01)	
			P-value	<.0001	
		Baseline disease severity: Severe	N	146	145
			n (%)	76 (52.1)	53 (36.6)
			95% CI[a]	(43.95, 60.16)	(28.71, 44.39)
			Relative Risk (95% CI)[a]	1.42 (1.09, 1.86)	
			P-value	0.0089	
			Test for interaction[b]	0.4029	
Gastrointestinal disorders	Overall	Baseline disease severity: Moderate	N	216	220
			n (%)	45 (20.8)	7 (3.2)
			95% CI[a]	(15.42, 26.25)	(0.86, 5.50)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
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Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
			Relative Risk (95% CI)[a]	6.55 (3.02, 14.20)	
			P-value	<.0001	
		Baseline disease severity: Severe	N	146	145
			n (%)	25 (17.1)	4 (2.8)
			95% CI[a]	(11.01, 23.23)	(0.09, 5.42)
			Relative Risk (95% CI)[a]	6.21 (2.22, 17.39)	
			P-value	0.0005	
			Test for interaction[b]	0.4477	
	Nausea	Baseline disease severity: Moderate	N	216	220
			n (%)	45 (20.8)	7 (3.2)
			95% CI[a]	(15.42, 26.25)	(0.86, 5.50)
			Relative Risk (95% CI)[a]	6.55 (3.02, 14.20)	
			P-value	<.0001	
		Baseline disease severity: Severe	N	146	145
			n (%)	25 (17.1)	1 (0.7)
			95% CI[a]	(11.01, 23.23)	(0.00, 2.04)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
			Relative Risk (95% CI)[a]	24.83 (3.41, 180.82)	
			P-value	0.0015	
			Test for interaction[b]	0.7016	
	Vomiting	Baseline disease severity: Moderate	N	216	220
			n (%)	5 (2.3)	2 (0.9)
			95% CI[a]	(0.31, 4.32)	(0.00, 2.16)
			Relative Risk (95% CI)[a]	2.55 (0.50, 12.98)	
			P-value	0.2608	
		Baseline disease severity: Severe	N	146	145
			n (%)	6 (4.1)	4 (2.8)
			95% CI[a]	(0.89, 7.33)	(0.09, 5.42)
			Relative Risk (95% CI)[a]	1.49 (0.43, 5.17)	
			P-value	0.5300	
			Test for interaction[b]	0.9906	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
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Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
General disorders and administration site conditions	Overall	Baseline disease severity: Moderate	N	216	220
			n (%)	6 (2.8)	3 (1.4)
			95% CI[a]	(0.59, 4.97)	(0.00, 2.90)
			Relative Risk (95% CI)[a]	2.04 (0.52, 8.04)	
			P-value	0.3098	
		Baseline disease severity: Severe	N	146	145
			n (%)	4 (2.7)	2 (1.4)
			95% CI[a]	(0.09, 5.39)	(0.00, 3.28)
			Relative Risk (95% CI)[a]	1.99 (0.37, 10.68)	
			P-value	0.4238	
			Test for interaction[b]	0.9801	
	Fatigue	Baseline disease severity: Moderate	N	216	220
			n (%)	6 (2.8)	3 (1.4)
			95% CI[a]	(0.59, 4.97)	(0.00, 2.90)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
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Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
			Relative Risk (95% CI)[a]	2.04 (0.52, 8.04)	
			P-value	0.3098	
		Baseline disease severity: Severe	N	146	145
			n (%)	4 (2.7)	2 (1.4)
			95% CI[a]	(0.09, 5.39)	(0.00, 3.28)
			Relative Risk (95% CI)[a]	1.99 (0.37, 10.68)	
			P-value	0.4238	
			Test for interaction[b]	0.9801	
Infections and infestations	Overall	Baseline disease severity: Moderate	N	216	220
			n (%)	44 (20.4)	45 (20.5)
			95% CI[a]	(15.00, 25.74)	(15.12, 25.78)
			Relative Risk (95% CI)[a]	1.00 (0.69, 1.44)	
			P-value	0.9826	
		Baseline disease severity: Severe	N	146	145
			n (%)	24 (16.4)	31 (21.4)
			95% CI[a]	(10.43, 22.45)	(14.71, 28.05)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
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Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
			Relative Risk (95% CI)[a]	0.77 (0.48, 1.24)	
			P-value	0.2840	
			Test for interaction[b]	0.4225	
	COVID-19	Baseline disease severity: Moderate	N	216	220
			n (%)	8 (3.7)	7 (3.2)
			95% CI[a]	(1.19, 6.22)	(0.86, 5.50)
			Relative Risk (95% CI)[a]	1.16 (0.43, 3.15)	
			P-value	0.7652	
		Baseline disease severity: Severe	N	146	145
			n (%)	7 (4.8)	5 (3.4)
			95% CI[a]	(1.33, 8.26)	(0.48, 6.42)
			Relative Risk (95% CI)[a]	1.39 (0.45, 4.28)	
			P-value	0.5656	
			Test for interaction[b]	0.7757	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
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Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
	Conjunctivitis	Baseline disease severity: Moderate	N	216	220
			n (%)	3 (1.4)	23 (10.5)
			95% CI[a]	(0.00, 2.95)	(6.41, 14.50)
			Relative Risk (95% CI)[a]	0.13 (0.04, 0.44)	
			P-value	0.0009	
		Baseline disease severity: Severe	N	146	145
			n (%)	5 (3.4)	12 (8.3)
			95% CI[a]	(0.47, 6.37)	(3.79, 12.76)
			Relative Risk (95% CI)[a]	0.41 (0.15, 1.14)	
			P-value	0.0893	
			Test for interaction[b]	0.2401	
	Folliculitis	Baseline disease severity: Moderate	N	216	220
			n (%)	9 (4.2)	1 (0.5)
			95% CI[a]	(1.50, 6.83)	(0.00, 1.34)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
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Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
			Relative Risk (95% CI)[a]	9.17 (1.17, 71.74)	
			P-value	0.0348	
		Baseline disease severity: Severe	N	146	145
			n (%)	3 (2.1)	2 (1.4)
			95% CI[a]	(0.00, 4.36)	(0.00, 3.28)
			Relative Risk (95% CI)[a]	1.49 (0.25, 8.78)	
			P-value	0.6597	
			Test for interaction[b]	0.1476	
	Herpes simplex	Baseline disease severity: Moderate	N	216	220
			n (%)	7 (3.2)	1 (0.5)
			95% CI[a]	(0.88, 5.60)	(0.00, 1.34)
			Relative Risk (95% CI)[a]	7.13 (0.88, 57.46)	
			P-value	0.0651	
		Baseline disease severity: Severe	N	146	145
			n (%)	5 (3.4)	4 (2.8)
			95% CI[a]	(0.47, 6.37)	(0.09, 5.42)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
			Relative Risk (95% CI)[a]	1.24 (0.34, 4.53)	
			P-value	0.7433	
			Test for interaction[b]	0.3854	
	Nasopharyngitis	Baseline disease severity: Moderate	N	216	220
			n (%)	9 (4.2)	10 (4.5)
			95% CI[a]	(1.50, 6.83)	(1.79, 7.30)
			Relative Risk (95% CI)[a]	0.92 (0.38, 2.21)	
			P-value	0.8465	
		Baseline disease severity: Severe	N	146	145
			n (%)	5 (3.4)	2 (1.4)
			95% CI[a]	(0.47, 6.37)	(0.00, 3.28)
			Relative Risk (95% CI)[a]	2.48 (0.49, 12.59)	
			P-value	0.2723	
			Test for interaction[b]	0.3651	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
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Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
	Oral herpes	Baseline disease severity: Moderate	N	216	220
			n (%)	5 (2.3)	7 (3.2)
			95% CI[a]	(0.31, 4.32)	(0.86, 5.50)
			Relative Risk (95% CI)[a]	0.73 (0.23, 2.26)	
			P-value	0.5818	
		Baseline disease severity: Severe	N	146	145
			n (%)	4 (2.7)	8 (5.5)
			95% CI[a]	(0.09, 5.39)	(1.80, 9.23)
			Relative Risk (95% CI)[a]	0.50 (0.15, 1.61)	
			P-value	0.2442	
			Test for interaction[b]	0.4927	
	Upper respiratory tract infection	Baseline disease severity: Moderate	N	216	220
			n (%)	9 (4.2)	5 (2.3)
			95% CI[a]	(1.50, 6.83)	(0.30, 4.24)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
			Relative Risk (95% CI)[a]	1.83 (0.62, 5.38)	
			P-value	0.2700	
		Baseline disease severity: Severe	N	146	145
			n (%)	1 (0.7)	4 (2.8)
			95% CI[a]	(0.00, 2.02)	(0.09, 5.42)
			Relative Risk (95% CI)[a]	0.25 (0.03, 2.19)	
			P-value	0.2102	
			Test for interaction[b]	0.0828	
Investigations	Overall	Baseline disease severity: Moderate	N	216	220
			n (%)	24 (11.1)	15 (6.8)
			95% CI[a]	(6.92, 15.30)	(3.49, 10.15)
			Relative Risk (95% CI)[a]	1.63 (0.88, 3.02)	
			P-value	0.1209	
		Baseline disease severity: Severe	N	146	145
			n (%)	14 (9.6)	11 (7.6)
			95% CI[a]	(4.81, 14.37)	(3.28, 11.90)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
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Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
			Relative Risk (95% CI)[a]	1.26 (0.59, 2.69)	
			P-value	0.5433	
			Test for interaction[b]	0.5906	
	Blood creatine phosphokinase increased	Baseline disease severity: Moderate	N	216	220
			n (%)	9 (4.2)	7 (3.2)
			95% CI[a]	(1.50, 6.83)	(0.86, 5.50)
			Relative Risk (95% CI)[a]	1.31 (0.50, 3.45)	
			P-value	0.5857	
		Baseline disease severity: Severe	N	146	145
			n (%)	5 (3.4)	6 (4.1)
			95% CI[a]	(0.47, 6.37)	(0.90, 7.38)
			Relative Risk (95% CI)[a]	0.83 (0.26, 2.65)	
			P-value	0.7501	
			Test for interaction[b]	0.5547	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
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Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
	Natural killer cell count decreased	Baseline disease severity: Moderate	N	216	220
			n (%)	6 (2.8)	0
			95% CI[a]	(0.59, 4.97)	(0.00, 1.66)
			Relative Risk (95% CI)[a]	12.25 (0.69, 217.98)	
			P-value	0.0880	
		Baseline disease severity: Severe	N	146	145
			n (%)	4 (2.7)	0
			95% CI[a]	(0.09, 5.39)	(0.00, 2.51)
			Relative Risk (95% CI)[a]	7.97 (0.43, 149.45)	
			P-value	0.1651	
			Test for interaction[b]	0.9343	
	SARS-CoV-2 test positive	Baseline disease severity: Moderate	N	216	220
			n (%)	10 (4.6)	8 (3.6)
			95% CI[a]	(1.83, 7.43)	(1.16, 6.11)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
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Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
			Relative Risk (95% CI)[a]	1.27 (0.51, 3.16)	
			P-value	0.6032	
		Baseline disease severity: Severe	N	146	145
			n (%)	5 (3.4)	5 (3.4)
			95% CI[a]	(0.47, 6.37)	(0.48, 6.42)
			Relative Risk (95% CI)[a]	0.99 (0.29, 3.36)	
			P-value	0.9912	
			Test for interaction[b]	0.7215	
Nervous system disorders	Overall	Baseline disease severity: Moderate	N	216	220
			n (%)	30 (13.9)	18 (8.2)
			95% CI[a]	(9.28, 18.50)	(4.56, 11.80)
			Relative Risk (95% CI)[a]	1.70 (0.98, 2.95)	
			P-value	0.0609	
		Baseline disease severity: Severe	N	146	145
			n (%)	25 (17.1)	9 (6.2)
			95% CI[a]	(11.01, 23.23)	(2.28, 10.13)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
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Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
			Relative Risk (95% CI)[a]	2.76 (1.33, 5.70)	
			P-value	0.0062	
			Test for interaction[b]	0.2787	
	Dizziness	Baseline disease severity: Moderate	N	216	220
			n (%)	4 (1.9)	3 (1.4)
			95% CI[a]	(0.05, 3.65)	(0.00, 2.90)
			Relative Risk (95% CI)[a]	1.36 (0.31, 6.00)	
			P-value	0.6863	
		Baseline disease severity: Severe	N	146	145
			n (%)	6 (4.1)	1 (0.7)
			95% CI[a]	(0.89, 7.33)	(0.00, 2.04)
			Relative Risk (95% CI)[a]	5.96 (0.73, 48.88)	
			P-value	0.0965	
			Test for interaction[b]	0.1749	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
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Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
	Headache	Baseline disease severity: Moderate	N	216	220
			n (%)	27 (12.5)	15 (6.8)
			95% CI[a]	(8.09, 16.91)	(3.49, 10.15)
			Relative Risk (95% CI)[a]	1.83 (1.00, 3.35)	
			P-value	0.0487	
		Baseline disease severity: Severe	N	146	145
			n (%)	20 (13.7)	9 (6.2)
			95% CI[a]	(8.12, 19.28)	(2.28, 10.13)
			Relative Risk (95% CI)[a]	2.21 (1.04, 4.68)	
			P-value	0.0392	
			Test for interaction[b]	0.6865	
Skin and subcutaneous tissue disorders	Overall	Baseline disease severity: Moderate	N	216	220
			n (%)	34 (15.7)	9 (4.1)
			95% CI[a]	(10.88, 20.60)	(1.47, 6.71)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
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Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
			Relative Risk (95% CI)[a]	3.85 (1.89, 7.83)	
			P-value	0.0002	
		Baseline disease severity: Severe	N	146	145
			n (%)	27 (18.5)	14 (9.7)
			95% CI[a]	(12.20, 24.79)	(4.85, 14.46)
			Relative Risk (95% CI)[a]	1.92 (1.05, 3.50)	
			P-value	0.0347	
			Test for interaction[b]	0.6464	
	Acne	Baseline disease severity: Moderate	N	216	220
			n (%)	29 (13.4)	2 (0.9)
			95% CI[a]	(8.88, 17.97)	(0.00, 2.16)
			Relative Risk (95% CI)[a]	14.77 (3.57, 61.13)	
			P-value	0.0002	
		Baseline disease severity: Severe	N	146	145
			n (%)	17 (11.6)	8 (5.5)
			95% CI[a]	(6.44, 16.85)	(1.80, 9.23)

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
System Organ Class	MedDRA Preferred Term	Subgroup		n (%)	n (%)
			Relative Risk (95% CI)[a]	2.11 (0.94, 4.74)	
			P-value	0.0701	
			Test for interaction[b]	0.1346	
	Dermatitis atopic	Baseline disease severity: Moderate	N	216	220
			n (%)	7 (3.2)	8 (3.6)
			95% CI[a]	(0.88, 5.60)	(1.16, 6.11)
			Relative Risk (95% CI)[a]	0.89 (0.33, 2.41)	
			P-value	0.8208	
		Baseline disease severity: Severe	N	146	145
			n (%)	10 (6.8)	6 (4.1)
			95% CI[a]	(2.75, 10.95)	(0.90, 7.38)
			Relative Risk (95% CI)[a]	1.66 (0.62, 4.44)	
			P-value	0.3163	
			Test for interaction[b]	0.3289	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:18)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_7

Proportion of Subjects with Treatment-Emergent Serious Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Table not created
No participant meets the reporting criteria

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_8

Proportion of Subjects with Treatment-Emergent Severe Adverse Events Occurring in >= 10 Subjects in any Treatment Group by Subgroup, System Organ Class and Preferred Term (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Table not created
No participant meets the reporting criteria

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:29)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_9

Proportion of Subjects with Non-Severe Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Age (years) group: <40	Overall	Overall	N	230	247
			n (%)	173 (75.2)	161 (65.2)
			95% CI[a]	(69.64, 80.80)	(59.24, 71.12)
			Relative Risk (95% CI)[a]	1.15 (1.03, 1.30)	
			P-value	0.0169	
Age (years) group: >=40	Overall	Overall	N	132	118
			n (%)	94 (71.2)	76 (64.4)
			95% CI[a]	(63.49, 78.94)	(55.77, 73.05)
			Relative Risk (95% CI)[a]	1.11 (0.93, 1.31)	
			P-value	0.2538	
			Test for interaction[b]	0.5853	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Non-Severe Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Sex

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Sex: Male	Overall	Overall	N	193	204
			n (%)	141 (73.1)	127 (62.3)
			95% CI[a]	(66.80, 79.32)	(55.60, 68.91)
			Relative Risk (95% CI)[a]	1.17 (1.02, 1.35)	
			P-value	0.0220	
Sex: Female	Overall	Overall	N	169	161
			n (%)	126 (74.6)	110 (68.3)
			95% CI[a]	(67.99, 81.12)	(61.14, 75.51)
			Relative Risk (95% CI)[a]	1.09 (0.95, 1.25)	
			P-value	0.2123	
			Test for interaction[b]	0.6078	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Non-Severe Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Region of enrollment: US/Canada/Australia	Overall	Overall	N	177	195
			n (%)	133 (75.1)	128 (65.6)
			95% CI[a]	(68.77, 81.51)	(58.98, 72.31)
			Relative Risk (95% CI)[a]	1.14 (1.00, 1.31)	
			P-value	0.0452	
Region of enrollment: Europe	Overall	Overall	N	150	132
			n (%)	111 (74.0)	90 (68.2)
			95% CI[a]	(66.98, 81.02)	(60.24, 76.13)
			Relative Risk (95% CI)[a]	1.09 (0.93, 1.26)	
			P-value	0.2855	
Region of enrollment: Asia	Overall	Overall	N	17	19
			n (%)	11 (64.7)	10 (52.6)
			95% CI[a]	(41.99, 87.42)	(30.18, 75.08)
			Relative Risk (95% CI)[a]	1.23 (0.71, 2.14)	
			P-value	0.4637	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_10_1

Proportion of Subjects with Non-Severe Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Region of enrollment: Latin America	Overall	Overall	N	18	19
			n (%)	12 (66.7)	9 (47.4)
			95% CI[a]	(44.89, 88.44)	(24.92, 69.82)
			Relative Risk (95% CI)[a]	1.41 (0.79, 2.50)	
			P-value	0.2446	
			Test for interaction[b]	0.9324	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_10_1

Proportion of Subjects with Non-Severe Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Baseline disease severity: Moderate	Overall	Overall	N	216	220
			n (%)	162 (75.0)	146 (66.4)
			95% CI[a]	(69.23, 80.77)	(60.12, 72.61)
			Relative Risk (95% CI)[a]	1.13 (1.00, 1.28)	
			P-value	0.0486	
Baseline disease severity: Severe	Overall	Overall	N	146	145
			n (%)	105 (71.9)	91 (62.8)
			95% CI[a]	(64.63, 79.21)	(54.89, 70.63)
			Relative Risk (95% CI)[a]	1.15 (0.98, 1.35)	
			P-value	0.0977	
			Test for interaction[b]	0.9495	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Superinfections of Infections (Treated with Antibiotics, Antiviral or Fungicidal Agents for a Duration > 2 Weeks) Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Age (years) group: <40	Overall	Overall	N	230	247
			n (%)	19 (8.3)	15 (6.1)
			95% CI[a]	(4.70, 11.82)	(3.09, 9.05)
			Relative Risk (95% CI)[a]	1.36 (0.71, 2.61)	
			P-value	0.3555	
Age (years) group: >=40	Overall	Overall	N	132	118
			n (%)	12 (9.1)	7 (5.9)
			95% CI[a]	(4.19, 14.00)	(1.67, 10.19)
			Relative Risk (95% CI)[a]	1.53 (0.62, 3.76)	
			P-value	0.3517	
			Test for interaction[b]	0.8103	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Superinfections of Infections (Treated with Antibiotics, Antiviral or Fungicidal Agents for a Duration > 2 Weeks) Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Sex

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Sex: Male	Overall	Overall	N	193	204
			n (%)	19 (9.8)	12 (5.9)
			95% CI[a]	(5.64, 14.05)	(2.65, 9.11)
			Relative Risk (95% CI)[a]	1.67 (0.83, 3.35)	
			P-value	0.1467	
Sex: Female	Overall	Overall	N	169	161
			n (%)	12 (7.1)	10 (6.2)
			95% CI[a]	(3.23, 10.97)	(2.48, 9.94)
			Relative Risk (95% CI)[a]	1.14 (0.51, 2.57)	
			P-value	0.7464	
			Test for interaction[b]	0.4216	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Superinfections of Infections (Treated with Antibiotics, Antiviral or Fungicidal Agents for a Duration > 2 Weeks) Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Region of enrollment: US/Canada/Australia	Overall	Overall	N	177	195
			n (%)	14 (7.9)	11 (5.6)
			95% CI[a]	(3.93, 11.89)	(2.40, 8.88)
			Relative Risk (95% CI)[a]	1.40 (0.65, 3.01)	
			P-value	0.3853	
Region of enrollment: Europe	Overall	Overall	N	150	132
			n (%)	15 (10.0)	11 (8.3)
			95% CI[a]	(5.20, 14.80)	(3.62, 13.05)
			Relative Risk (95% CI)[a]	1.20 (0.57, 2.52)	
			P-value	0.6301	
Region of enrollment: Asia	Overall	Overall	N	17	19
			n (%)	1 (5.9)	0
			95% CI[a]	(0.00, 17.07)	(0.00, 17.65)
			Relative Risk (95% CI)[a]	2.29 (0.08, 64.21)	
			P-value	0.6252	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_11

Proportion of Subjects with Superinfections of Infections (Treated with Antibiotics, Antiviral or Fungicidal Agents for a Duration > 2 Weeks) Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Region of enrollment: Latin America	Overall	Overall	N	18	19
			n (%)	1 (5.6)	0
			95% CI[a]	(0.00, 16.14)	(0.00, 17.65)
			Relative Risk (95% CI)[a]	2.17 (0.08, 60.76)	
			P-value	0.6494	
			Test for interaction[b]	0.9965	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_11

Proportion of Subjects with Superinfections of Infections (Treated with Antibiotics, Antiviral or Fungicidal Agents for a Duration > 2 Weeks) Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Baseline disease severity: Moderate	Overall	Overall	N	216	220
			n (%)	18 (8.3)	11 (5.0)
			95% CI[a]	(4.65, 12.02)	(2.12, 7.88)
			Relative Risk (95% CI)[a]	1.67 (0.81, 3.45)	
			P-value	0.1680	
Baseline disease severity: Severe	Overall	Overall	N	146	145
			n (%)	13 (8.9)	11 (7.6)
			95% CI[a]	(4.28, 13.52)	(3.28, 11.90)
			Relative Risk (95% CI)[a]	1.17 (0.54, 2.53)	
			P-value	0.6832	
			Test for interaction[b]	0.6238	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Herpes Zoster) by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Age (years) group: <40	Overall	Overall	N	230	247
			n (%)	4 (1.7)	1 (0.4)
			95% CI[a]	(0.05, 3.43)	(0.00, 1.20)
			Relative Risk (95% CI)[a]	4.30 (0.48, 38.15)	
			P-value	0.1908	
Age (years) group: >=40	Overall	Overall	N	132	118
			n (%)	5 (3.8)	1 (0.8)
			95% CI[a]	(0.53, 7.04)	(0.00, 2.50)
			Relative Risk (95% CI)[a]	4.47 (0.53, 37.71)	
			P-value	0.1688	
			Test for interaction[b]	0.4405	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Herpes Zoster) by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Sex

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Sex: Male	Overall	Overall	N	193	204
			n (%)	5 (2.6)	1 (0.5)
			95% CI[a]	(0.35, 4.83)	(0.00, 1.45)
			Relative Risk (95% CI)[a]	5.28 (0.62, 44.83)	
			P-value	0.1270	
Sex: Female	Overall	Overall	N	169	161
			n (%)	4 (2.4)	1 (0.6)
			95% CI[a]	(0.07, 4.66)	(0.00, 1.83)
			Relative Risk (95% CI)[a]	3.81 (0.43, 33.73)	
			P-value	0.2292	
			Test for interaction[b]	0.8457	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_13

Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Herpes Zoster) by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Region of enrollment: US/Canada/Australia	Overall	Overall	N	177	195
			n (%)	5 (2.8)	1 (0.5)
			95% CI[a]	(0.38, 5.27)	(0.00, 1.52)
			Relative Risk (95% CI)[a]	5.51 (0.65, 46.70)	
			P-value	0.1177	
Region of enrollment: Europe	Overall	Overall	N	150	132
			n (%)	4 (2.7)	1 (0.8)
			95% CI[a]	(0.09, 5.24)	(0.00, 2.24)
			Relative Risk (95% CI)[a]	3.52 (0.40, 31.10)	
			P-value	0.2576	
Region of enrollment: Asia	Overall	Overall	N	17	19
			n (%)	0	0
Region of enrollment: Latin America	Overall	Overall	N	18	19
			n (%)	0	0
			Test for interaction[b]	0.9636	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Herpes Zoster) by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Baseline disease severity: Moderate	Overall	Overall	N	216	220
			n (%)	4 (1.9)	2 (0.9)
			95% CI[a]	(0.05, 3.65)	(0.00, 2.16)
			Relative Risk (95% CI)[a]	2.04 (0.38, 11.01)	
			P-value	0.4084	
Baseline disease severity: Severe	Overall	Overall	N	146	145
			n (%)	5 (3.4)	0
			95% CI[a]	(0.47, 6.37)	(0.00, 2.51)
			Relative Risk (95% CI)[a]	9.97 (0.55, 180.76)	
			P-value	0.1200	
			Test for interaction[b]	0.2721	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_13

Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Acne) by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Age (years) group: <40	Overall	Overall	N	230	247
			n (%)	34 (14.8)	10 (4.0)
			95% CI[a]	(10.20, 19.37)	(1.59, 6.51)
			Relative Risk (95% CI)[a]	3.65 (1.85, 7.22)	
			P-value	0.0002	
Age (years) group: >=40	Overall	Overall	N	132	118
			n (%)	14 (10.6)	1 (0.8)
			95% CI[a]	(5.35, 15.86)	(0.00, 2.50)
			Relative Risk (95% CI)[a]	12.52 (1.67, 93.73)	
			P-value	0.0139	
			Test for interaction[b]	0.7300	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Acne) by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Sex

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Sex: Male	Overall	Overall	N	193	204
			n (%)	26 (13.5)	4 (2.0)
			95% CI[a]	(8.65, 18.29)	(0.06, 3.86)
			Relative Risk (95% CI)[a]	6.87 (2.44, 19.32)	
			P-value	0.0003	
Sex: Female	Overall	Overall	N	169	161
			n (%)	22 (13.0)	7 (4.3)
			95% CI[a]	(7.94, 18.09)	(1.20, 7.50)
			Relative Risk (95% CI)[a]	2.99 (1.32, 6.82)	
			P-value	0.0090	
			Test for interaction[b]	0.5116	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:26)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_13_1

Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Acne) by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Region of enrollment: US/Canada/Australia	Overall	Overall	N	177	195
			n (%)	30 (16.9)	8 (4.1)
			95% CI[a]	(11.42, 22.48)	(1.32, 6.89)
			Relative Risk (95% CI)[a]	4.13 (1.95, 8.77)	
			P-value	0.0002	
Region of enrollment: Europe	Overall	Overall	N	150	132
			n (%)	14 (9.3)	1 (0.8)
			95% CI[a]	(4.68, 13.99)	(0.00, 2.24)
			Relative Risk (95% CI)[a]	12.32 (1.64, 92.43)	
			P-value	0.0146	
Region of enrollment: Asia	Overall	Overall	N	17	19
			n (%)	4 (23.5)	2 (10.5)
			95% CI[a]	(3.37, 43.69)	(0.00, 24.33)
			Relative Risk (95% CI)[a]	2.24 (0.47, 10.70)	
			P-value	0.3141	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Acne) by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Region of enrollment: Latin America	Overall	Overall	N	18	19
			n (%)	0	0
			Test for interaction[b]	0.1721	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:26)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_13_1

Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Acne) by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Baseline disease severity: Moderate	Overall	Overall	N	216	220
			n (%)	30 (13.9)	3 (1.4)
			95% CI[a]	(9.28, 18.50)	(0.00, 2.90)
			Relative Risk (95% CI)[a]	10.19 (3.16, 32.88)	
			P-value	0.0001	
Baseline disease severity: Severe	Overall	Overall	N	146	145
			n (%)	18 (12.3)	8 (5.5)
			95% CI[a]	(7.00, 17.66)	(1.80, 9.23)
			Relative Risk (95% CI)[a]	2.23 (1.00, 4.98)	
			P-value	0.0490	
			Test for interaction[b]	0.1911	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:26)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_13_1

Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Folliculitis) by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Age (years) group: <40	Overall	Overall	N	230	247
			n (%)	7 (3.0)	2 (0.8)
			95% CI[a]	(0.82, 5.26)	(0.00, 1.93)
			Relative Risk (95% CI)[a]	3.76 (0.79, 17.91)	
			P-value	0.0965	
Age (years) group: >=40	Overall	Overall	N	132	118
			n (%)	4 (3.0)	1 (0.8)
			95% CI[a]	(0.11, 5.95)	(0.00, 2.50)
			Relative Risk (95% CI)[a]	3.58 (0.41, 31.54)	
			P-value	0.2514	
			Test for interaction[b]	0.9812	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Folliculitis) by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Sex

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Sex: Male	Overall	Overall	N	193	204
			n (%)	9 (4.7)	2 (1.0)
			95% CI[a]	(1.69, 7.64)	(0.00, 2.33)
			Relative Risk (95% CI)[a]	4.76 (1.04, 21.74)	
			P-value	0.0443	
Sex: Female	Overall	Overall	N	169	161
			n (%)	2 (1.2)	1 (0.6)
			95% CI[a]	(0.00, 2.81)	(0.00, 1.83)
			Relative Risk (95% CI)[a]	1.91 (0.17, 20.81)	
			P-value	0.5972	
			Test for interaction[b]	0.1122	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_13_2

Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Folliculitis) by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Region of enrollment: US/Canada/Australia	Overall	Overall	N	177	195
			n (%)	4 (2.3)	3 (1.5)
			95% CI[a]	(0.07, 4.45)	(0.00, 3.27)
			Relative Risk (95% CI)[a]	1.47 (0.33, 6.47)	
			P-value	0.6113	
Region of enrollment: Europe	Overall	Overall	N	150	132
			n (%)	5 (3.3)	0
			95% CI[a]	(0.46, 6.21)	(0.00, 2.76)
			Relative Risk (95% CI)[a]	8.83 (0.49, 160.17)	
			P-value	0.1406	
Region of enrollment: Asia	Overall	Overall	N	17	19
			n (%)	2 (11.8)	0
			95% CI[a]	(0.00, 27.08)	(0.00, 17.65)
			Relative Risk (95% CI)[a]	4.59 (0.22, 94.96)	
			P-value	0.3244	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_13_2

Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Folliculitis) by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Region of enrollment: Latin America	Overall	Overall	N	18	19
			n (%)	0	0
			Test for interaction[b]	0.5893	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_13_2

Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Folliculitis) by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Baseline disease severity: Moderate	Overall	Overall	N	216	220
			n (%)	8 (3.7)	1 (0.5)
			95% CI[a]	(1.19, 6.22)	(0.00, 1.34)
			Relative Risk (95% CI)[a]	8.15 (1.03, 64.60)	
			P-value	0.0470	
Baseline disease severity: Severe	Overall	Overall	N	146	145
			n (%)	3 (2.1)	2 (1.4)
			95% CI[a]	(0.00, 4.36)	(0.00, 3.28)
			Relative Risk (95% CI)[a]	1.49 (0.25, 8.78)	
			P-value	0.6597	
			Test for interaction[b]	0.2092	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_13_2

Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Conjonctivitis) by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Age (years) group: <40	Overall	Overall	N	230	247
			n (%)	4 (1.7)	25 (10.1)
			95% CI[a]	(0.05, 3.43)	(6.36, 13.88)
			Relative Risk (95% CI)[a]	0.17 (0.06, 0.49)	
			P-value	0.0009	
Age (years) group: >=40	Overall	Overall	N	132	118
			n (%)	6 (4.5)	14 (11.9)
			95% CI[a]	(0.99, 8.10)	(6.03, 17.70)
			Relative Risk (95% CI)[a]	0.38 (0.15, 0.96)	
			P-value	0.0417	
			Test for interaction[b]	0.8350	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Conjonctivitis) by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Sex

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Sex: Male	Overall	Overall	N	193	204
			n (%)	9 (4.7)	22 (10.8)
			95% CI[a]	(1.69, 7.64)	(6.53, 15.04)
			Relative Risk (95% CI)[a]	0.43 (0.20, 0.92)	
			P-value	0.0285	
Sex: Female	Overall	Overall	N	169	161
			n (%)	1 (0.6)	17 (10.6)
			95% CI[a]	(0.00, 1.75)	(5.81, 15.31)
			Relative Risk (95% CI)[a]	0.06 (0.01, 0.42)	
			P-value	0.0049	
			Test for interaction[b]	0.3281	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Conjonctivitis) by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Region of enrollment: US/Canada/Australia	Overall	Overall	N	177	195
			n (%)	4 (2.3)	22 (11.3)
			95% CI[a]	(0.07, 4.45)	(6.84, 15.72)
			Relative Risk (95% CI)[a]	0.20 (0.07, 0.57)	
			P-value	0.0026	
Region of enrollment: Europe	Overall	Overall	N	150	132
			n (%)	4 (2.7)	16 (12.1)
			95% CI[a]	(0.09, 5.24)	(6.55, 17.69)
			Relative Risk (95% CI)[a]	0.22 (0.08, 0.64)	
			P-value	0.0056	
Region of enrollment: Asia	Overall	Overall	N	17	19
			n (%)	2 (11.8)	1 (5.3)
			95% CI[a]	(0.00, 27.08)	(0.00, 15.30)
			Relative Risk (95% CI)[a]	2.24 (0.22, 22.51)	
			P-value	0.4948	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_13_3

Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Conjonctivitis) by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Region of enrollment: Latin America	Overall	Overall	N	18	19
			n (%)	0	0
			Test for interaction[b]	0.1573	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_13_3

Proportion of Subjects with Special Interest Treatment-Emergent Adverse Events (Conjonctivitis) by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Baseline disease severity: Moderate	Overall	Overall	N	216	220
			n (%)	3 (1.4)	28 (12.7)
			95% CI[a]	(0.00, 2.95)	(8.32, 17.13)
			Relative Risk (95% CI)[a]	0.11 (0.03, 0.35)	
			P-value	0.0002	
Baseline disease severity: Severe	Overall	Overall	N	146	145
			n (%)	7 (4.8)	11 (7.6)
			95% CI[a]	(1.33, 8.26)	(3.28, 11.90)
			Relative Risk (95% CI)[a]	0.63 (0.25, 1.58)	
			P-value	0.3280	
			Test for interaction[b]	0.0225	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_13_3

Proportion of Subjects with Special Interest Treatment-Emergent Serious Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Table not created
No participant meets the reporting criteria

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Special Interest Treatment-Emergent Severe Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Table not created
No participant meets the reporting criteria

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Serious Superinfections of Infections (Treated with Antibiotics, Antiviral or Fungicidal Agents for a Duration > 2 Weeks) Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Table not created
No participant meets the reporting criteria

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Severe Superinfections of Infections (Treated with Antibiotics, Antiviral or Fungicidal Agents for a Duration > 2 Weeks) Treatment-Emergent Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Table not created
No participant meets the reporting criteria

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Discontinuations from Study Drug due to Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Age group (<40, >=40)

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Age (years) group: <40	Overall	Overall	N	230	247
			n (%)	5 (2.2)	8 (3.2)
			95% CI[a]	(0.29, 4.06)	(1.03, 5.45)
			Relative Risk (95% CI)[a]	0.67 (0.22, 2.02)	
			P-value	0.4786	
Age (years) group: >=40	Overall	Overall	N	132	118
			n (%)	4 (3.0)	1 (0.8)
			95% CI[a]	(0.11, 5.95)	(0.00, 2.50)
			Relative Risk (95% CI)[a]	3.58 (0.41, 31.54)	
			P-value	0.2514	
			Test for interaction[b]	0.1535	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Discontinuations from Study Drug due to Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Sex

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Sex: Male	Overall	Overall	N	193	204
			n (%)	2 (1.0)	4 (2.0)
			95% CI[a]	(0.00, 2.46)	(0.06, 3.86)
			Relative Risk (95% CI)[a]	0.53 (0.10, 2.85)	
			P-value	0.4585	
Sex: Female	Overall	Overall	N	169	161
			n (%)	7 (4.1)	5 (3.1)
			95% CI[a]	(1.14, 7.15)	(0.43, 5.79)
			Relative Risk (95% CI)[a]	1.33 (0.43, 4.12)	
			P-value	0.6165	
			Test for interaction[b]	0.4137	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Discontinuations from Study Drug due to Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Region of enrollment: US/Canada/Australia	Overall	Overall	N	177	195
			n (%)	5 (2.8)	3 (1.5)
			95% CI[a]	(0.38, 5.27)	(0.00, 3.27)
			Relative Risk (95% CI)[a]	1.84 (0.45, 7.57)	
			P-value	0.4006	
Region of enrollment: Europe	Overall	Overall	N	150	132
			n (%)	3 (2.0)	6 (4.5)
			95% CI[a]	(0.00, 4.24)	(0.99, 8.10)
			Relative Risk (95% CI)[a]	0.44 (0.11, 1.72)	
			P-value	0.2388	
Region of enrollment: Asia	Overall	Overall	N	17	19
			n (%)	1 (5.9)	0
			95% CI[a]	(0.00, 17.07)	(0.00, 17.65)
			Relative Risk (95% CI)[a]	2.29 (0.08, 64.21)	
			P-value	0.6252	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_18

Proportion of Subjects with Discontinuations from Study Drug due to Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Region

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Region of enrollment: Latin America	Overall	Overall	N	18	19
			n (%)	0	0
			Test for interaction[b]	0.5066	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.

Proportion of Subjects with Discontinuations from Study Drug due to Adverse Events by Subgroup (All Causalities) - Safety Analysis Set
(Protocol B7451050)

Baseline disease severity

				Abrocitinib 200mg QD (N=362)	Dupilumab 300mg Q2W (N=365)
Subgroup	System Organ Class	MedDRA Preferred Term		n (%)	n (%)
Baseline disease severity: Moderate	Overall	Overall	N	216	220
			n (%)	7 (3.2)	5 (2.3)
			95% CI[a]	(0.88, 5.60)	(0.30, 4.24)
			Relative Risk (95% CI)[a]	1.43 (0.46, 4.42)	
			P-value	0.5391	
Baseline disease severity: Severe	Overall	Overall	N	146	145
			n (%)	2 (1.4)	4 (2.8)
			95% CI[a]	(0.00, 3.26)	(0.09, 5.42)
			Relative Risk (95% CI)[a]	0.50 (0.09, 2.67)	
			P-value	0.4146	
			Test for interaction[b]	0.3041	

Included data up to 28 days after last dose of study.
Subjects were counted only once per treatment per event.
.5 was added to 0 count cells when RR can't be calculated.
a. Results calculated with normal approximation.
b. For test of treatment and subgroup interaction, a log regression model with covariates treatment, subgroup category and treatment by subgroup interaction was used.
The two sided P-value was based on a type 3 wald test with the null hypothesis: all the parameters associated with the interaction effect (treatment by subgroup category) were zero.
MedDRA v24.0 coding dictionary applied.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (02:02) Source Data: adae Table Generation: 26SEP2021 (07:28)
Output File: ./nda1_cdisc/B7451050_GBA/adae_propsub_18

Non-Severe Treatment Emergent Subset Flag Adverse Events, overall and by SOC/PT - Safety Population

System Organ Class (SOC) Preferred Term (PT)	Abrocitinib 200mg QD N=362	Dupilumab 300mg Q2W N=365	Total Population N=727
Overall	195 (53.9%)	129 (35.3%)	324 (44.6%)
Infections and infestations	67 (18.5%)	76 (20.8%)	143 (19.7%)
Conjunctivitis	8 (2.2%)	35 (9.6%)	43 (5.9%)
COVID-19	14 (3.9%)	12 (3.3%)	26 (3.6%)
Nasopharyngitis	14 (3.9%)	12 (3.3%)	26 (3.6%)
Oral herpes	9 (2.5%)	15 (4.1%)	24 (3.3%)
Upper respiratory tract infection	10 (2.8%)	9 (2.5%)	19 (2.6%)
Herpes simplex	12 (3.3%)	5 (1.4%)	17 (2.3%)
Folliculitis	12 (3.3%)	3 (0.8%)	15 (2.1%)
Skin and subcutaneous tissue disorders	60 (16.6%)	23 (6.3%)	83 (11.4%)
Acne	46 (12.7%)	10 (2.7%)	56 (7.7%)
Dermatitis atopic	16 (4.4%)	14 (3.8%)	30 (4.1%)
Gastrointestinal disorders	70 (19.3%)	11 (3.0%)	81 (11.1%)
Nausea	70 (19.3%)	8 (2.2%)	78 (10.7%)
Vomiting	11 (3.0%)	6 (1.6%)	17 (2.3%)
Nervous system disorders	54 (14.9%)	27 (7.4%)	81 (11.1%)
Headache	46 (12.7%)	24 (6.6%)	70 (9.6%)
Dizziness	10 (2.8%)	4 (1.1%)	14 (1.9%)
Investigations	38 (10.5%)	26 (7.1%)	64 (8.8%)
SARS-CoV-2 test positive	15 (4.1%)	13 (3.6%)	28 (3.9%)
Blood creatine phosphokinase increased	14 (3.9%)	13 (3.6%)	27 (3.7%)
Natural killer cell count decreased	10 (2.8%)	0	10 (1.4%)
General disorders and administration site conditions	10 (2.8%)	5 (1.4%)	15 (2.1%)
Fatigue	10 (2.8%)	5 (1.4%)	15 (2.1%)

Note(s):
Safety Population
CTCAE: Common Terminology Criteria for Adverse Events; PT: (MedDRA) Preferred Term; SOC: (MedDRA) System Organ Class.
Analysis Cut Off date: 06AUG2021
[[root]\02 Programs\02.05 Safety Incidences SOCPT.sas] run Thursday, November 11, 2021 at 11:26:34

Responderanalysen JADE DARE (Woche 12)

Binary Outcome Analysis: SCORAD-75 response at week 12 - Full Analysis Set Safety Population
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Week 12									
Full Analysis Set Safety Population	362	133 (36.7%) (31.8%, 41.9%)	365	93 (25.5%) (21.1%, 30.3%)	1.70 (1.24, 2.34)	1.44 (1.16, 1.80)	11.3% (4.6%, 18.0%)	0.0010+*	--
Baseline Disease Severity									
Week 12									
Moderate baseline disease (IGA=3)	216	80 (37.0%) (30.6%, 43.9%)	220	58 (26.4%) (20.7%, 32.7%)	1.64 (1.09, 2.47)	1.40 (1.06, 1.86)	10.7% (2.0%, 19.4%)	0.0180*	0.8589
Severe baseline disease (IGA=4)	146	53 (36.3%) (28.5%, 44.7%)	145	35 (24.1%) (17.4%, 31.9%)	1.79 (1.08, 2.98)	1.50 (1.05, 2.16)	12.2% (1.7%, 22.6%)	0.0298*	
Gender									
Week 12									
Male	193	64 (33.2%) (26.6%, 40.3%)	204	47 (23.0%) (17.4%, 29.4%)	1.66 (1.06, 2.58)	1.44 (1.04, 1.98)	10.1% (1.3%, 18.9%)	0.0258*	0.6462
Female	169	69 (40.8%) (33.3%, 48.6%)	161	46 (28.6%) (21.7%, 36.2%)	1.73 (1.09, 2.73)	1.43 (1.05, 1.94)	12.3% (2.1%, 22.4%)	0.0211*	

Notes:
Number of subjects: Full Analysis Set Safety Population
Analysis on overall population is calculated based on stratified CMH (Cochran-Mantel-Haenszel) models, for OR, RR, and RD, stratified by by disease activity (moderate, severe) at enrollment.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: SCORAD-75 response at week 12 - Full Analysis Set Safety Population
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Region									
Week 12									
US/Canada/Australia	177	77 (43.5%) (36.1%, 51.1%)	195	47 (24.1%) (18.3%, 30.7%)	2.42 (1.56, 3.78)	1.80 (1.34, 2.44)	19.4% (9.9%, 28.9%)	0.0001*	0.0045*
Europe	150	36 (24.0%) (17.4%, 31.6%)	132	32 (24.2%) (17.2%, 32.5%)	0.99 (0.57, 1.70)	0.99 (0.65, 1.50)	-0.2% (-10.3%, 9.8%)	1.0000	
Asia	17	5 (29.4%) (10.3%, 56.0%)	19	5 (26.3%) (9.1%, 51.2%)	1.17 (0.27, 5.02)	1.12 (0.39, 3.20)	3.1% (-26.2%, 32.4%)	1.0000	
Latin America	18	15 (83.3%) (58.6%, 96.4%)	19	9 (47.4%) (24.4%, 71.1%)	5.56 (1.20, 25.71)	1.76 (1.05, 2.95)	36.0% (7.7%, 64.3%)	0.0382*	
Age Subgroup									
Week 12									
<40 years	230	80 (34.8%) (28.6%, 41.3%)	247	64 (25.9%) (20.6%, 31.8%)	1.53 (1.03, 2.26)	1.34 (1.02, 1.77)	8.9% (0.6%, 17.1%)	0.0366*	0.3334
>=40 years	132	53 (40.2%) (31.7%, 49.0%)	118	29 (24.6%) (17.1%, 33.4%)	2.06 (1.19, 3.55)	1.63 (1.12, 2.39)	15.6% (4.2%, 27.0%)	0.0104*	

Notes:
Number of subjects: Full Analysis Set Safety Population
Analysis on overall population is calculated based on stratified CMH (Cochran-Mantel-Haenszel) models, for OR, RR, and RD, stratified by by disease activity (moderate, severe) at enrollment.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: SCORAD-90 response at week 12 - Full Analysis Set Safety Population
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Week 12									
Full Analysis Set Safety Population	362	60 (16.6%) (12.9%, 20.8%)	365	24 (6.6%) (4.3%, 9.6%)	2.82 (1.71, 4.64)	2.52 (1.61, 3.96)	10.0% (5.4%, 14.6%)	<0.0001+*	--
Baseline Disease Severity									
Week 12									
Moderate baseline disease (IGA=3)	216	33 (15.3%) (10.8%, 20.8%)	220	16 (7.3%) (4.2%, 11.5%)	2.30 (1.23, 4.31)	2.10 (1.19, 3.70)	8.0% (2.1%, 13.9%)	0.0096*	0.3015
Severe baseline disease (IGA=4)	146	27 (18.5%) (12.6%, 25.8%)	145	8 (5.5%) (2.4%, 10.6%)	3.89 (1.70, 8.88)	3.35 (1.58, 7.13)	13.0% (5.7%, 20.3%)	0.0009*	
Gender									
Week 12									
Male	193	33 (17.1%) (12.1%, 23.2%)	204	9 (4.4%) (2.0%, 8.2%)	4.47 (2.08, 9.61)	3.88 (1.90, 7.89)	12.7% (6.7%, 18.7%)	<0.0001*	0.2318
Female	169	27 (16.0%) (10.8%, 22.4%)	161	15 (9.3%) (5.3%, 14.9%)	1.85 (0.95, 3.62)	1.71 (0.95, 3.10)	6.7% (-0.5%, 13.8%)	0.0976	

Notes:
Number of subjects: Full Analysis Set Safety Population
Analysis on overall population is calculated based on stratified CMH (Cochran-Mantel-Haenszel) models, for OR, RR, and RD, stratified by by disease activity (moderate, severe) at enrollment.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: SCORAD-90 response at week 12 - Full Analysis Set Safety Population
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Region									
Week 12									
US/Canada/Australia	177	32 (18.1%) (12.7%, 24.6%)	195	8 (4.1%) (1.8%, 7.9%)	5.16 (2.31, 11.53)	4.41 (2.09, 9.31)	14.0% (7.7%, 20.3%)	<0.0001*	0.0573
Europe	150	19 (12.7%) (7.8%, 19.1%)	132	8 (6.1%) (2.7%, 11.6%)	2.25 (0.95, 5.32)	2.09 (0.95, 4.62)	6.6% (-0.1%, 13.3%)	0.0693	
Asia	17	0 (0.0%)	19	2 (10.5%) (1.3%, 33.1%)	0.20 (0.01, 4.47)	0.22 (0.01, 4.33)	-9.7% (-26.1%, 6.6%)	0.4873	
Latin America	18	9 (50.0%) (26.0%, 74.0%)	19	6 (31.6%) (12.6%, 56.6%)	2.17 (0.57, 8.26)	1.58 (0.71, 3.55)	18.4% (-12.7%, 49.6%)	0.3245	
Age Subgroup									
Week 12									
<40 years	230	35 (15.2%) (10.8%, 20.5%)	247	16 (6.5%) (3.7%, 10.3%)	2.59 (1.39, 4.82)	2.35 (1.34, 4.13)	8.7% (3.2%, 14.3%)	0.0027*	0.4752
>=40 years	132	25 (18.9%) (12.6%, 26.7%)	118	8 (6.8%) (3.0%, 12.9%)	3.21 (1.39, 7.44)	2.79 (1.31, 5.95)	12.2% (4.1%, 20.2%)	0.0049*	

Notes:
Number of subjects: Full Analysis Set Safety Population
Analysis on overall population is calculated based on stratified CMH (Cochran-Mantel-Haenszel) models, for OR, RR, and RD, stratified by by disease activity (moderate, severe) at enrollment.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: SCORAD-100 response at week 12 - Full Analysis Set Safety Population
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Week 12									
Full Analysis Set Safety Population	362	21 (5.8%) (3.6%, 8.7%)	365	6 (1.6%) (0.6%, 3.5%)	3.68 (1.47, 9.24)	3.52 (1.44, 8.61)	4.1% (1.4%, 6.9%)	0.0031+*	--
Baseline Disease Severity									
Week 12									
Moderate baseline disease (IGA=3)	216	10 (4.6%) (2.2%, 8.3%)	220	3 (1.4%) (0.3%, 3.9%)	3.51 (0.95, 12.94)	3.40 (0.95, 12.17)	3.3% (0.1%, 6.5%)	0.0519	0.4451
Severe baseline disease (IGA=4)	146	11 (7.5%) (3.8%, 13.1%)	145	3 (2.1%) (0.4%, 5.9%)	3.86 (1.05, 14.13)	3.64 (1.04, 12.78)	5.5% (0.6%, 10.3%)	0.0516	
Gender									
Week 12									
Male	193	11 (5.7%) (2.9%, 10.0%)	204	3 (1.5%) (0.3%, 4.2%)	4.05 (1.11, 14.74)	3.88 (1.10, 13.68)	4.2% (0.6%, 7.9%)	0.0284*	0.9547
Female	169	10 (5.9%) (2.9%, 10.6%)	161	3 (1.9%) (0.4%, 5.3%)	3.31 (0.89, 12.26)	3.18 (0.89, 11.33)	4.1% (-0.1%, 8.2%)	0.0872	

Notes:
Number of subjects: Full Analysis Set Safety Population
Analysis on overall population is calculated based on stratified CMH (Cochran-Mantel-Haenszel) models, for OR, RR, and RD, stratified by by disease activity (moderate, severe) at enrollment.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: SCORAD-100 response at week 12 - Full Analysis Set Safety Population
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Region									
Week 12									
US/Canada/Australia	177	12 (6.8%) (3.6%, 11.5%)	195	2 (1.0%) (0.1%, 3.7%)	7.02 (1.55, 31.81)	6.61 (1.50, 29.13)	5.8% (1.8%, 9.7%)	0.0047*	0.5209
Europe	150	8 (5.3%) (2.3%, 10.2%)	132	3 (2.3%) (0.5%, 6.5%)	2.42 (0.63, 9.33)	2.35 (0.64, 8.66)	3.1% (-1.3%, 7.5%)	0.2280	
Asia	17	0 (0.0%)	19	1 (5.3%) (0.1%, 26.0%)	0.35 (0.01, 9.24)	0.37 (0.02, 8.53)	-4.7% (-18.5%, 9.1%)	1.0000	
Latin America	18	1 (5.6%) (0.1%, 27.3%)	19	0 (0.0%)	3.34 (0.13, 87.52)	3.16 (0.14, 72.84)	5.4% (-8.5%, 19.3%)	0.4865	
Age Subgroup									
Week 12									
<40 years	230	12 (5.2%) (2.7%, 8.9%)	247	5 (2.0%) (0.7%, 4.7%)	2.66 (0.92, 7.68)	2.58 (0.92, 7.20)	3.2% (-0.2%, 6.6%)	0.0823	0.3360
>=40 years	132	9 (6.8%) (3.2%, 12.5%)	118	1 (0.8%) (0.0%, 4.6%)	8.56 (1.07, 68.62)	8.05 (1.03, 62.56)	6.0% (1.4%, 10.6%)	0.0209*	

Notes:
Number of subjects: Full Analysis Set Safety Population
Analysis on overall population is calculated based on stratified CMH (Cochran-Mantel-Haenszel) models, for OR, RR, and RD, stratified by by disease activity (moderate, severe) at enrollment.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: EASI-75 response at week 12 - Full Analysis Set Safety Population
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Week 12									
Full Analysis Set Safety Population	362	274 (75.7%) (70.9%, 80.0%)	365	223 (61.1%) (55.9%, 66.1%)	1.98 (1.44, 2.72)	1.24 (1.12, 1.37)	14.6% (7.9%, 21.3%)	<0.0001+*	--
Baseline Disease Severity									
Week 12									
Moderate baseline disease (IGA=3)	216	160 (74.1%) (67.7%, 79.8%)	220	137 (62.3%) (55.5%, 68.7%)	1.73 (1.15, 2.60)	1.19 (1.04, 1.35)	11.8% (3.1%, 20.5%)	0.0101*	0.2971
Severe baseline disease (IGA=4)	146	114 (78.1%) (70.5%, 84.5%)	145	86 (59.3%) (50.8%, 67.4%)	2.44 (1.46, 4.08)	1.32 (1.12, 1.54)	18.8% (8.3%, 29.2%)	0.0006*	
Gender									
Week 12									
Male	193	148 (76.7%) (70.1%, 82.5%)	204	111 (54.4%) (47.3%, 61.4%)	2.76 (1.79, 4.25)	1.41 (1.22, 1.63)	22.3% (13.2%, 31.3%)	<0.0001*	0.0347*
Female	169	126 (74.6%) (67.3%, 80.9%)	161	112 (69.6%) (61.8%, 76.6%)	1.28 (0.79, 2.08)	1.07 (0.94, 1.23)	5.0% (-4.7%, 14.7%)	0.3280	

Notes:
Number of subjects: Full Analysis Set Safety Population
Analysis on overall population is calculated based on stratified CMH (Cochran-Mantel-Haenszel) models, for OR, RR, and RD, stratified by by disease activity (moderate, severe) at enrollment.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: EASI-75 response at week 12 - Full Analysis Set Safety Population
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Region									
Week 12									
US/Canada/Australia	177	137 (77.4%) (70.5%, 83.3%)	195	116 (59.5%) (52.2%, 66.4%)	2.33 (1.48, 3.67)	1.30 (1.13, 1.50)	17.9% (8.7%, 27.2%)	0.0002*	0.6301
Europe	150	110 (73.3%) (65.5%, 80.2%)	132	78 (59.1%) (50.2%, 67.6%)	1.90 (1.15, 3.14)	1.24 (1.05, 1.47)	14.2% (3.3%, 25.2%)	0.0159*	
Asia	17	11 (64.7%) (38.3%, 85.8%)	19	12 (63.2%) (38.4%, 83.7%)	1.07 (0.27, 4.18)	1.02 (0.63, 1.67)	1.5% (-29.9%, 33.0%)	1.0000	
Latin America	18	16 (88.9%) (65.3%, 98.6%)	19	17 (89.5%) (66.9%, 98.7%)	0.94 (0.12, 7.50)	0.99 (0.79, 1.24)	-0.6% (-20.6%, 19.4%)	1.0000	
Age Subgroup									
Week 12									
<40 years	230	171 (74.3%) (68.2%, 79.9%)	247	157 (63.6%) (57.2%, 69.6%)	1.66 (1.12, 2.46)	1.17 (1.04, 1.32)	10.8% (2.5%, 19.0%)	0.0134*	0.1457
>=40 years	132	103 (78.0%) (70.0%, 84.8%)	118	66 (55.9%) (46.5%, 65.1%)	2.80 (1.62, 4.85)	1.40 (1.16, 1.68)	22.1% (10.7%, 33.5%)	0.0002*	

Notes:
Number of subjects: Full Analysis Set Safety Population
Analysis on overall population is calculated based on stratified CMH (Cochran-Mantel-Haenszel) models, for OR, RR, and RD, stratified by by disease activity (moderate, severe) at enrollment.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: EASI-90 response at week 12 - Full Analysis Set Safety Population
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Week 12									
Full Analysis Set Safety Population	362	171 (47.2%) (42.0%, 52.5%)	365	122 (33.4%) (28.6%, 38.5%)	1.79 (1.32, 2.41)	1.41 (1.18, 1.69)	13.8% (6.8%, 20.9%)	0.0001+*	--
Baseline Disease Severity									
Week 12									
Moderate baseline disease (IGA=3)	216	104 (48.1%) (41.3%, 55.0%)	220	78 (35.5%) (29.1%, 42.2%)	1.69 (1.15, 2.48)	1.36 (1.08, 1.70)	12.7% (3.5%, 21.9%)	0.0087*	0.7880
Severe baseline disease (IGA=4)	146	67 (45.9%) (37.6%, 54.3%)	145	44 (30.3%) (23.0%, 38.5%)	1.95 (1.20, 3.15)	1.51 (1.12, 2.05)	15.5% (4.5%, 26.6%)	0.0079*	
Gender									
Week 12									
Male	193	89 (46.1%) (38.9%, 53.4%)	204	55 (27.0%) (21.0%, 33.6%)	2.32 (1.52, 3.53)	1.71 (1.30, 2.25)	19.2% (9.9%, 28.5%)	0.0001*	0.1618
Female	169	82 (48.5%) (40.8%, 56.3%)	161	67 (41.6%) (33.9%, 49.6%)	1.32 (0.86, 2.04)	1.17 (0.92, 1.48)	6.9% (-3.8%, 17.6%)	0.2246	

Notes:
Number of subjects: Full Analysis Set Safety Population
Analysis on overall population is calculated based on stratified CMH (Cochran-Mantel-Haenszel) models, for OR, RR, and RD, stratified by by disease activity (moderate, severe) at enrollment.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: EASI-90 response at week 12 - Full Analysis Set Safety Population
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Region									
Week 12									
US/Canada/Australia	177	93 (52.5%) (44.9%, 60.1%)	195	62 (31.8%) (25.3%, 38.8%)	2.38 (1.56, 3.62)	1.65 (1.29, 2.12)	20.7% (10.9%, 30.6%)	<0.0001*	0.1067
Europe	150	58 (38.7%) (30.8%, 47.0%)	132	43 (32.6%) (24.7%, 41.3%)	1.30 (0.80, 2.13)	1.19 (0.86, 1.63)	6.1% (-5.1%, 17.3%)	0.3202	
Asia	17	5 (29.4%) (10.3%, 56.0%)	19	5 (26.3%) (9.1%, 51.2%)	1.17 (0.27, 5.02)	1.12 (0.39, 3.20)	3.1% (-26.2%, 32.4%)	1.0000	
Latin America	18	15 (83.3%) (58.6%, 96.4%)	19	12 (63.2%) (38.4%, 83.7%)	2.92 (0.62, 13.76)	1.32 (0.88, 1.97)	20.2% (-7.5%, 47.9%)	0.2691	
Age Subgroup									
Week 12									
<40 years	230	102 (44.3%) (37.8%, 51.0%)	247	81 (32.8%) (27.0%, 39.0%)	1.63 (1.13, 2.37)	1.35 (1.07, 1.70)	11.6% (2.9%, 20.2%)	0.0110*	0.3564
>=40 years	132	69 (52.3%) (43.4%, 61.0%)	118	41 (34.7%) (26.2%, 44.1%)	2.06 (1.24, 3.43)	1.50 (1.12, 2.02)	17.5% (5.4%, 29.6%)	0.0072*	

Notes:
Number of subjects: Full Analysis Set Safety Population
Analysis on overall population is calculated based on stratified CMH (Cochran-Mantel-Haenszel) models, for OR, RR, and RD, stratified by by disease activity (moderate, severe) at enrollment.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: EASI-100 response at week 12 - Full Analysis Set Safety Population
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Week 12									
Full Analysis Set Safety Population	362	56 (15.5%) (11.9%, 19.6%)	365	20 (5.5%) (3.4%, 8.3%)	3.16 (1.85, 5.39)	2.83 (1.73, 4.61)	10.0% (5.6%, 14.4%)	<0.0001+*	--
Baseline Disease Severity									
Week 12									
Moderate baseline disease (IGA=3)	216	34 (15.7%) (11.2%, 21.3%)	220	13 (5.9%) (3.2%, 9.9%)	2.97 (1.52, 5.81)	2.66 (1.45, 4.91)	9.8% (4.1%, 15.6%)	0.0011*	0.9467
Severe baseline disease (IGA=4)	146	22 (15.1%) (9.7%, 21.9%)	145	7 (4.8%) (2.0%, 9.7%)	3.50 (1.44, 8.47)	3.12 (1.38, 7.08)	10.2% (3.5%, 17.0%)	0.0054*	
Gender									
Week 12									
Male	193	30 (15.5%) (10.7%, 21.4%)	204	8 (3.9%) (1.7%, 7.6%)	4.51 (2.01, 10.11)	3.96 (1.86, 8.43)	11.6% (5.9%, 17.4%)	0.0001*	0.4518
Female	169	26 (15.4%) (10.3%, 21.7%)	161	12 (7.5%) (3.9%, 12.7%)	2.26 (1.10, 4.64)	2.06 (1.08, 3.95)	7.9% (1.1%, 14.7%)	0.0257*	

Notes:
Number of subjects: Full Analysis Set Safety Population
Analysis on overall population is calculated based on stratified CMH (Cochran-Mantel-Haenszel) models, for OR, RR, and RD, stratified by by disease activity (moderate, severe) at enrollment.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: EASI-100 response at week 12 - Full Analysis Set Safety Population
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Region									
Week 12									
US/Canada/Australia	177	31 (17.5%) (12.2%, 23.9%)	195	8 (4.1%) (1.8%, 7.9%)	4.96 (2.21, 11.12)	4.27 (2.02, 9.04)	13.4% (7.2%, 19.7%)	<0.0001*	0.1169
Europe	150	17 (11.3%) (6.7%, 17.5%)	132	7 (5.3%) (2.2%, 10.6%)	2.28 (0.92, 5.69)	2.14 (0.91, 4.99)	6.0% (-0.3%, 12.4%)	0.0874	
Asia	17	1 (5.9%) (0.1%, 28.7%)	19	2 (10.5%) (1.3%, 33.1%)	0.53 (0.04, 6.44)	0.56 (0.06, 5.63)	-4.6% (-22.4%, 13.1%)	1.0000	
Latin America	18	7 (38.9%) (17.3%, 64.3%)	19	3 (15.8%) (3.4%, 39.6%)	3.39 (0.72, 16.07)	2.46 (0.75, 8.09)	23.1% (-4.8%, 51.0%)	0.1510	
Age Subgroup									
Week 12									
<40 years	230	34 (14.8%) (10.5%, 20.0%)	247	13 (5.3%) (2.8%, 8.8%)	3.12 (1.60, 6.08)	2.81 (1.52, 5.19)	9.5% (4.2%, 14.9%)	0.0006*	0.7809
>=40 years	132	22 (16.7%) (10.7%, 24.1%)	118	7 (5.9%) (2.4%, 11.8%)	3.17 (1.30, 7.73)	2.81 (1.25, 6.34)	10.7% (3.1%, 18.4%)	0.0096*	

Notes:
Number of subjects: Full Analysis Set Safety Population
Analysis on overall population is calculated based on stratified CMH (Cochran-Mantel-Haenszel) models, for OR, RR, and RD, stratified by by disease activity (moderate, severe) at enrollment.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Achieving 0-2 in POEM total score at week 12 - Full Analysis Set Safety Population
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Week 12									
Full Analysis Set Safety Population	358	108 (30.2%) (25.5%, 35.2%)	363	61 (16.8%) (13.1%, 21.1%)	2.14 (1.50, 3.05)	1.79 (1.36, 2.37)	13.4% (7.2%, 19.5%)	<0.0001+*	--
Baseline Disease Severity									
Week 12									
Moderate baseline disease (IGA=3)	213	65 (30.5%) (24.4%, 37.2%)	219	34 (15.5%) (11.0%, 21.0%)	2.39 (1.50, 3.81)	1.97 (1.36, 2.84)	15.0% (7.2%, 22.8%)	0.0002*	0.5525
Severe baseline disease (IGA=4)	145	43 (29.7%) (22.4%, 37.8%)	144	27 (18.8%) (12.7%, 26.1%)	1.83 (1.05, 3.17)	1.58 (1.04, 2.41)	10.9% (1.1%, 20.7%)	0.0391*	
Gender									
Week 12									
Male	190	56 (29.5%) (23.1%, 36.5%)	202	28 (13.9%) (9.4%, 19.4%)	2.60 (1.56, 4.31)	2.13 (1.41, 3.20)	15.6% (7.6%, 23.7%)	0.0002*	0.4891
Female	168	52 (31.0%) (24.1%, 38.5%)	161	33 (20.5%) (14.5%, 27.6%)	1.74 (1.05, 2.88)	1.51 (1.03, 2.21)	10.5% (1.1%, 19.8%)	0.0328*	

Notes:
Number of subjects: Full Analysis Set Safety Population
Number of subjects: Full Analysis Set Safety Population, excluding subjects with baseline POEM 0-2.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Achieving 0-2 in POEM total score at week 12 - Full Analysis Set Safety Population
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Region									
Week 12									
US/Canada/Australia	177	51 (28.8%) (22.3%, 36.1%)	193	29 (15.0%) (10.3%, 20.9%)	2.29 (1.37, 3.82)	1.92 (1.28, 2.88)	13.8% (5.4%, 22.2%)	0.0015*	0.8576
Europe	150	43 (28.7%) (21.6%, 36.6%)	132	21 (15.9%) (10.1%, 23.3%)	2.12 (1.18, 3.81)	1.80 (1.13, 2.87)	12.8% (3.2%, 22.3%)	0.0150*	
Asia	14	7 (50.0%) (23.0%, 77.0%)	19	8 (42.1%) (20.3%, 66.5%)	1.38 (0.34, 5.51)	1.19 (0.56, 2.50)	7.9% (-26.4%, 42.2%)	0.7325	
Latin America	17	7 (41.2%) (18.4%, 67.1%)	19	3 (15.8%) (3.4%, 39.6%)	3.73 (0.78, 17.88)	2.61 (0.80, 8.52)	25.4% (-3.2%, 54.0%)	0.1394	
Age Subgroup									
Week 12									
<40 years	226	63 (27.9%) (22.1%, 34.2%)	246	42 (17.1%) (12.6%, 22.4%)	1.88 (1.21, 2.92)	1.63 (1.16, 2.31)	10.8% (3.3%, 18.3%)	0.0056*	0.2639
>=40 years	132	45 (34.1%) (26.1%, 42.8%)	117	19 (16.2%) (10.1%, 24.2%)	2.67 (1.45, 4.91)	2.10 (1.31, 3.38)	17.9% (7.4%, 28.3%)	0.0014*	

Notes:
Number of subjects: Full Analysis Set Safety Population
Number of subjects: Full Analysis Set Safety Population, excluding subjects with baseline POEM 0-2.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Achieving 0 in POEM total score at week 12 - Full Analysis Set Safety Population
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Week 12									
Full Analysis Set Safety Population	359	49 (13.6%) (10.3%, 17.6%)	365	11 (3.0%) (1.5%, 5.3%)	5.13 (2.62, 10.05)	4.54 (2.40, 8.59)	10.7% (6.7%, 14.6%)	<0.0001+*	--
Baseline Disease Severity									
Week 12									
Moderate baseline disease (IGA=3)	214	33 (15.4%) (10.9%, 21.0%)	220	8 (3.6%) (1.6%, 7.0%)	4.83 (2.18, 10.73)	4.24 (2.00, 8.97)	11.8% (6.3%, 17.2%)	<0.0001*	0.4476
Severe baseline disease (IGA=4)	145	16 (11.0%) (6.4%, 17.3%)	145	3 (2.1%) (0.4%, 5.9%)	5.87 (1.67, 20.61)	5.33 (1.59, 17.91)	9.0% (3.4%, 14.6%)	0.0033*	
Gender									
Week 12									
Male	191	23 (12.0%) (7.8%, 17.5%)	204	3 (1.5%) (0.3%, 4.2%)	9.17 (2.71, 31.08)	8.19 (2.50, 26.83)	10.6% (5.7%, 15.5%)	<0.0001*	0.9376
Female	168	26 (15.5%) (10.4%, 21.8%)	161	8 (5.0%) (2.2%, 9.6%)	3.50 (1.54, 7.99)	3.11 (1.45, 6.68)	10.5% (4.1%, 16.9%)	0.0019*	

Notes:
Number of subjects: Full Analysis Set Safety Population
Number of subjects: Full Analysis Set Safety Population, excluding subjects with baseline POEM 0.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Achieving 0 in POEM total score at week 12 - Full Analysis Set Safety Population
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Region									
Week 12									
US/Canada/Australia	177	21 (11.9%) (7.5%, 17.6%)	195	3 (1.5%) (0.3%, 4.4%)	8.62 (2.52, 29.42)	7.71 (2.34, 25.41)	10.3% (5.3%, 15.4%)	<0.0001*	0.8118
Europe	150	23 (15.3%) (10.0%, 22.1%)	132	7 (5.3%) (2.2%, 10.6%)	3.23 (1.34, 7.81)	2.89 (1.28, 6.52)	10.0% (3.1%, 16.9%)	0.0067*	
Asia	15	3 (20.0%) (4.3%, 48.1%)	19	0 (0.0%)	10.92 (0.52, 229.91)	8.75 (0.49, 157.34)	19.4% (-2.0%, 40.8%)	0.0760	
Latin America	17	2 (11.8%) (1.5%, 36.4%)	19	1 (5.3%) (0.1%, 26.0%)	2.40 (0.20, 29.13)	2.24 (0.22, 22.51)	6.5% (-11.8%, 24.8%)	0.5929	
Age Subgroup									
Week 12									
<40 years	227	28 (12.3%) (8.4%, 17.3%)	247	6 (2.4%) (0.9%, 5.2%)	5.65 (2.29, 13.92)	5.08 (2.14, 12.04)	9.9% (5.2%, 14.6%)	<0.0001*	0.6465
>=40 years	132	21 (15.9%) (10.1%, 23.3%)	118	5 (4.2%) (1.4%, 9.6%)	4.28 (1.56, 11.74)	3.75 (1.46, 9.64)	11.7% (4.5%, 18.9%)	0.0031*	

Notes:
Number of subjects: Full Analysis Set Safety Population
Number of subjects: Full Analysis Set Safety Population, excluding subjects with baseline POEM 0.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Achieving 0-1 in CDLQI total score at week 12 - Full Analysis Set Safety Population
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Week 12									
Full Analysis Set Safety Population	358	126 (35.2%) (30.2%, 40.4%)	361	110 (30.5%) (25.8%, 35.5%)	1.24 (0.91, 1.69)	1.16 (0.94, 1.43)	4.7% (-2.1%, 11.6%)	0.1758+	--
Baseline Disease Severity									
Week 12									
Moderate baseline disease (IGA=3)	212	77 (36.3%) (29.8%, 43.2%)	217	68 (31.3%) (25.2%, 38.0%)	1.25 (0.84, 1.87)	1.16 (0.89, 1.51)	5.0% (-4.0%, 13.9%)	0.3076	0.9146
Severe baseline disease (IGA=4)	146	49 (33.6%) (26.0%, 41.8%)	144	42 (29.2%) (21.9%, 37.3%)	1.23 (0.75, 2.02)	1.15 (0.82, 1.62)	4.4% (-6.3%, 15.1%)	0.4492	
Gender									
Week 12									
Male	191	73 (38.2%) (31.3%, 45.5%)	201	61 (30.3%) (24.1%, 37.2%)	1.42 (0.93, 2.16)	1.26 (0.96, 1.66)	7.9% (-1.5%, 17.2%)	0.1106	0.3205
Female	167	53 (31.7%) (24.8%, 39.4%)	160	49 (30.6%) (23.6%, 38.4%)	1.05 (0.66, 1.68)	1.04 (0.75, 1.43)	1.1% (-8.9%, 11.2%)	0.9050	

Notes:
Number of subjects: Full Analysis Set Safety Population
Number of subjects: Full Analysis Set Safety Population, excluding subjects with baseline DLQI 0-1.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Achieving 0-1 in CDLQI total score at week 12 - Full Analysis Set Safety Population
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Region									
Week 12									
US/Canada/Australia	174	69 (39.7%) (32.3%, 47.3%)	191	66 (34.6%) (27.8%, 41.8%)	1.24 (0.81, 1.90)	1.15 (0.88, 1.50)	5.1% (-4.8%, 15.0%)	0.3301	0.7702
Europe	150	46 (30.7%) (23.4%, 38.7%)	132	35 (26.5%) (19.2%, 34.9%)	1.23 (0.73, 2.06)	1.16 (0.80, 1.68)	4.2% (-6.4%, 14.7%)	0.5099	
Asia	16	3 (18.8%) (4.0%, 45.6%)	19	4 (21.1%) (6.1%, 45.6%)	0.87 (0.16, 4.60)	0.89 (0.23, 3.41)	-2.3% (-28.8%, 24.2%)	1.0000	
Latin America	18	8 (44.4%) (21.5%, 69.2%)	19	5 (26.3%) (9.1%, 51.2%)	2.24 (0.56, 8.91)	1.69 (0.68, 4.21)	18.1% (-12.2%, 48.4%)	0.3133	
Age Subgroup									
Week 12									
<40 years	227	67 (29.5%) (23.7%, 35.9%)	243	67 (27.6%) (22.1%, 33.6%)	1.10 (0.74, 1.64)	1.07 (0.80, 1.43)	1.9% (-6.2%, 10.1%)	0.6830	0.3267
>=40 years	131	59 (45.0%) (36.3%, 54.0%)	118	43 (36.4%) (27.8%, 45.8%)	1.43 (0.86, 2.38)	1.24 (0.91, 1.68)	8.6% (-3.6%, 20.8%)	0.1972	

Notes:
Number of subjects: Full Analysis Set Safety Population
Number of subjects: Full Analysis Set Safety Population, excluding subjects with baseline DLQI 0-1.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: PP-NRS total score 4-point improvement at week 12 - Full Analysis Set Safety Population
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Week 12									
Full Analysis Set Safety Population	357	235 (65.8%) (60.7%, 70.7%)	364	224 (61.5%) (56.3%, 66.6%)	1.20 (0.89, 1.63)	1.07 (0.96, 1.19)	4.3% (-2.7%, 11.3%)	0.2346+	--
Baseline Disease Severity									
Week 12									
Moderate baseline disease (IGA=3)	213	132 (62.0%) (55.1%, 68.5%)	219	131 (59.8%) (53.0%, 66.4%)	1.09 (0.74, 1.61)	1.04 (0.89, 1.21)	2.2% (-7.0%, 11.4%)	0.6935	0.4025
Severe baseline disease (IGA=4)	144	103 (71.5%) (63.4%, 78.7%)	145	93 (64.1%) (55.8%, 71.9%)	1.40 (0.86, 2.31)	1.12 (0.95, 1.31)	7.4% (-3.3%, 18.1%)	0.2082	
Gender									
Week 12									
Male	191	124 (64.9%) (57.7%, 71.7%)	204	120 (58.8%) (51.7%, 65.6%)	1.30 (0.86, 1.95)	1.10 (0.95, 1.29)	6.1% (-3.5%, 15.7%)	0.2161	0.5999
Female	166	111 (66.9%) (59.2%, 74.0%)	160	104 (65.0%) (57.1%, 72.4%)	1.09 (0.69, 1.72)	1.03 (0.88, 1.20)	1.9% (-8.4%, 12.2%)	0.7275	

Notes:
Number of subjects: Full Analysis Set Safety Population
Number of subjects: Full Analysis Set Safety Population, excluding subjects with baseline PP-NRS score <4.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: PP-NRS total score 4-point improvement at week 12 - Full Analysis Set Safety Population
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Region									
Week 12									
US/Canada/Australia	174	116 (66.7%) (59.1%, 73.6%)	195	118 (60.5%) (53.3%, 67.4%)	1.31 (0.85, 2.00)	1.10 (0.94, 1.29)	6.2% (-3.7%, 16.0%)	0.2350	0.1069
Europe	148	96 (64.9%) (56.6%, 72.5%)	131	81 (61.8%) (52.9%, 70.2%)	1.14 (0.70, 1.86)	1.05 (0.88, 1.26)	3.0% (-8.3%, 14.4%)	0.6201	
Asia	17	8 (47.1%) (23.0%, 72.2%)	19	14 (73.7%) (48.8%, 90.9%)	0.32 (0.08, 1.28)	0.64 (0.36, 1.13)	-26.6% (-57.5%, 4.3%)	0.1711	
Latin America	18	15 (83.3%) (58.6%, 96.4%)	19	11 (57.9%) (33.5%, 79.7%)	3.64 (0.78, 16.93)	1.44 (0.93, 2.23)	25.4% (-2.7%, 53.5%)	0.1510	
Age Subgroup									
Week 12									
<40 years	227	135 (59.5%) (52.8%, 65.9%)	246	148 (60.2%) (53.7%, 66.3%)	0.97 (0.67, 1.40)	0.99 (0.85, 1.15)	-0.7% (-9.5%, 8.2%)	0.9253	0.0495*
>=40 years	130	100 (76.9%) (68.7%, 83.9%)	118	76 (64.4%) (55.1%, 73.0%)	1.84 (1.06, 3.21)	1.19 (1.01, 1.41)	12.5% (1.2%, 23.8%)	0.0358*	

Notes:
Number of subjects: Full Analysis Set Safety Population
Number of subjects: Full Analysis Set Safety Population, excluding subjects with baseline PP-NRS score <4.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Achieving 0-1 in PP-NRS total score at week 12 - Full Analysis Set Safety Population
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Week 12									
Full Analysis Set Safety Population	362	135 (37.3%) (32.3%, 42.5%)	365	91 (24.9%) (20.6%, 29.7%)	1.79 (1.30, 2.46)	1.50 (1.20, 1.87)	12.4% (5.7%, 19.0%)	0.0003+*	--
Baseline Disease Severity									
Week 12									
Moderate baseline disease (IGA=3)	216	80 (37.0%) (30.6%, 43.9%)	220	59 (26.8%) (21.1%, 33.2%)	1.61 (1.07, 2.41)	1.38 (1.04, 1.83)	10.2% (1.5%, 18.9%)	0.0240*	0.4747
Severe baseline disease (IGA=4)	146	55 (37.7%) (29.8%, 46.1%)	145	32 (22.1%) (15.6%, 29.7%)	2.13 (1.27, 3.58)	1.71 (1.18, 2.47)	15.6% (5.2%, 26.0%)	0.0047*	
Gender									
Week 12									
Male	193	71 (36.8%) (30.0%, 44.0%)	204	46 (22.5%) (17.0%, 28.9%)	2.00 (1.29, 3.10)	1.63 (1.19, 2.23)	14.2% (5.3%, 23.1%)	0.0021*	0.5906
Female	169	64 (37.9%) (30.5%, 45.6%)	161	45 (28.0%) (21.2%, 35.6%)	1.57 (0.99, 2.50)	1.35 (0.99, 1.86)	9.9% (-0.2%, 20.0%)	0.0615	

Notes:
Number of subjects: Full Analysis Set Safety Population
Analysis on overall population is calculated based on stratified CMH (Cochran-Mantel-Haenszel) models, for OR, RR, and RD, stratified by by disease activity (moderate, severe) at enrollment.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Achieving 0-1 in PP-NRS total score at week 12 - Full Analysis Set Safety Population
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Region									
Week 12									
US/Canada/Australia	177	69 (39.0%) (31.8%, 46.6%)	195	50 (25.6%) (19.7%, 32.4%)	1.85 (1.19, 2.88)	1.52 (1.12, 2.06)	13.3% (3.9%, 22.8%)	0.0075*	0.8815
Europe	150	53 (35.3%) (27.7%, 43.5%)	132	34 (25.8%) (18.5%, 34.1%)	1.57 (0.94, 2.63)	1.37 (0.96, 1.97)	9.6% (-1.1%, 20.3%)	0.0936	
Asia	17	7 (41.2%) (18.4%, 67.1%)	19	4 (21.1%) (6.1%, 45.6%)	2.63 (0.61, 11.37)	1.96 (0.69, 5.53)	20.1% (-9.6%, 49.8%)	0.2814	
Latin America	18	6 (33.3%) (13.3%, 59.0%)	19	3 (15.8%) (3.4%, 39.6%)	2.67 (0.55, 12.88)	2.11 (0.62, 7.20)	17.5% (-9.7%, 44.8%)	0.2691	
Age Subgroup									
Week 12									
<40 years	230	73 (31.7%) (25.8%, 38.2%)	247	59 (23.9%) (18.7%, 29.7%)	1.48 (0.99, 2.22)	1.33 (0.99, 1.78)	7.9% (-0.2%, 15.9%)	0.0652	0.0658
>=40 years	132	62 (47.0%) (38.2%, 55.8%)	118	32 (27.1%) (19.3%, 36.1%)	2.38 (1.40, 4.05)	1.73 (1.22, 2.45)	19.9% (8.2%, 31.5%)	0.0016*	

Notes:
Number of subjects: Full Analysis Set Safety Population
Analysis on overall population is calculated based on stratified CMH (Cochran-Mantel-Haenszel) models, for OR, RR, and RD, stratified by by disease activity (moderate, severe) at enrollment.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: EQ-5D VAS 15-point improvement at week 12 - Full Analysis Set Safety Population
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Week 12									
Full Analysis Set Safety Population	302	120 (39.7%) (34.2%, 45.5%)	309	123 (39.8%) (34.3%, 45.5%)	0.99 (0.71, 1.38)	0.99 (0.82, 1.21)	-0.2% (-7.9%, 7.5%)	0.9591+	--
Baseline Disease Severity									
Week 12									
Moderate baseline disease (IGA=3)	177	57 (32.2%) (25.4%, 39.6%)	184	66 (35.9%) (28.9%, 43.3%)	0.85 (0.55, 1.31)	0.90 (0.67, 1.20)	-3.7% (-13.4%, 6.1%)	0.5056	0.3014
Severe baseline disease (IGA=4)	125	63 (50.4%) (41.3%, 59.5%)	125	57 (45.6%) (36.7%, 54.7%)	1.21 (0.74, 1.99)	1.11 (0.85, 1.43)	4.8% (-7.6%, 17.2%)	0.5268	
Gender									
Week 12									
Male	161	59 (36.6%) (29.2%, 44.6%)	172	59 (34.3%) (27.2%, 41.9%)	1.11 (0.71, 1.74)	1.07 (0.80, 1.43)	2.3% (-7.9%, 12.6%)	0.7310	0.4648
Female	141	61 (43.3%) (35.0%, 51.9%)	137	64 (46.7%) (38.1%, 55.4%)	0.87 (0.54, 1.40)	0.93 (0.71, 1.20)	-3.5% (-15.1%, 8.2%)	0.6298	

Notes:
Number of subjects: Full Analysis Set Safety Population
Number of subjects: Full Analysis Set Safety Population, excluding subjects with baseline EQ5D-VAS >85.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: EQ-5D VAS 15-point improvement at week 12 - Full Analysis Set Safety Population
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Region									
Week 12									
US/Canada/Australia	138	41 (29.7%) (22.2%, 38.1%)	155	53 (34.2%) (26.8%, 42.2%)	0.81 (0.50, 1.33)	0.87 (0.62, 1.22)	-4.5% (-15.2%, 6.2%)	0.4528	0.2849
Europe	131	65 (49.6%) (40.8%, 58.5%)	119	54 (45.4%) (36.2%, 54.8%)	1.19 (0.72, 1.95)	1.09 (0.84, 1.42)	4.2% (-8.1%, 16.6%)	0.5279	
Asia	16	3 (18.8%) (4.0%, 45.6%)	19	8 (42.1%) (20.3%, 66.5%)	0.32 (0.07, 1.50)	0.45 (0.14, 1.40)	-23.4% (-52.7%, 5.9%)	0.1667	
Latin America	17	11 (64.7%) (38.3%, 85.8%)	16	8 (50.0%) (24.7%, 75.3%)	1.83 (0.45, 7.41)	1.29 (0.71, 2.36)	14.7% (-18.7%, 48.1%)	0.4905	
Age Subgroup									
Week 12									
<40 years	198	79 (39.9%) (33.0%, 47.1%)	209	88 (42.1%) (35.3%, 49.1%)	0.91 (0.61, 1.36)	0.95 (0.75, 1.20)	-2.2% (-11.8%, 7.4%)	0.6872	0.4273
>=40 years	104	41 (39.4%) (30.0%, 49.5%)	100	35 (35.0%) (25.7%, 45.2%)	1.21 (0.68, 2.13)	1.13 (0.79, 1.61)	4.4% (-8.8%, 17.7%)	0.5635	

Notes:
Number of subjects: Full Analysis Set Safety Population
Number of subjects: Full Analysis Set Safety Population, excluding subjects with baseline EQ5D-VAS >85.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events-Total mortality at 12 weeks (TEAE leading to death) - Safety Set
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Safety Set	362	2 (0.6%) (0.1%, 2.0%)	365	0 (0.0%) .	>99.99 (>99.99, >99.99)	>99.99 (>99.99, >99.99)	0.6% (-9.7%, 10.8%)	0.9162+	--
Baseline Disease Severity									
Moderate baseline disease (IGA=3)	216	1 (0.5%) (0.0%, 2.6%)	220	0 (0.0%) .	3.07 (0.12, 75.77)	3.06 (0.13, 74.59)	0.5% (-0.8%, 1.7%)	0.4954	0.8525
Severe baseline disease (IGA=4)	146	1 (0.7%) (0.0%, 3.8%)	145	0 (0.0%) .	3.00 (0.12, 74.25)	2.98 (0.12, 72.54)	0.7% (-1.2%, 2.6%)	1.0000	
Gender									
Male	193	1 (0.5%) (0.0%, 2.9%)	204	0 (0.0%) .	3.19 (0.13, 78.71)	3.17 (0.13, 77.35)	0.5% (-0.9%, 1.9%)	0.4861	0.9677
Female	169	1 (0.6%) (0.0%, 3.3%)	161	0 (0.0%) .	2.88 (0.12, 71.10)	2.86 (0.12, 69.67)	0.6% (-1.1%, 2.2%)	1.0000	
Region									
US/Canada/Australia	177	1 (0.6%) (0.0%, 3.1%)	195	0 (0.0%) .	3.32 (0.13, 82.10)	3.30 (0.14, 80.57)	0.6% (-0.9%, 2.1%)	0.4758	0.9997
Europe	150	1 (0.7%) (0.0%, 3.7%)	132	0 (0.0%) .	2.66 (0.11, 65.83)	2.64 (0.11, 64.31)	0.6% (-1.3%, 2.5%)	1.0000	
Asia	17	0 (0.0%)	19	0 (0.0%) .	1.11 (0.02, 59.20)	1.11 (0.02, 53.16)	0.3% (-9.9%, 10.5%)	NE	
Latin America	18	0 (0.0%)	19	0 (0.0%) .	1.05 (0.02, 55.92)	1.05 (0.02, 50.43)	0.1% (-9.8%, 10.1%)	NE	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events-Total mortality at 12 weeks (TEAE leading to death) - Safety Set
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Age Subgroup									
<40 years	230	0 (0.0%)	247	0 (0.0%)	1.07	1.07	0.0%	NE	0.2880
				.	(0.02, 54.34)	(0.02, 53.88)	(-0.8%, 0.8%)		
>=40 years	132	2 (1.5%)	118	0 (0.0%)	4.54	4.47	1.5%	0.4996	
		(0.2%, 5.4%)		.	(0.22, 95.54)	(0.22, 92.25)	(-1.1%, 4.0%)		

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events-Any Treatment Emergent Adverse Events at 12 weeks - Safety Set
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Safety Set	362	228 (63.0%) (57.8%, 68.0%)	365	182 (49.9%) (44.6%, 55.1%)	1.71 (1.27, 2.30)	1.26 (1.11, 1.44)	13.1% (6.0%, 20.3%)	0.000	--
Baseline Disease Severity									
Moderate baseline disease (IGA=3)	216	144 (66.7%) (60.0%, 72.9%)	220	110 (50.0%) (43.2%, 56.8%)	2.00 (1.36, 2.95)	1.33 (1.13, 1.57)	16.7% (7.5%, 25.8%)	0.0005*	0.1736
Severe baseline disease (IGA=4)	146	84 (57.5%) (49.1%, 65.7%)	145	72 (49.7%) (41.3%, 58.1%)	1.37 (0.87, 2.18)	1.16 (0.93, 1.44)	7.9% (-3.5%, 19.3%)	0.1968	
Gender									
Male	193	117 (60.6%) (53.3%, 67.6%)	204	94 (46.1%) (39.1%, 53.2%)	1.80 (1.21, 2.68)	1.32 (1.09, 1.59)	14.5% (4.8%, 24.3%)	0.0048*	0.8388
Female	169	111 (65.7%) (58.0%, 72.8%)	161	88 (54.7%) (46.6%, 62.5%)	1.59 (1.02, 2.47)	1.20 (1.01, 1.44)	11.0% (0.5%, 21.5%)	0.0435*	
Region									
US/Canada/Australia	177	118 (66.7%) (59.2%, 73.6%)	195	100 (51.3%) (44.0%, 58.5%)	1.90 (1.25, 2.89)	1.30 (1.09, 1.54)	15.4% (5.5%, 25.3%)	0.0031*	0.5431
Europe	150	92 (61.3%) (53.0%, 69.2%)	132	66 (50.0%) (41.2%, 58.8%)	1.59 (0.99, 2.55)	1.23 (0.99, 1.52)	11.3% (-0.2%, 22.9%)	0.0712	
Asia	17	8 (47.1%) (23.0%, 72.2%)	19	10 (52.6%) (28.9%, 75.6%)	0.80 (0.22, 2.97)	0.89 (0.46, 1.73)	-5.6% (-38.2%, 27.1%)	1.0000	
Latin America	18	10 (55.6%) (30.8%, 78.5%)	19	6 (31.6%) (12.6%, 56.6%)	2.71 (0.71, 10.36)	1.76 (0.81, 3.84)	24.0% (-7.1%, 55.0%)	0.1914	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events-Any Treatment Emergent Adverse Events at 12 weeks - Safety Set
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Age Subgroup									
<40 years	230	145 (63.0%) (56.5%, 69.3%)	247	120 (48.6%) (42.2%, 55.0%)	1.81 (1.25, 2.60)	1.30 (1.10, 1.53)	14.5% (5.6%, 23.3%)	0.0017*	0.6440
>=40 years	132	83 (62.9%) (54.0%, 71.1%)	118	62 (52.5%) (43.1%, 61.8%)	1.53 (0.92, 2.54)	1.20 (0.96, 1.49)	10.3% (-1.9%, 22.5%)	0.1234	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events-Severe Treatment Emergent Adverse Events at 12 weeks - Safety Set
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Safety Set	362	7 (1.9%) (0.8%, 3.9%)	365	5 (1.4%) (0.4%, 3.2%)	1.42 (0.45, 4.52)	1.41 (0.45, 4.41)	0.6% (-1.3%, 2.4%)	0.5510+	--
Baseline Disease Severity									
Moderate baseline disease (IGA=3)	216	3 (1.4%) (0.3%, 4.0%)	220	3 (1.4%) (0.3%, 3.9%)	1.02 (0.20, 5.10)	1.02 (0.21, 4.99)	0.0% (-2.2%, 2.2%)	1.0000	0.5017
Severe baseline disease (IGA=4)	146	4 (2.7%) (0.8%, 6.9%)	145	2 (1.4%) (0.2%, 4.9%)	2.01 (0.36, 11.17)	1.99 (0.37, 10.68)	1.4% (-1.9%, 4.6%)	0.6842	
Gender									
Male	193	4 (2.1%) (0.6%, 5.2%)	204	2 (1.0%) (0.1%, 3.5%)	2.14 (0.39, 11.81)	2.11 (0.39, 11.41)	1.1% (-1.3%, 3.5%)	0.4379	0.5386
Female	169	3 (1.8%) (0.4%, 5.1%)	161	3 (1.9%) (0.4%, 5.3%)	0.95 (0.19, 4.79)	0.95 (0.20, 4.65)	-0.1% (-3.0%, 2.8%)	1.0000	
Region									
US/Canada/Australia	177	4 (2.3%) (0.6%, 5.7%)	195	3 (1.5%) (0.3%, 4.4%)	1.48 (0.33, 6.71)	1.47 (0.33, 6.47)	0.7% (-2.1%, 3.5%)	0.7128	0.9990
Europe	150	3 (2.0%) (0.4%, 5.7%)	132	2 (1.5%) (0.2%, 5.4%)	1.33 (0.22, 8.06)	1.32 (0.22, 7.78)	0.5% (-2.6%, 3.5%)	1.0000	
Asia	17	0 (0.0%)	19	0 (0.0%)	1.11 (0.02, 59.20)	1.11 (0.02, 53.16)	0.3% (-9.9%, 10.5%)	NE	
Latin America	18	0 (0.0%)	19	0 (0.0%)	1.05 (0.02, 55.92)	1.05 (0.02, 50.43)	0.1% (-9.8%, 10.1%)	NE	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events-Severe Treatment Emergent Adverse Events at 12 weeks - Safety Set
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Age Subgroup									
<40 years	230	4 (1.7%) (0.5%, 4.4%)	247	4 (1.6%) (0.4%, 4.1%)	1.08 (0.27, 4.35)	1.07 (0.27, 4.24)	0.1% (-2.2%, 2.4%)	1.0000	0.5005
>=40 years	132	3 (2.3%) (0.5%, 6.5%)	118	1 (0.8%) (0.0%, 4.6%)	2.72 (0.28, 26.52)	2.68 (0.28, 25.43)	1.4% (-1.6%, 4.5%)	0.6244	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events-Serious Treatment Emergent Adverse Events at 12 weeks - Safety Set
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Safety Set	362	5 (1.4%) (0.4%, 3.2%)	365	2 (0.5%) (0.1%, 2.0%)	2.54 (0.49, 13.19)	2.52 (0.49, 12.91)	0.8% (-0.6%, 2.3%)	0.2504+	--
Baseline Disease Severity									
Moderate baseline disease (IGA=3)	216	4 (1.9%) (0.5%, 4.7%)	220	2 (0.9%) (0.1%, 3.2%)	2.06 (0.37, 11.35)	2.04 (0.38, 11.01)	0.9% (-1.2%, 3.1%)	0.4462	0.8551
Severe baseline disease (IGA=4)	146	1 (0.7%) (0.0%, 3.8%)	145	0 (0.0%)	3.00 (0.12, 74.25)	2.98 (0.12, 72.54)	0.7% (-1.2%, 2.6%)	1.0000	
Gender									
Male	193	3 (1.6%) (0.3%, 4.5%)	204	1 (0.5%) (0.0%, 2.7%)	3.21 (0.33, 31.08)	3.17 (0.33, 30.22)	1.1% (-0.9%, 3.1%)	0.3597	0.7294
Female	169	2 (1.2%) (0.1%, 4.2%)	161	1 (0.6%) (0.0%, 3.4%)	1.92 (0.17, 21.34)	1.91 (0.17, 20.81)	0.6% (-1.5%, 2.6%)	1.0000	
Region									
US/Canada/Australia	177	2 (1.1%) (0.1%, 4.0%)	195	2 (1.0%) (0.1%, 3.7%)	1.10 (0.15, 7.91)	1.10 (0.16, 7.74)	0.1% (-2.0%, 2.2%)	1.0000	0.7499
Europe	150	3 (2.0%) (0.4%, 5.7%)	132	0 (0.0%)	6.29 (0.32, 122.87)	6.17 (0.32, 118.27)	1.9% (-0.7%, 4.6%)	0.2504	
Asia	17	0 (0.0%)	19	0 (0.0%)	1.11 (0.02, 59.20)	1.11 (0.02, 53.16)	0.3% (-9.9%, 10.5%)	NE	
Latin America	18	0 (0.0%)	19	0 (0.0%)	1.05 (0.02, 55.92)	1.05 (0.02, 50.43)	0.1% (-9.8%, 10.1%)	NE	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events-Serious Treatment Emergent Adverse Events at 12 weeks - Safety Set
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Age Subgroup									
<40 years	230	2 (0.9%) (0.1%, 3.1%)	247	1 (0.4%) (0.0%, 2.2%)	2.16 (0.19, 23.96)	2.15 (0.20, 23.53)	0.5% (-1.0%, 1.9%)	0.6113	0.5703
>=40 years	132	3 (2.3%) (0.5%, 6.5%)	118	1 (0.8%) (0.0%, 4.6%)	2.72 (0.28, 26.52)	2.68 (0.28, 25.43)	1.4% (-1.6%, 4.5%)	0.6244	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events-Treatment Emergent Adverse Events leading to therapy discontinuation - Safety Set
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Safety Set	362	10 (2.8%) (1.3%, 5.0%)	365	4 (1.1%) (0.3%, 2.8%)	2.56 (0.80, 8.25)	2.52 (0.80, 7.96)	1.7% (-0.3%, 3.7%)	0.1021+	--
Baseline Disease Severity									
Moderate baseline disease (IGA=3)	216	8 (3.7%) (1.6%, 7.2%)	220	3 (1.4%) (0.3%, 3.9%)	2.78 (0.73, 10.63)	2.72 (0.73, 10.10)	2.3% (-0.6%, 5.3%)	0.1378	0.3852
Severe baseline disease (IGA=4)	146	2 (1.4%) (0.2%, 4.9%)	145	1 (0.7%) (0.0%, 3.8%)	2.00 (0.18, 22.30)	1.99 (0.18, 21.67)	0.7% (-1.6%, 3.0%)	1.0000	
Gender									
Male	193	2 (1.0%) (0.1%, 3.7%)	204	1 (0.5%) (0.0%, 2.7%)	2.13 (0.19, 23.63)	2.11 (0.19, 23.13)	0.5% (-1.2%, 2.3%)	0.6139	0.2710
Female	169	8 (4.7%) (2.1%, 9.1%)	161	3 (1.9%) (0.4%, 5.3%)	2.62 (0.68, 10.04)	2.54 (0.69, 9.41)	2.9% (-1.0%, 6.7%)	0.2202	
Region									
US/Canada/Australia	177	6 (3.4%) (1.3%, 7.2%)	195	2 (1.0%) (0.1%, 3.7%)	3.39 (0.67, 17.00)	3.31 (0.68, 16.16)	2.4% (-0.7%, 5.4%)	0.1579	0.9284
Europe	150	4 (2.7%) (0.7%, 6.7%)	132	2 (1.5%) (0.2%, 5.4%)	1.78 (0.32, 9.88)	1.76 (0.33, 9.45)	1.2% (-2.2%, 4.5%)	0.6880	
Asia	17	0 (0.0%)	19	0 (0.0%)	1.11 (0.02, 59.20)	1.11 (0.02, 53.16)	0.3% (-9.9%, 10.5%)	NE	
Latin America	18	0 (0.0%)	19	0 (0.0%)	1.05 (0.02, 55.92)	1.05 (0.02, 50.43)	0.1% (-9.8%, 10.1%)	NE	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events-Treatment Emergent Adverse Events leading to therapy discontinuation - Safety Set
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Age Subgroup									
<40 years	230	5 (2.2%) (0.7%, 5.0%)	247	3 (1.2%) (0.3%, 3.5%)	1.81 (0.43, 7.65)	1.79 (0.43, 7.41)	1.0% (-1.4%, 3.3%)	0.4907	0.3617
>=40 years	132	5 (3.8%) (1.2%, 8.6%)	118	1 (0.8%) (0.0%, 4.6%)	4.61 (0.53, 40.01)	4.47 (0.53, 37.71)	2.9% (-0.7%, 6.6%)	0.2175	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events-Any Treatment Emergent Adverse Events at 12 weeks excluding progression events - Safety Set
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Safety Set	362	228 (63.0%) (57.8%, 68.0%)	365	181 (49.6%) (44.3%, 54.8%)	1.73 (1.29, 2.33)	1.27 (1.12, 1.45)	13.4% (6.2%, 20.5%)	0.000	--
Baseline Disease Severity									
Moderate baseline disease (IGA=3)	216	144 (66.7%) (60.0%, 72.9%)	220	110 (50.0%) (43.2%, 56.8%)	2.00 (1.36, 2.95)	1.33 (1.13, 1.57)	16.7% (7.5%, 25.8%)	0.0005*	0.1984
Severe baseline disease (IGA=4)	146	84 (57.5%) (49.1%, 65.7%)	145	71 (49.0%) (40.6%, 57.4%)	1.41 (0.89, 2.24)	1.17 (0.95, 1.46)	8.6% (-2.9%, 20.0%)	0.1593	
Gender									
Male	193	117 (60.6%) (53.3%, 67.6%)	204	93 (45.6%) (38.6%, 52.7%)	1.84 (1.23, 2.74)	1.33 (1.10, 1.61)	15.0% (5.3%, 24.7%)	0.0035*	0.7986
Female	169	111 (65.7%) (58.0%, 72.8%)	161	88 (54.7%) (46.6%, 62.5%)	1.59 (1.02, 2.47)	1.20 (1.01, 1.44)	11.0% (0.5%, 21.5%)	0.0435*	
Region									
US/Canada/Australia	177	118 (66.7%) (59.2%, 73.6%)	195	100 (51.3%) (44.0%, 58.5%)	1.90 (1.25, 2.89)	1.30 (1.09, 1.54)	15.4% (5.5%, 25.3%)	0.0031*	0.6674
Europe	150	92 (61.3%) (53.0%, 69.2%)	132	66 (50.0%) (41.2%, 58.8%)	1.59 (0.99, 2.55)	1.23 (0.99, 1.52)	11.3% (-0.2%, 22.9%)	0.0712	
Asia	17	8 (47.1%) (23.0%, 72.2%)	19	9 (47.4%) (24.4%, 71.1%)	0.99 (0.27, 3.66)	0.99 (0.50, 1.98)	-0.3% (-33.0%, 32.4%)	1.0000	
Latin America	18	10 (55.6%) (30.8%, 78.5%)	19	6 (31.6%) (12.6%, 56.6%)	2.71 (0.71, 10.36)	1.76 (0.81, 3.84)	24.0% (-7.1%, 55.0%)	0.1914	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events-Any Treatment Emergent Adverse Events at 12 weeks excluding progression events - Safety Set
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Age Subgroup									
<40 years	230	145 (63.0%) (56.5%, 69.3%)	247	119 (48.2%) (41.8%, 54.6%)	1.83 (1.27, 2.65)	1.31 (1.11, 1.54)	14.9% (6.0%, 23.7%)	0.0013*	0.6133
>=40 years	132	83 (62.9%) (54.0%, 71.1%)	118	62 (52.5%) (43.1%, 61.8%)	1.53 (0.92, 2.54)	1.20 (0.96, 1.49)	10.3% (-1.9%, 22.5%)	0.1234	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events-Severe Treatment Emergent Adverse Events at 12 weeks excluding progression events - Safety Set
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Safety Set	362	7 (1.9%) (0.8%, 3.9%)	365	5 (1.4%) (0.4%, 3.2%)	1.42 (0.45, 4.52)	1.41 (0.45, 4.41)	0.6% (-1.3%, 2.4%)	0.5510+	--
Baseline Disease Severity									
Moderate baseline disease (IGA=3)	216	3 (1.4%) (0.3%, 4.0%)	220	3 (1.4%) (0.3%, 3.9%)	1.02 (0.20, 5.10)	1.02 (0.21, 4.99)	0.0% (-2.2%, 2.2%)	1.0000	0.5017
Severe baseline disease (IGA=4)	146	4 (2.7%) (0.8%, 6.9%)	145	2 (1.4%) (0.2%, 4.9%)	2.01 (0.36, 11.17)	1.99 (0.37, 10.68)	1.4% (-1.9%, 4.6%)	0.6842	
Gender									
Male	193	4 (2.1%) (0.6%, 5.2%)	204	2 (1.0%) (0.1%, 3.5%)	2.14 (0.39, 11.81)	2.11 (0.39, 11.41)	1.1% (-1.3%, 3.5%)	0.4379	0.5386
Female	169	3 (1.8%) (0.4%, 5.1%)	161	3 (1.9%) (0.4%, 5.3%)	0.95 (0.19, 4.79)	0.95 (0.20, 4.65)	-0.1% (-3.0%, 2.8%)	1.0000	
Region									
US/Canada/Australia	177	4 (2.3%) (0.6%, 5.7%)	195	3 (1.5%) (0.3%, 4.4%)	1.48 (0.33, 6.71)	1.47 (0.33, 6.47)	0.7% (-2.1%, 3.5%)	0.7128	0.9990
Europe	150	3 (2.0%) (0.4%, 5.7%)	132	2 (1.5%) (0.2%, 5.4%)	1.33 (0.22, 8.06)	1.32 (0.22, 7.78)	0.5% (-2.6%, 3.5%)	1.0000	
Asia	17	0 (0.0%)	19	0 (0.0%)	1.11 (0.02, 59.20)	1.11 (0.02, 53.16)	0.3% (-9.9%, 10.5%)	NE	
Latin America	18	0 (0.0%)	19	0 (0.0%)	1.05 (0.02, 55.92)	1.05 (0.02, 50.43)	0.1% (-9.8%, 10.1%)	NE	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events-Severe Treatment Emergent Adverse Events at 12 weeks excluding progression events - Safety Set
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Age Subgroup									
<40 years	230	4 (1.7%) (0.5%, 4.4%)	247	4 (1.6%) (0.4%, 4.1%)	1.08 (0.27, 4.35)	1.07 (0.27, 4.24)	0.1% (-2.2%, 2.4%)	1.0000	0.5005
>=40 years	132	3 (2.3%) (0.5%, 6.5%)	118	1 (0.8%) (0.0%, 4.6%)	2.72 (0.28, 26.52)	2.68 (0.28, 25.43)	1.4% (-1.6%, 4.5%)	0.6244	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events-Serious Treatment Emergent Adverse Events at 12 weeks excluding progression events - Safety Set
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Safety Set	362	5 (1.4%) (0.4%, 3.2%)	365	2 (0.5%) (0.1%, 2.0%)	2.54 (0.49, 13.19)	2.52 (0.49, 12.91)	0.8% (-0.6%, 2.3%)	0.2504+	--
Baseline Disease Severity									
Moderate baseline disease (IGA=3)	216	4 (1.9%) (0.5%, 4.7%)	220	2 (0.9%) (0.1%, 3.2%)	2.06 (0.37, 11.35)	2.04 (0.38, 11.01)	0.9% (-1.2%, 3.1%)	0.4462	0.8551
Severe baseline disease (IGA=4)	146	1 (0.7%) (0.0%, 3.8%)	145	0 (0.0%)	3.00 (0.12, 74.25)	2.98 (0.12, 72.54)	0.7% (-1.2%, 2.6%)	1.0000	
Gender									
Male	193	3 (1.6%) (0.3%, 4.5%)	204	1 (0.5%) (0.0%, 2.7%)	3.21 (0.33, 31.08)	3.17 (0.33, 30.22)	1.1% (-0.9%, 3.1%)	0.3597	0.7294
Female	169	2 (1.2%) (0.1%, 4.2%)	161	1 (0.6%) (0.0%, 3.4%)	1.92 (0.17, 21.34)	1.91 (0.17, 20.81)	0.6% (-1.5%, 2.6%)	1.0000	
Region									
US/Canada/Australia	177	2 (1.1%) (0.1%, 4.0%)	195	2 (1.0%) (0.1%, 3.7%)	1.10 (0.15, 7.91)	1.10 (0.16, 7.74)	0.1% (-2.0%, 2.2%)	1.0000	0.7499
Europe	150	3 (2.0%) (0.4%, 5.7%)	132	0 (0.0%)	6.29 (0.32, 122.87)	6.17 (0.32, 118.27)	1.9% (-0.7%, 4.6%)	0.2504	
Asia	17	0 (0.0%)	19	0 (0.0%)	1.11 (0.02, 59.20)	1.11 (0.02, 53.16)	0.3% (-9.9%, 10.5%)	NE	
Latin America	18	0 (0.0%)	19	0 (0.0%)	1.05 (0.02, 55.92)	1.05 (0.02, 50.43)	0.1% (-9.8%, 10.1%)	NE	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events-Serious Treatment Emergent Adverse Events at 12 weeks excluding progression events - Safety Set
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Age Subgroup									
<40 years	230	2 (0.9%) (0.1%, 3.1%)	247	1 (0.4%) (0.0%, 2.2%)	2.16 (0.19, 23.96)	2.15 (0.20, 23.53)	0.5% (-1.0%, 1.9%)	0.6113	0.5703
>=40 years	132	3 (2.3%) (0.5%, 6.5%)	118	1 (0.8%) (0.0%, 4.6%)	2.72 (0.28, 26.52)	2.68 (0.28, 25.43)	1.4% (-1.6%, 4.5%)	0.6244	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events of Special Interest (AESI)-Superinfections at 12 weeks - Safety Set
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Safety Set	362	14 (3.9%) (2.1%, 6.4%)	365	10 (2.7%) (1.3%, 5.0%)	1.43 (0.63, 3.26)	1.41 (0.64, 3.14)	1.1% (-1.5%, 3.7%)	0.3949+	--
Baseline Disease Severity									
Moderate baseline disease (IGA=3)	216	6 (2.8%) (1.0%, 5.9%)	220	5 (2.3%) (0.7%, 5.2%)	1.23 (0.37, 4.09)	1.22 (0.38, 3.95)	0.5% (-2.4%, 3.5%)	0.7697	0.5869
Severe baseline disease (IGA=4)	146	8 (5.5%) (2.4%, 10.5%)	145	5 (3.4%) (1.1%, 7.9%)	1.62 (0.52, 5.08)	1.59 (0.53, 4.74)	2.0% (-2.7%, 6.8%)	0.5722	
Gender									
Male	193	8 (4.1%) (1.8%, 8.0%)	204	6 (2.9%) (1.1%, 6.3%)	1.43 (0.49, 4.19)	1.41 (0.50, 3.99)	1.2% (-2.4%, 4.8%)	0.5924	0.9565
Female	169	6 (3.6%) (1.3%, 7.6%)	161	4 (2.5%) (0.7%, 6.2%)	1.44 (0.40, 5.22)	1.43 (0.41, 4.97)	1.1% (-2.6%, 4.7%)	0.7508	
Region									
US/Canada/Australia	177	8 (4.5%) (2.0%, 8.7%)	195	4 (2.1%) (0.6%, 5.2%)	2.26 (0.67, 7.64)	2.20 (0.68, 7.19)	2.5% (-1.2%, 6.1%)	0.2422	0.5669
Europe	150	5 (3.3%) (1.1%, 7.6%)	132	6 (4.5%) (1.7%, 9.6%)	0.72 (0.22, 2.43)	0.73 (0.23, 2.35)	-1.2% (-5.8%, 3.4%)	0.7602	
Asia	17	1 (5.9%) (0.1%, 28.7%)	19	0 (0.0%)	3.55 (0.14, 93.01)	3.33 (0.14, 76.75)	5.8% (-8.7%, 20.3%)	0.4722	
Latin America	18	0 (0.0%)	19	0 (0.0%)	1.05 (0.02, 55.92)	1.05 (0.02, 50.43)	0.1% (-9.8%, 10.1%)	NE	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events of Special Interest (AESI)-Superinfections at 12 weeks - Safety Set
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Age Subgroup									
<40 years	230	6 (2.6%) (1.0%, 5.6%)	247	6 (2.4%) (0.9%, 5.2%)	1.08 (0.34, 3.38)	1.07 (0.35, 3.28)	0.2% (-2.6%, 3.0%)	1.0000	0.4081
>=40 years	132	8 (6.1%) (2.7%, 11.6%)	118	4 (3.4%) (0.9%, 8.5%)	1.84 (0.54, 6.27)	1.79 (0.55, 5.79)	2.7% (-2.5%, 7.9%)	0.3853	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events of Special Interest (AESI)-Herpes Zoster at 12 weeks - Safety Set
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Safety Set	362	2 (0.6%) (0.1%, 2.0%)	365	0 (0.0%) .	>99.99 (>99.99, >99.99)	>99.99 (>99.99, >99.99)	0.6% (-9.7%, 10.8%)	0.9162+	--
Baseline Disease Severity									
Moderate baseline disease (IGA=3)	216	1 (0.5%) (0.0%, 2.6%)	220	0 (0.0%) .	3.07 (0.12, 75.77)	3.06 (0.13, 74.59)	0.5% (-0.8%, 1.7%)	0.4954	0.8525
Severe baseline disease (IGA=4)	146	1 (0.7%) (0.0%, 3.8%)	145	0 (0.0%) .	3.00 (0.12, 74.25)	2.98 (0.12, 72.54)	0.7% (-1.2%, 2.6%)	1.0000	
Gender									
Male	193	1 (0.5%) (0.0%, 2.9%)	204	0 (0.0%) .	3.19 (0.13, 78.71)	3.17 (0.13, 77.35)	0.5% (-0.9%, 1.9%)	0.4861	0.9677
Female	169	1 (0.6%) (0.0%, 3.3%)	161	0 (0.0%) .	2.88 (0.12, 71.10)	2.86 (0.12, 69.67)	0.6% (-1.1%, 2.2%)	1.0000	
Region									
US/Canada/Australia	177	2 (1.1%) (0.1%, 4.0%)	195	0 (0.0%) .	5.57 (0.27, 116.81)	5.51 (0.27, 113.90)	1.1% (-0.7%, 3.0%)	0.2257	0.7853
Europe	150	0 (0.0%)	132	0 (0.0%) .	0.88 (0.02, 44.68)	0.88 (0.02, 44.08)	-0.0% (-1.4%, 1.3%)	NE	
Asia	17	0 (0.0%)	19	0 (0.0%) .	1.11 (0.02, 59.20)	1.11 (0.02, 53.16)	0.3% (-9.9%, 10.5%)	NE	
Latin America	18	0 (0.0%)	19	0 (0.0%) .	1.05 (0.02, 55.92)	1.05 (0.02, 50.43)	0.1% (-9.8%, 10.1%)	NE	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events of Special Interest (AESI)-Herpes Zoster at 12 weeks - Safety Set
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Age Subgroup									
<40 years	230	0 (0.0%)	247	0 (0.0%)	1.07	1.07	0.0%	NE	0.2880
				.	(0.02, 54.34)	(0.02, 53.88)	(-0.8%, 0.8%)		
>=40 years	132	2 (1.5%)	118	0 (0.0%)	4.54	4.47	1.5%	0.4996	
		(0.2%, 5.4%)		.	(0.22, 95.54)	(0.22, 92.25)	(-1.1%, 4.0%)		

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events of Special Interest (AESI)-Conjunctivitis at 12 weeks - Safety Set
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Safety Set	362	9 (2.5%) (1.1%, 4.7%)	365	28 (7.7%) (5.2%, 10.9%)	0.31 (0.14, 0.66)	0.32 (0.16, 0.68)	-5.2% (-8.4%, -2.0%)	0.001	--
Baseline Disease Severity									
Moderate baseline disease (IGA=3)	216	3 (1.4%) (0.3%, 4.0%)	220	17 (7.7%) (4.6%, 12.1%)	0.17 (0.05, 0.58)	0.18 (0.05, 0.60)	-6.3% (-10.2%, -2.5%)	0.0021*	0.4179
Severe baseline disease (IGA=4)	146	6 (4.1%) (1.5%, 8.7%)	145	11 (7.6%) (3.8%, 13.2%)	0.52 (0.19, 1.45)	0.54 (0.21, 1.43)	-3.5% (-8.9%, 1.9%)	0.2230	
Gender									
Male	193	8 (4.1%) (1.8%, 8.0%)	204	14 (6.9%) (3.8%, 11.2%)	0.59 (0.24, 1.43)	0.60 (0.26, 1.41)	-2.7% (-7.2%, 1.7%)	0.2768	0.0986
Female	169	1 (0.6%) (0.0%, 3.3%)	161	14 (8.7%) (4.8%, 14.2%)	0.06 (0.01, 0.48)	0.07 (0.01, 0.51)	-8.1% (-12.6%, -3.6%)	0.0003*	
Region									
US/Canada/Australia	177	4 (2.3%) (0.6%, 5.7%)	195	15 (7.7%) (4.4%, 12.4%)	0.28 (0.09, 0.85)	0.29 (0.10, 0.87)	-5.4% (-9.8%, -1.1%)	0.0188*	0.4118
Europe	150	3 (2.0%) (0.4%, 5.7%)	132	12 (9.1%) (4.8%, 15.3%)	0.20 (0.06, 0.74)	0.22 (0.06, 0.76)	-7.1% (-12.5%, -1.7%)	0.0140*	
Asia	17	2 (11.8%) (1.5%, 36.4%)	19	1 (5.3%) (0.1%, 26.0%)	2.40 (0.20, 29.13)	2.24 (0.22, 22.51)	6.5% (-11.8%, 24.8%)	0.5929	
Latin America	18	0 (0.0%)	19	0 (0.0%)	1.05 (0.02, 55.92)	1.05 (0.02, 50.43)	0.1% (-9.8%, 10.1%)	NE	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events of Special Interest (AESI)-Conjunctivitis at 12 weeks - Safety Set
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Age Subgroup									
<40 years	230	4 (1.7%) (0.5%, 4.4%)	247	18 (7.3%) (4.4%, 11.3%)	0.23 (0.08, 0.68)	0.24 (0.08, 0.69)	-5.5% (-9.2%, -1.9%)	0.0040*	0.8323
>=40 years	132	5 (3.8%) (1.2%, 8.6%)	118	10 (8.5%) (4.1%, 15.0%)	0.43 (0.14, 1.28)	0.45 (0.16, 1.27)	-4.7% (-10.7%, 1.3%)	0.1811	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events of Special Interest (AESI)-Acne (PT) at 12 weeks - Safety Set
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Safety Set	362	36 (9.9%) (7.1%, 13.5%)	365	6 (1.6%) (0.6%, 3.5%)	6.61 (2.75, 15.88)	6.05 (2.58, 14.18)	8.3% (5.0%, 11.6%)	<0.0001+*	--
Baseline Disease Severity									
Moderate baseline disease (IGA=3)	216	23 (10.6%) (6.9%, 15.5%)	220	2 (0.9%) (0.1%, 3.2%)	12.99 (3.02, 55.81)	11.71 (2.80, 49.08)	9.7% (5.4%, 14.0%)	<0.0001*	0.3234
Severe baseline disease (IGA=4)	146	13 (8.9%) (4.8%, 14.7%)	145	4 (2.8%) (0.8%, 6.9%)	3.45 (1.10, 10.83)	3.23 (1.08, 9.67)	6.1% (0.8%, 11.5%)	0.0427*	
Gender									
Male	193	19 (9.8%) (6.0%, 14.9%)	204	3 (1.5%) (0.3%, 4.2%)	7.32 (2.13, 25.14)	6.69 (2.01, 22.26)	8.4% (3.9%, 12.9%)	0.0003*	0.9659
Female	169	17 (10.1%) (6.0%, 15.6%)	161	3 (1.9%) (0.4%, 5.3%)	5.89 (1.69, 20.51)	5.40 (1.61, 18.07)	8.2% (3.2%, 13.2%)	0.0020*	
Region									
US/Canada/Australia	177	22 (12.4%) (8.0%, 18.2%)	195	4 (2.1%) (0.6%, 5.2%)	6.78 (2.29, 20.08)	6.06 (2.13, 17.24)	10.4% (5.1%, 15.6%)	<0.0001*	0.3836
Europe	150	11 (7.3%) (3.7%, 12.7%)	132	1 (0.8%) (0.0%, 4.1%)	10.37 (1.32, 81.42)	9.68 (1.27, 73.98)	6.6% (2.1%, 11.0%)	0.0065*	
Asia	17	3 (17.6%) (3.8%, 43.4%)	19	1 (5.3%) (0.1%, 26.0%)	3.86 (0.36, 41.20)	3.35 (0.38, 29.26)	12.4% (-8.3%, 33.1%)	0.3255	
Latin America	18	0 (0.0%)	19	0 (0.0%)	1.05 (0.02, 55.92)	1.05 (0.02, 50.43)	0.1% (-9.8%, 10.1%)	NE	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events of Special Interest (AESI)-Acne (PT) at 12 weeks - Safety Set
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Age Subgroup									
<40 years	230	25 (10.9%) (7.2%, 15.6%)	247	6 (2.4%) (0.9%, 5.2%)	4.90 (1.97, 12.17)	4.47 (1.87, 10.71)	8.4% (4.0%, 12.9%)	0.0003*	0.9090
>=40 years	132	11 (8.3%) (4.2%, 14.4%)	118	0 (0.0%)	22.43 (1.31, 384.98)	20.58 (1.23, 345.46)	8.2% (3.3%, 13.1%)	0.0009*	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events of Special Interest (AESI)-Folliculitis (PT) at 12 weeks - Safety Set
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Safety Set	362	7 (1.9%) (0.8%, 3.9%)	365	3 (0.8%) (0.2%, 2.4%)	2.38 (0.61, 9.27)	2.35 (0.61, 9.03)	1.1% (-0.6%, 2.8%)	0.1984+	--
Baseline Disease Severity									
Moderate baseline disease (IGA=3)	216	4 (1.9%) (0.5%, 4.7%)	220	1 (0.5%) (0.0%, 2.5%)	4.13 (0.46, 37.27)	4.07 (0.46, 36.16)	1.4% (-0.6%, 3.4%)	0.2124	0.6984
Severe baseline disease (IGA=4)	146	3 (2.1%) (0.4%, 5.9%)	145	2 (1.4%) (0.2%, 4.9%)	1.50 (0.25, 9.11)	1.49 (0.25, 8.78)	0.7% (-2.3%, 3.7%)	1.0000	
Gender									
Male	193	7 (3.6%) (1.5%, 7.3%)	204	2 (1.0%) (0.1%, 3.5%)	3.80 (0.78, 18.53)	3.70 (0.78, 17.59)	2.6% (-0.3%, 5.6%)	0.0972	0.0511
Female	169	0 (0.0%)	161	1 (0.6%) (0.0%, 3.4%)	0.32 (0.01, 7.80)	0.32 (0.01, 7.74)	-0.6% (-2.3%, 1.1%)	0.4879	
Region									
US/Canada/Australia	177	4 (2.3%) (0.6%, 5.7%)	195	3 (1.5%) (0.3%, 4.4%)	1.48 (0.33, 6.71)	1.47 (0.33, 6.47)	0.7% (-2.1%, 3.5%)	0.7128	0.9020
Europe	150	2 (1.3%) (0.2%, 4.7%)	132	0 (0.0%)	4.46 (0.21, 93.77)	4.40 (0.21, 90.91)	1.3% (-1.0%, 3.6%)	0.5003	
Asia	17	1 (5.9%) (0.1%, 28.7%)	19	0 (0.0%)	3.55 (0.14, 93.01)	3.33 (0.14, 76.75)	5.8% (-8.7%, 20.3%)	0.4722	
Latin America	18	0 (0.0%)	19	0 (0.0%)	1.05 (0.02, 55.92)	1.05 (0.02, 50.43)	0.1% (-9.8%, 10.1%)	NE	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events of Special Interest (AESI)-Folliculitis (PT) at 12 weeks - Safety Set
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Age Subgroup									
<40 years	230	2 (0.9%) (0.1%, 3.1%)	247	2 (0.8%) (0.1%, 2.9%)	1.07 (0.15, 7.69)	1.07 (0.15, 7.56)	0.1% (-1.6%, 1.7%)	1.0000	0.1512
>=40 years	132	5 (3.8%) (1.2%, 8.6%)	118	1 (0.8%) (0.0%, 4.6%)	4.61 (0.53, 40.01)	4.47 (0.53, 37.71)	2.9% (-0.7%, 6.6%)	0.2175	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events by SOC/PT-Any Treatment Emergent Adverse Events at 12 weeks - Infections and infestations [SOC] – Safety Set
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Safety Set	362	74 (20.4%) (16.4%, 25.0%)	365	71 (19.5%) (15.5%, 23.9%)	1.06 (0.74, 1.53)	1.05 (0.79, 1.41)	1.0% (-4.8%, 6.8%)	0.7384+	--
Baseline Disease Severity									
Moderate baseline disease (IGA=3)	216	49 (22.7%) (17.3%, 28.9%)	220	39 (17.7%) (12.9%, 23.4%)	1.36 (0.85, 2.18)	1.28 (0.88, 1.86)	5.0% (-2.6%, 12.5%)	0.2328	0.1004
Severe baseline disease (IGA=4)	146	25 (17.1%) (11.4%, 24.2%)	145	32 (22.1%) (15.6%, 29.7%)	0.73 (0.41, 1.31)	0.78 (0.48, 1.24)	-4.9% (-14.1%, 4.2%)	0.3045	
Gender									
Male	193	43 (22.3%) (16.6%, 28.8%)	204	36 (17.6%) (12.7%, 23.6%)	1.34 (0.82, 2.19)	1.26 (0.85, 1.88)	4.6% (-3.2%, 12.5%)	0.2600	0.1778
Female	169	31 (18.3%) (12.8%, 25.0%)	161	35 (21.7%) (15.6%, 28.9%)	0.81 (0.47, 1.39)	0.84 (0.55, 1.30)	-3.4% (-12.0%, 5.2%)	0.4921	
Region									
US/Canada/Australia	177	36 (20.3%) (14.7%, 27.0%)	195	34 (17.4%) (12.4%, 23.5%)	1.21 (0.72, 2.03)	1.17 (0.76, 1.78)	2.9% (-5.1%, 10.9%)	0.5081	0.1630
Europe	150	32 (21.3%) (15.1%, 28.8%)	132	34 (25.8%) (18.5%, 34.1%)	0.78 (0.45, 1.36)	0.83 (0.54, 1.26)	-4.4% (-14.4%, 5.5%)	0.4006	
Asia	17	1 (5.9%) (0.1%, 28.7%)	19	2 (10.5%) (1.3%, 33.1%)	0.53 (0.04, 6.44)	0.56 (0.06, 5.63)	-4.6% (-22.4%, 13.1%)	1.0000	
Latin America	18	5 (27.8%) (9.7%, 53.5%)	19	1 (5.3%) (0.1%, 26.0%)	6.92 (0.72, 66.51)	5.28 (0.68, 40.91)	22.5% (-0.5%, 45.5%)	0.0897	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05

NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events by SOC/PT-Any Treatment Emergent Adverse Events at 12 weeks - Infections and infestations [SOC] – Safety Set
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Age Subgroup									
<40 years	230	43 (18.7%) (13.9%, 24.3%)	247	46 (18.6%) (14.0%, 24.0%)	1.00 (0.63, 1.59)	1.00 (0.69, 1.46)	0.1% (-6.9%, 7.1%)	1.0000	0.7226
>=40 years	132	31 (23.5%) (16.5%, 31.6%)	118	25 (21.2%) (14.2%, 29.7%)	1.14 (0.63, 2.08)	1.11 (0.70, 1.76)	2.3% (-8.0%, 12.6%)	0.7615	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events by SOC/PT-Any Treatment Emergent Adverse Events at 12 weeks - Gastrointestinal disorders [SOC] – Safety Set
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Safety Set	362	88 (24.3%) (20.0%, 29.1%)	365	23 (6.3%) (4.0%, 9.3%)	4.78 (2.94, 7.76)	3.86 (2.50, 5.96)	18.0% (12.9%, 23.1%)	<0.0001+*	--
Baseline Disease Severity									
Moderate baseline disease (IGA=3)	216	55 (25.5%) (19.8%, 31.8%)	220	18 (8.2%) (4.9%, 12.6%)	3.83 (2.17, 6.79)	3.11 (1.89, 5.12)	17.3% (10.4%, 24.1%)	<0.0001*	0.8460
Severe baseline disease (IGA=4)	146	33 (22.6%) (16.1%, 30.3%)	145	5 (3.4%) (1.1%, 7.9%)	8.18 (3.09, 21.63)	6.55 (2.63, 16.32)	19.2% (11.7%, 26.6%)	<0.0001*	
Gender									
Male	193	31 (16.1%) (11.2%, 22.0%)	204	7 (3.4%) (1.4%, 6.9%)	5.39 (2.31, 12.55)	4.68 (2.11, 10.38)	12.6% (6.9%, 18.4%)	<0.0001*	0.0150*
Female	169	57 (33.7%) (26.6%, 41.4%)	161	16 (9.9%) (5.8%, 15.6%)	4.61 (2.51, 8.46)	3.39 (2.04, 5.66)	23.8% (15.3%, 32.3%)	<0.0001*	
Region									
US/Canada/Australia	177	50 (28.2%) (21.7%, 35.5%)	195	10 (5.1%) (2.5%, 9.2%)	7.28 (3.56, 14.90)	5.51 (2.88, 10.53)	23.1% (15.8%, 30.4%)	<0.0001*	0.0142*
Europe	150	36 (24.0%) (17.4%, 31.6%)	132	10 (7.6%) (3.7%, 13.5%)	3.85 (1.83, 8.12)	3.17 (1.64, 6.13)	16.4% (8.2%, 24.6%)	0.0002*	
Asia	17	2 (11.8%) (1.5%, 36.4%)	19	3 (15.8%) (3.4%, 39.6%)	0.71 (0.10, 4.86)	0.75 (0.14, 3.94)	-4.0% (-26.5%, 18.4%)	1.0000	
Latin America	18	0 (0.0%)	19	0 (0.0%)	1.05 (0.02, 55.92)	1.05 (0.02, 50.43)	0.1% (-9.8%, 10.1%)	NE	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events by SOC/PT-Any Treatment Emergent Adverse Events at 12 weeks - Gastrointestinal disorders [SOC] – Safety Set
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Age Subgroup									
<40 years	230	62 (27.0%) (21.3%, 33.2%)	247	16 (6.5%) (3.7%, 10.3%)	5.33 (2.97, 9.56)	4.16 (2.48, 7.00)	20.5% (14.0%, 27.0%)	<0.0001*	0.1790
>=40 years	132	26 (19.7%) (13.3%, 27.5%)	118	7 (5.9%) (2.4%, 11.8%)	3.89 (1.62, 9.34)	3.32 (1.50, 7.37)	13.8% (5.8%, 21.8%)	0.0013*	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events by SOC/PT-Any Treatment Emergent Adverse Events at 12 weeks - Skin and subcutaneous tissue disorders[SOC] - Safety Set
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Safety Set	362	59 (16.3%) (12.6%, 20.5%)	365	36 (9.9%) (7.0%, 13.4%)	1.78 (1.14, 2.77)	1.65 (1.12, 2.44)	6.4% (1.6%, 11.3%)	0.009	--
Baseline Disease Severity									
Moderate baseline disease (IGA=3)	216	35 (16.2%) (11.6%, 21.8%)	220	20 (9.1%) (5.6%, 13.7%)	1.93 (1.08, 3.47)	1.78 (1.06, 2.99)	7.1% (0.9%, 13.3%)	0.0302*	0.7526
Severe baseline disease (IGA=4)	146	24 (16.4%) (10.8%, 23.5%)	145	16 (11.0%) (6.4%, 17.3%)	1.59 (0.80, 3.13)	1.49 (0.83, 2.69)	5.4% (-2.5%, 13.3%)	0.2332	
Gender									
Male	193	29 (15.0%) (10.3%, 20.9%)	204	17 (8.3%) (4.9%, 13.0%)	1.95 (1.03, 3.67)	1.80 (1.02, 3.17)	6.7% (0.4%, 13.0%)	0.0419*	0.9193
Female	169	30 (17.8%) (12.3%, 24.4%)	161	19 (11.8%) (7.3%, 17.8%)	1.61 (0.87, 3.00)	1.50 (0.88, 2.56)	6.0% (-1.7%, 13.6%)	0.1631	
Region									
US/Canada/Australia	177	32 (18.1%) (12.7%, 24.6%)	195	19 (9.7%) (6.0%, 14.8%)	2.04 (1.11, 3.76)	1.86 (1.09, 3.15)	8.3% (1.3%, 15.4%)	0.0234*	0.4334
Europe	150	24 (16.0%) (10.5%, 22.9%)	132	13 (9.8%) (5.3%, 16.3%)	1.74 (0.85, 3.58)	1.62 (0.86, 3.06)	6.2% (-1.6%, 13.9%)	0.1576	
Asia	17	3 (17.6%) (3.8%, 43.4%)	19	3 (15.8%) (3.4%, 39.6%)	1.14 (0.20, 6.60)	1.12 (0.26, 4.81)	1.9% (-22.6%, 26.3%)	1.0000	
Latin America	18	0 (0.0%)	19	1 (5.3%) (0.1%, 26.0%)	0.33 (0.01, 8.73)	0.35 (0.02, 8.09)	-4.9% (-18.5%, 8.7%)	1.0000	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05

NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

TABLE 2.16: Binary Outcome Analysis: Adverse Events by SOC/PT-Any Treatment Emergent Adverse Events at 12 weeks - Skin and subcutaneous tissue disorders SOC] - Safety Set
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Age Subgroup									
<40 years	230	39 (17.0%) (12.3%, 22.4%)	247	23 (9.3%) (6.0%, 13.6%)	1.99 (1.15, 3.45)	1.82 (1.12, 2.95)	7.6% (1.6%, 13.7%)	0.0143*	0.5064
>=40 years	132	20 (15.2%) (9.5%, 22.4%)	118	13 (11.0%) (6.0%, 18.1%)	1.44 (0.68, 3.05)	1.38 (0.72, 2.64)	4.1% (-4.2%, 12.5%)	0.3560	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events by SOC/PT-Any Treatment Emergent Adverse Events at 12 weeks - Investigations [SOC] - Safety Set
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Safety Set	362	52 (14.4%) (10.9%, 18.4%)	365	33 (9.0%) (6.3%, 12.5%)	1.69 (1.06, 2.68)	1.59 (1.05, 2.40)	5.3% (0.7%, 10.0%)	0.025	--
Baseline Disease Severity									
Moderate baseline disease (IGA=3)	216	35 (16.2%) (11.6%, 21.8%)	220	21 (9.5%) (6.0%, 14.2%)	1.83 (1.03, 3.26)	1.70 (1.02, 2.82)	6.7% (0.4%, 12.9%)	0.0449*	0.4691
Severe baseline disease (IGA=4)	146	17 (11.6%) (6.9%, 18.0%)	145	12 (8.3%) (4.3%, 14.0%)	1.46 (0.67, 3.18)	1.41 (0.70, 2.84)	3.4% (-3.5%, 10.2%)	0.4343	
Gender									
Male	193	25 (13.0%) (8.6%, 18.5%)	204	19 (9.3%) (5.7%, 14.2%)	1.45 (0.77, 2.73)	1.39 (0.79, 2.44)	3.6% (-2.6%, 9.8%)	0.2663	0.4406
Female	169	27 (16.0%) (10.8%, 22.4%)	161	14 (8.7%) (4.8%, 14.2%)	2.00 (1.01, 3.96)	1.84 (1.00, 3.38)	7.3% (0.2%, 14.3%)	0.0471*	
Region									
US/Canada/Australia	177	19 (10.7%) (6.6%, 16.3%)	195	18 (9.2%) (5.6%, 14.2%)	1.18 (0.60, 2.33)	1.16 (0.63, 2.14)	1.5% (-4.6%, 7.6%)	0.7292	0.3324
Europe	150	27 (18.0%) (12.2%, 25.1%)	132	14 (10.6%) (5.9%, 17.2%)	1.85 (0.93, 3.70)	1.70 (0.93, 3.10)	7.4% (-0.7%, 15.5%)	0.0914	
Asia	17	2 (11.8%) (1.5%, 36.4%)	19	0 (0.0%)	6.29 (0.28, 140.86)	5.56 (0.29, 108.16)	11.4% (-6.0%, 28.8%)	0.2159	
Latin America	18	4 (22.2%) (6.4%, 47.6%)	19	1 (5.3%) (0.1%, 26.0%)	5.14 (0.52, 51.29)	4.22 (0.52, 34.28)	17.0% (-4.7%, 38.6%)	0.1797	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events by SOC/PT-Any Treatment Emergent Adverse Events at 12 weeks - Investigations [SOC] - Safety Set
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Age Subgroup									
<40 years	230	30 (13.0%) (9.0%, 18.1%)	247	24 (9.7%) (6.3%, 14.1%)	1.39 (0.79, 2.46)	1.34 (0.81, 2.23)	3.3% (-2.4%, 9.0%)	0.3115	0.2524
>=40 years	132	22 (16.7%) (10.7%, 24.1%)	118	9 (7.6%) (3.5%, 14.0%)	2.42 (1.07, 5.50)	2.19 (1.05, 4.56)	9.0% (1.1%, 17.0%)	0.0349*	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events by SOC/PT-Any Treatment Emergent Adverse Events at 12 weeks - Nervous system disorders [SOC] – Safety Set
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Safety Set	362	60 (16.6%) (12.9%, 20.8%)	365	25 (6.8%) (4.5%, 9.9%)	2.70 (1.65, 4.42)	2.42 (1.55, 3.77)	9.7% (5.1%, 14.4%)	<0.0001+*	--
Baseline Disease Severity									
Moderate baseline disease (IGA=3)	216	36 (16.7%) (12.0%, 22.3%)	220	18 (8.2%) (4.9%, 12.6%)	2.24 (1.23, 4.09)	2.04 (1.19, 3.47)	8.5% (2.3%, 14.6%)	0.0086*	0.5451
Severe baseline disease (IGA=4)	146	24 (16.4%) (10.8%, 23.5%)	145	7 (4.8%) (2.0%, 9.7%)	3.88 (1.61, 9.32)	3.41 (1.51, 7.65)	11.6% (4.7%, 18.6%)	0.0019*	
Gender									
Male	193	30 (15.5%) (10.7%, 21.4%)	204	10 (4.9%) (2.4%, 8.8%)	3.57 (1.69, 7.52)	3.17 (1.59, 6.31)	10.6% (4.7%, 16.6%)	0.0004*	0.7065
Female	169	30 (17.8%) (12.3%, 24.4%)	161	15 (9.3%) (5.3%, 14.9%)	2.10 (1.08, 4.07)	1.91 (1.07, 3.41)	8.4% (1.1%, 15.7%)	0.0361*	
Region									
US/Canada/Australia	177	32 (18.1%) (12.7%, 24.6%)	195	12 (6.2%) (3.2%, 10.5%)	3.37 (1.67, 6.77)	2.94 (1.56, 5.52)	11.9% (5.3%, 18.5%)	0.0004*	0.6765
Europe	150	25 (16.7%) (11.1%, 23.6%)	132	11 (8.3%) (4.2%, 14.4%)	2.20 (1.04, 4.67)	2.00 (1.02, 3.91)	8.3% (0.7%, 15.9%)	0.0483*	
Asia	17	2 (11.8%) (1.5%, 36.4%)	19	2 (10.5%) (1.3%, 33.1%)	1.13 (0.14, 9.07)	1.12 (0.18, 7.09)	1.2% (-19.4%, 21.9%)	1.0000	
Latin America	18	1 (5.6%) (0.1%, 27.3%)	19	0 (0.0%)	3.34 (0.13, 87.52)	3.16 (0.14, 72.84)	5.4% (-8.5%, 19.3%)	0.4865	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05

NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events by SOC/PT-Any Treatment Emergent Adverse Events at 12 weeks - Nervous system disorders [SOC] – Safety Set
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Age Subgroup									
<40 years	230	38 (16.5%) (12.0%, 22.0%)	247	17 (6.9%) (4.1%, 10.8%)	2.68 (1.46, 4.89)	2.40 (1.39, 4.13)	9.6% (3.9%, 15.4%)	0.0014*	0.9605
>=40 years	132	22 (16.7%) (10.7%, 24.1%)	118	8 (6.8%) (3.0%, 12.9%)	2.75 (1.17, 6.44)	2.46 (1.14, 5.31)	9.9% (2.1%, 17.7%)	0.0191*	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events by SOC/PT-Any Treatment Emergent Adverse Events at 12 weeks - Nausea [PT] - Safety Set
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Safety Set	362	69 (19.1%) (15.1%, 23.5%)	365	7 (1.9%) (0.8%, 3.9%)	12.04 (5.45, 26.61)	9.94 (4.63, 21.33)	17.1% (12.9%, 21.4%)	<0.0001+*	--
Baseline Disease Severity									
Moderate baseline disease (IGA=3)	216	45 (20.8%) (15.6%, 26.9%)	220	6 (2.7%) (1.0%, 5.8%)	9.39 (3.91, 22.52)	7.64 (3.33, 17.53)	18.1% (12.3%, 23.9%)	<0.0001*	0.5278
Severe baseline disease (IGA=4)	146	24 (16.4%) (10.8%, 23.5%)	145	1 (0.7%) (0.0%, 3.8%)	28.33 (3.78, 212.45)	23.84 (3.27, 173.87)	15.7% (9.6%, 21.9%)	<0.0001*	
Gender									
Male	193	21 (10.9%) (6.9%, 16.2%)	204	2 (1.0%) (0.1%, 3.5%)	12.33 (2.85, 53.34)	11.10 (2.64, 46.70)	9.9% (5.3%, 14.5%)	<0.0001*	0.0003*
Female	169	48 (28.4%) (21.7%, 35.8%)	161	5 (3.1%) (1.0%, 7.1%)	12.38 (4.78, 32.04)	9.15 (3.74, 22.39)	25.3% (18.0%, 32.6%)	<0.0001*	
Region									
US/Canada/Australia	177	39 (22.0%) (16.2%, 28.9%)	195	3 (1.5%) (0.3%, 4.4%)	18.09 (5.48, 59.72)	14.32 (4.51, 45.53)	20.5% (14.1%, 26.8%)	<0.0001*	0.0543
Europe	150	29 (19.3%) (13.3%, 26.6%)	132	4 (3.0%) (0.8%, 7.6%)	7.67 (2.62, 22.46)	6.38 (2.30, 17.67)	16.3% (9.3%, 23.3%)	<0.0001*	
Asia	17	1 (5.9%) (0.1%, 28.7%)	19	0 (0.0%)	3.55 (0.14, 93.01)	3.33 (0.14, 76.75)	5.8% (-8.7%, 20.3%)	0.4722	
Latin America	18	0 (0.0%)	19	0 (0.0%)	1.05 (0.02, 55.92)	1.05 (0.02, 50.43)	0.1% (-9.8%, 10.1%)	NE	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events by SOC/PT-Any Treatment Emergent Adverse Events at 12 weeks - Nausea [PT] - Safety Set
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Age Subgroup									
<40 years	230	52 (22.6%) (17.4%, 28.6%)	247	4 (1.6%) (0.4%, 4.1%)	17.75 (6.30, 49.97)	13.96 (5.13, 37.99)	21.0% (15.4%, 26.6%)	<0.0001*	0.0166*
>=40 years	132	17 (12.9%) (7.7%, 19.8%)	118	3 (2.5%) (0.5%, 7.3%)	5.67 (1.62, 19.86)	5.07 (1.52, 16.85)	10.3% (4.0%, 16.7%)	0.0040*	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events by SOC/PT-Any Treatment Emergent Adverse Events at 12 weeks - Headache [PT] - Safety Set
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Safety Set	362	43 (11.9%) (8.7%, 15.7%)	365	18 (4.9%) (2.9%, 7.7%)	2.60 (1.47, 4.60)	2.41 (1.42, 4.09)	6.9% (2.9%, 11.0%)	0.000	--
Baseline Disease Severity									
Moderate baseline disease (IGA=3)	216	26 (12.0%) (8.0%, 17.1%)	220	13 (5.9%) (3.2%, 9.9%)	2.18 (1.09, 4.36)	2.04 (1.08, 3.86)	6.1% (0.8%, 11.5%)	0.0290*	0.6372
Severe baseline disease (IGA=4)	146	17 (11.6%) (6.9%, 18.0%)	145	5 (3.4%) (1.1%, 7.9%)	3.69 (1.32, 10.29)	3.38 (1.28, 8.91)	8.2% (2.2%, 14.2%)	0.0131*	
Gender									
Male	193	23 (11.9%) (7.7%, 17.3%)	204	7 (3.4%) (1.4%, 6.9%)	3.81 (1.59, 9.09)	3.47 (1.53, 7.91)	8.5% (3.3%, 13.7%)	0.0019*	0.4249
Female	169	20 (11.8%) (7.4%, 17.7%)	161	11 (6.8%) (3.5%, 11.9%)	1.83 (0.85, 3.95)	1.73 (0.86, 3.50)	5.0% (-1.2%, 11.2%)	0.1339	
Region									
US/Canada/Australia	177	21 (11.9%) (7.5%, 17.6%)	195	9 (4.6%) (2.1%, 8.6%)	2.78 (1.24, 6.25)	2.57 (1.21, 5.46)	7.2% (1.6%, 12.8%)	0.0127*	0.9516
Europe	150	19 (12.7%) (7.8%, 19.1%)	132	7 (5.3%) (2.2%, 10.6%)	2.59 (1.05, 6.37)	2.39 (1.04, 5.50)	7.4% (0.8%, 13.9%)	0.0391*	
Asia	17	2 (11.8%) (1.5%, 36.4%)	19	2 (10.5%) (1.3%, 33.1%)	1.13 (0.14, 9.07)	1.12 (0.18, 7.09)	1.2% (-19.4%, 21.9%)	1.0000	
Latin America	18	1 (5.6%) (0.1%, 27.3%)	19	0 (0.0%)	3.34 (0.13, 87.52)	3.16 (0.14, 72.84)	5.4% (-8.5%, 19.3%)	0.4865	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events by SOC/PT-Any Treatment Emergent Adverse Events at 12 weeks - Headache [PT] - Safety Set
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Age Subgroup									
<40 years	230	26 (11.3%) (7.5%, 16.1%)	247	14 (5.7%) (3.1%, 9.3%)	2.12 (1.08, 4.17)	1.99 (1.07, 3.72)	5.6% (0.6%, 10.6%)	0.0314*	0.3699
>=40 years	132	17 (12.9%) (7.7%, 19.8%)	118	4 (3.4%) (0.9%, 8.5%)	4.21 (1.38, 12.91)	3.80 (1.32, 10.97)	9.5% (2.9%, 16.1%)	0.0105*	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events by SOC/PT-Any Treatment Emergent Adverse Events at 12 weeks - Acne [PT] - Safety Set
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Safety Set	362	36 (9.9%) (7.1%, 13.5%)	365	6 (1.6%) (0.6%, 3.5%)	6.61 (2.75, 15.88)	6.05 (2.58, 14.18)	8.3% (5.0%, 11.6%)	<0.0001+*	--
Baseline Disease Severity									
Moderate baseline disease (IGA=3)	216	23 (10.6%) (6.9%, 15.5%)	220	2 (0.9%) (0.1%, 3.2%)	12.99 (3.02, 55.81)	11.71 (2.80, 49.08)	9.7% (5.4%, 14.0%)	<0.0001*	0.3234
Severe baseline disease (IGA=4)	146	13 (8.9%) (4.8%, 14.7%)	145	4 (2.8%) (0.8%, 6.9%)	3.45 (1.10, 10.83)	3.23 (1.08, 9.67)	6.1% (0.8%, 11.5%)	0.0427*	
Gender									
Male	193	19 (9.8%) (6.0%, 14.9%)	204	3 (1.5%) (0.3%, 4.2%)	7.32 (2.13, 25.14)	6.69 (2.01, 22.26)	8.4% (3.9%, 12.9%)	0.0003*	0.9659
Female	169	17 (10.1%) (6.0%, 15.6%)	161	3 (1.9%) (0.4%, 5.3%)	5.89 (1.69, 20.51)	5.40 (1.61, 18.07)	8.2% (3.2%, 13.2%)	0.0020*	
Region									
US/Canada/Australia	177	22 (12.4%) (8.0%, 18.2%)	195	4 (2.1%) (0.6%, 5.2%)	6.78 (2.29, 20.08)	6.06 (2.13, 17.24)	10.4% (5.1%, 15.6%)	<0.0001*	0.3836
Europe	150	11 (7.3%) (3.7%, 12.7%)	132	1 (0.8%) (0.0%, 4.1%)	10.37 (1.32, 81.42)	9.68 (1.27, 73.98)	6.6% (2.1%, 11.0%)	0.0065*	
Asia	17	3 (17.6%) (3.8%, 43.4%)	19	1 (5.3%) (0.1%, 26.0%)	3.86 (0.36, 41.20)	3.35 (0.38, 29.26)	12.4% (-8.3%, 33.1%)	0.3255	
Latin America	18	0 (0.0%)	19	0 (0.0%)	1.05 (0.02, 55.92)	1.05 (0.02, 50.43)	0.1% (-9.8%, 10.1%)	NE	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events by SOC/PT-Any Treatment Emergent Adverse Events at 12 weeks - Acne [PT] - Safety Set
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Age Subgroup									
<40 years	230	25 (10.9%) (7.2%, 15.6%)	247	6 (2.4%) (0.9%, 5.2%)	4.90 (1.97, 12.17)	4.47 (1.87, 10.71)	8.4% (4.0%, 12.9%)	0.0003*	0.9090
>=40 years	132	11 (8.3%) (4.2%, 14.4%)	118	0 (0.0%)	22.43 (1.31, 384.98)	20.58 (1.23, 345.46)	8.2% (3.3%, 13.1%)	0.0009*	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Selected Adverse Events (PT)-PT Natural killer cell count decreased at 12 weeks - Safety Set
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Safety Set	362	7 (1.9%) (0.8%, 3.9%)	365	0 (0.0%) .	>99.99 (>99.99, >99.99)	>99.99 (>99.99, >99.99)	1.9% (-8.4%, 12.3%)	0.7144+	--
Baseline Disease Severity									
Moderate baseline disease (IGA=3)	216	4 (1.9%) (0.5%, 4.7%)	220	0 (0.0%) .	9.34 (0.50, 174.51)	9.17 (0.50, 169.22)	1.8% (-0.1%, 3.8%)	0.0594	0.9084
Severe baseline disease (IGA=4)	146	3 (2.1%) (0.4%, 5.9%)	145	0 (0.0%) .	7.10 (0.36, 138.64)	6.95 (0.36, 133.41)	2.0% (-0.6%, 4.7%)	0.2474	
Gender									
Male	193	2 (1.0%) (0.1%, 3.7%)	204	0 (0.0%) .	5.34 (0.25, 111.93)	5.28 (0.26, 109.36)	1.0% (-0.7%, 2.8%)	0.2357	0.2508
Female	169	5 (3.0%) (1.0%, 6.8%)	161	0 (0.0%) .	10.80 (0.59, 196.90)	10.48 (0.58, 188.06)	2.9% (0.1%, 5.7%)	0.0610	
Region									
US/Canada/Australia	177	0 (0.0%)	195	0 (0.0%) .	1.10 (0.02, 55.80)	1.10 (0.02, 55.20)	0.0% (-1.0%, 1.1%)	NE	0.1069
Europe	150	7 (4.7%) (1.9%, 9.4%)	132	0 (0.0%) .	13.85 (0.78, 244.87)	13.21 (0.76, 229.14)	4.6% (1.0%, 8.2%)	0.0158*	
Asia	17	0 (0.0%)	19	0 (0.0%) .	1.11 (0.02, 59.20)	1.11 (0.02, 53.16)	0.3% (-9.9%, 10.5%)	NE	
Latin America	18	0 (0.0%)	19	0 (0.0%) .	1.05 (0.02, 55.92)	1.05 (0.02, 50.43)	0.1% (-9.8%, 10.1%)	NE	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Selected Adverse Events (PT)-PT Natural killer cell count decreased at 12 weeks - Safety Set
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Age Subgroup									
<40 years	230	4 (1.7%) (0.5%, 4.4%)	247	0 (0.0%) .	9.83 (0.53, 183.68)	9.66 (0.52, 178.48)	1.7% (-0.1%, 3.6%)	0.0533	0.7901
>=40 years	132	3 (2.3%) (0.5%, 6.5%)	118	0 (0.0%) .	6.41 (0.33, 125.31)	6.26 (0.33, 120.00)	2.2% (-0.7%, 5.2%)	0.2493	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Selected Adverse Events (PT)-PT Headache at 12 weeks - Safety Set
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Safety Set	362	43 (11.9%) (8.7%, 15.7%)	365	18 (4.9%) (2.9%, 7.7%)	2.60 (1.47, 4.60)	2.41 (1.42, 4.09)	6.9% (2.9%, 11.0%)	0.000	--
Baseline Disease Severity									
Moderate baseline disease (IGA=3)	216	26 (12.0%) (8.0%, 17.1%)	220	13 (5.9%) (3.2%, 9.9%)	2.18 (1.09, 4.36)	2.04 (1.08, 3.86)	6.1% (0.8%, 11.5%)	0.0290*	0.6372
Severe baseline disease (IGA=4)	146	17 (11.6%) (6.9%, 18.0%)	145	5 (3.4%) (1.1%, 7.9%)	3.69 (1.32, 10.29)	3.38 (1.28, 8.91)	8.2% (2.2%, 14.2%)	0.0131*	
Gender									
Male	193	23 (11.9%) (7.7%, 17.3%)	204	7 (3.4%) (1.4%, 6.9%)	3.81 (1.59, 9.09)	3.47 (1.53, 7.91)	8.5% (3.3%, 13.7%)	0.0019*	0.4249
Female	169	20 (11.8%) (7.4%, 17.7%)	161	11 (6.8%) (3.5%, 11.9%)	1.83 (0.85, 3.95)	1.73 (0.86, 3.50)	5.0% (-1.2%, 11.2%)	0.1339	
Region									
US/Canada/Australia	177	21 (11.9%) (7.5%, 17.6%)	195	9 (4.6%) (2.1%, 8.6%)	2.78 (1.24, 6.25)	2.57 (1.21, 5.46)	7.2% (1.6%, 12.8%)	0.0127*	0.9516
Europe	150	19 (12.7%) (7.8%, 19.1%)	132	7 (5.3%) (2.2%, 10.6%)	2.59 (1.05, 6.37)	2.39 (1.04, 5.50)	7.4% (0.8%, 13.9%)	0.0391*	
Asia	17	2 (11.8%) (1.5%, 36.4%)	19	2 (10.5%) (1.3%, 33.1%)	1.13 (0.14, 9.07)	1.12 (0.18, 7.09)	1.2% (-19.4%, 21.9%)	1.0000	
Latin America	18	1 (5.6%) (0.1%, 27.3%)	19	0 (0.0%)	3.34 (0.13, 87.52)	3.16 (0.14, 72.84)	5.4% (-8.5%, 19.3%)	0.4865	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Selected Adverse Events (PT)-PT Headache at 12 weeks - Safety Set
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Age Subgroup									
<40 years	230	26 (11.3%) (7.5%, 16.1%)	247	14 (5.7%) (3.1%, 9.3%)	2.12 (1.08, 4.17)	1.99 (1.07, 3.72)	5.6% (0.6%, 10.6%)	0.0314*	0.3699
>=40 years	132	17 (12.9%) (7.7%, 19.8%)	118	4 (3.4%) (0.9%, 8.5%)	4.21 (1.38, 12.91)	3.80 (1.32, 10.97)	9.5% (2.9%, 16.1%)	0.0105*	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Selected Adverse Events (PT)-SOC Nervous system disorders at 12 weeks - Safety Set
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Safety Set	362	60 (16.6%) (12.9%, 20.8%)	365	25 (6.8%) (4.5%, 9.9%)	2.70 (1.65, 4.42)	2.42 (1.55, 3.77)	9.7% (5.1%, 14.4%)	<0.0001+*	--
Baseline Disease Severity									
Moderate baseline disease (IGA=3)	216	36 (16.7%) (12.0%, 22.3%)	220	18 (8.2%) (4.9%, 12.6%)	2.24 (1.23, 4.09)	2.04 (1.19, 3.47)	8.5% (2.3%, 14.6%)	0.0086*	0.5451
Severe baseline disease (IGA=4)	146	24 (16.4%) (10.8%, 23.5%)	145	7 (4.8%) (2.0%, 9.7%)	3.88 (1.61, 9.32)	3.41 (1.51, 7.65)	11.6% (4.7%, 18.6%)	0.0019*	
Gender									
Male	193	30 (15.5%) (10.7%, 21.4%)	204	10 (4.9%) (2.4%, 8.8%)	3.57 (1.69, 7.52)	3.17 (1.59, 6.31)	10.6% (4.7%, 16.6%)	0.0004*	0.7065
Female	169	30 (17.8%) (12.3%, 24.4%)	161	15 (9.3%) (5.3%, 14.9%)	2.10 (1.08, 4.07)	1.91 (1.07, 3.41)	8.4% (1.1%, 15.7%)	0.0361*	
Region									
US/Canada/Australia	177	32 (18.1%) (12.7%, 24.6%)	195	12 (6.2%) (3.2%, 10.5%)	3.37 (1.67, 6.77)	2.94 (1.56, 5.52)	11.9% (5.3%, 18.5%)	0.0004*	0.6765
Europe	150	25 (16.7%) (11.1%, 23.6%)	132	11 (8.3%) (4.2%, 14.4%)	2.20 (1.04, 4.67)	2.00 (1.02, 3.91)	8.3% (0.7%, 15.9%)	0.0483*	
Asia	17	2 (11.8%) (1.5%, 36.4%)	19	2 (10.5%) (1.3%, 33.1%)	1.13 (0.14, 9.07)	1.12 (0.18, 7.09)	1.2% (-19.4%, 21.9%)	1.0000	
Latin America	18	1 (5.6%) (0.1%, 27.3%)	19	0 (0.0%)	3.34 (0.13, 87.52)	3.16 (0.14, 72.84)	5.4% (-8.5%, 19.3%)	0.4865	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Selected Adverse Events (PT)-SOC Nervous system disorders at 12 weeks - Safety Set
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Age Subgroup									
<40 years	230	38 (16.5%) (12.0%, 22.0%)	247	17 (6.9%) (4.1%, 10.8%)	2.68 (1.46, 4.89)	2.40 (1.39, 4.13)	9.6% (3.9%, 15.4%)	0.0014*	0.9605
>=40 years	132	22 (16.7%) (10.7%, 24.1%)	118	8 (6.8%) (3.0%, 12.9%)	2.75 (1.17, 6.44)	2.46 (1.14, 5.31)	9.9% (2.1%, 17.7%)	0.0191*	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Selected Adverse Events (SOC)-SOC Skin and subcutaneous tissue disorders at 12 weeks - Safety Set
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Safety Set	362	59 (16.3%) (12.6%, 20.5%)	365	36 (9.9%) (7.0%, 13.4%)	1.78 (1.14, 2.77)	1.65 (1.12, 2.44)	6.4% (1.6%, 11.3%)	0.009	--
Baseline Disease Severity									
Moderate baseline disease (IGA=3)	216	35 (16.2%) (11.6%, 21.8%)	220	20 (9.1%) (5.6%, 13.7%)	1.93 (1.08, 3.47)	1.78 (1.06, 2.99)	7.1% (0.9%, 13.3%)	0.0302*	0.7526
Severe baseline disease (IGA=4)	146	24 (16.4%) (10.8%, 23.5%)	145	16 (11.0%) (6.4%, 17.3%)	1.59 (0.80, 3.13)	1.49 (0.83, 2.69)	5.4% (-2.5%, 13.3%)	0.2332	
Gender									
Male	193	29 (15.0%) (10.3%, 20.9%)	204	17 (8.3%) (4.9%, 13.0%)	1.95 (1.03, 3.67)	1.80 (1.02, 3.17)	6.7% (0.4%, 13.0%)	0.0419*	0.9193
Female	169	30 (17.8%) (12.3%, 24.4%)	161	19 (11.8%) (7.3%, 17.8%)	1.61 (0.87, 3.00)	1.50 (0.88, 2.56)	6.0% (-1.7%, 13.6%)	0.1631	
Region									
US/Canada/Australia	177	32 (18.1%) (12.7%, 24.6%)	195	19 (9.7%) (6.0%, 14.8%)	2.04 (1.11, 3.76)	1.86 (1.09, 3.15)	8.3% (1.3%, 15.4%)	0.0234*	0.4334
Europe	150	24 (16.0%) (10.5%, 22.9%)	132	13 (9.8%) (5.3%, 16.3%)	1.74 (0.85, 3.58)	1.62 (0.86, 3.06)	6.2% (-1.6%, 13.9%)	0.1576	
Asia	17	3 (17.6%) (3.8%, 43.4%)	19	3 (15.8%) (3.4%, 39.6%)	1.14 (0.20, 6.60)	1.12 (0.26, 4.81)	1.9% (-22.6%, 26.3%)	1.0000	
Latin America	18	0 (0.0%)	19	1 (5.3%) (0.1%, 26.0%)	0.33 (0.01, 8.73)	0.35 (0.02, 8.09)	-4.9% (-18.5%, 8.7%)	1.0000	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Selected Adverse Events (SOC)-SOC Skin and subcutaneous tissue disorders at 12 weeks - Safety Set
JADE DARE (PF-04965842) - 2023 datacut

	Abrocitinib 200mg QD		Dupilumab 300mg Q2W		Dupilumab 300mg Q2W vs. Abrocitinib 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Age Subgroup									
<40 years	230	39 (17.0%) (12.3%, 22.4%)	247	23 (9.3%) (6.0%, 13.6%)	1.99 (1.15, 3.45)	1.82 (1.12, 2.95)	7.6% (1.6%, 13.7%)	0.0143*	0.5064
>=40 years	132	20 (15.2%) (9.5%, 22.4%)	118	13 (11.0%) (6.0%, 18.1%)	1.44 (0.68, 3.05)	1.38 (0.72, 2.64)	4.1% (-4.2%, 12.5%)	0.3560	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

MMRM Analysen JADE DARE

Descriptive Summary of Total EASI Score, Change from Baseline and Percent Change from Baseline up to Week 26 (FAS, OD)
(Protocol B7451050)

		Abrocitinib 200mg QD (N=362)						Dupilumab 300mg Q2W (N=365)					
		n (%)	Mean	Median	SD	Q1	Q3	n (%)	Mean	Median	SD	Q1	Q3
Observed Data	Baseline	362 (100.0)	28.1	24.5	11.5	19.4	33.6	365 (100.0)	28.1	24.5	11.9	19.2	33.5
	Week 2	350 (96.7)	12.7	10.0	10.6	4.8	17.6	350 (95.9)	15.3	12.8	11.3	7.8	19.7
	Week 4	342 (94.5)	7.6	5.2	8.8	1.8	10.0	351 (96.2)	10.9	8.3	9.9	3.8	15.4
	Week 8	336 (92.8)	5.1	2.8	6.6	0.8	6.6	348 (95.3)	7.8	5.4	8.2	2.4	10.6
	Week 12	329 (90.9)	4.1	2.4	5.8	0.7	5.6	341 (93.4)	6.3	4.0	7.3	1.6	8.2
	Week 16	324 (89.5)	3.8	1.6	6.1	0.4	4.8	336 (92.1)	5.3	3.4	6.7	1.2	6.7
	Week 20	320 (88.4)	3.5	1.4	5.9	0.3	4.3	333 (91.2)	4.7	2.4	6.6	0.8	6.0
	Week 26	301 (83.1)	3.3	1.5	5.2	0.0	4.3	324 (88.8)	4.2	2.4	5.8	0.6	5.6
Change from Baseline	Week 2	350 (96.7)	-15.5	-15.2	9.4	-20.8	-8.7	350 (95.9)	-12.8	-11.0	10.3	-18.5	-5.5
	Week 4	342 (94.5)	-20.7	-19.3	10.2	-25.9	-15.1	351 (96.2)	-17.2	-15.5	10.7	-22.4	-10.9
	Week 8	336 (92.8)	-23.1	-21.0	10.8	-29.2	-16.8	348 (95.3)	-20.2	-18.4	10.7	-24.8	-13.6
	Week 12	329 (90.9)	-24.0	-21.4	11.0	-29.3	-17.3	341 (93.4)	-21.9	-19.2	11.1	-26.9	-15.1
	Week 16	324 (89.5)	-24.4	-21.7	10.7	-29.6	-17.7	336 (92.1)	-22.9	-20.8	11.5	-27.9	-15.7
	Week 20	320 (88.4)	-24.8	-21.8	10.9	-30.0	-17.8	333 (91.2)	-23.3	-20.8	11.2	-28.0	-16.4
	Week 26	301 (83.1)	-24.7	-22.5	10.6	-29.2	-17.8	324 (88.8)	-23.8	-21.8	11.3	-28.5	-16.8
Percent Change from Baseline	Week 2	350 (96.7)	-56.3	-60.1	28.0	-80.6	-33.9	350 (95.9)	-45.7	-44.2	29.4	-71.1	-22.8
	Week 4	342 (94.5)	-74.0	-80.3	24.3	-92.4	-64.2	351 (96.2)	-61.9	-65.3	26.6	-84.2	-44.8
	Week 8	336 (92.8)	-81.9	-89.5	22.6	-96.8	-74.9	348 (95.3)	-72.6	-79.2	23.7	-90.8	-61.1
	Week 12	329 (90.9)	-85.2	-91.2	17.9	-97.6	-79.3	341 (93.4)	-78.0	-83.9	20.3	-94.1	-67.5
	Week 16	324 (89.5)	-87.1	-93.2	17.6	-98.3	-82.8	336 (92.1)	-81.1	-88.4	19.9	-95.5	-72.9

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
Data after dropout or use of rescue therapy was censored.
EASI = eczema area and severity index; N = number of subjects in the analysis set; n = number of subjects in the analysis set with observed data at the specified visit;
OD = observed data.
PFIZER CONFIDENTIAL SDTM Creation: 09AUG2021 (01:16) Source Data: adea Table Generation: 15SEP2021 (01:53)
Output File: ./nda1_cdisc/B7451050_GBA/adea_s001

Descriptive Summary of Total EASI Score, Change from Baseline and Percent Change from Baseline up to Week 26 (FAS, OD)
(Protocol B7451050)

		Abrocitinib 200mg QD (N=362)						Dupilumab 300mg Q2W (N=365)					
		n (%)	Mean	Median	SD	Q1	Q3	n (%)	Mean	Median	SD	Q1	Q3
Percent Change from Baseline	Week 20	320 (88.4)	-88.3	-94.6	16.8	-99.0	-84.0	333 (91.2)	-83.7	-89.9	18.6	-96.8	-76.6
	Week 26	301 (83.1)	-88.4	-94.2	17.0	-100.0	-83.5	324 (88.8)	-85.2	-91.1	17.8	-97.3	-80.1

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
Data after dropout or use of rescue therapy was censored.
EASI = eczema area and severity index; N = number of subjects in the analysis set; n = number of subjects in the analysis set with observed data at the specified visit;
OD = observed data.
PFIZER CONFIDENTIAL SDTM Creation: 09AUG2021 (01:16) Source Data: adea Table Generation: 15SEP2021 (01:53)
Output File: ./nda1_cdisc/B7451050_GBA/adea_s001

Least Squares Mean of Percent Change from Baseline in Total EASI Score at Weeks 2, 4, 8, 12, 16, 20 and 26 - MMRM (FAS, OD)
(Protocol B7451050)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	N	362	365
Week 2	N1	351	353
	N2 (%)	350 (99.7)	350 (99.2)
	LSM (SE)	-56.18 (1.53)	-45.72 (1.53)
	95% CI	(-59.19, -53.18)	(-48.72, -42.72)
	Abrocitinib - Dupilumab		
	LSM	-10.46	
	95% CI	(-14.71, -6.22)	
	Two-sided P-value	<.0001	
	Hedges'g	-0.37	
	95% CI of Hedges'g	(-0.52, -0.22)	
Week 4	N1	350	352
	N2 (%)	342 (97.7)	351 (99.7)
	LSM (SE)	-73.76 (1.36)	-61.76 (1.36)
	95% CI	(-76.44, -71.08)	(-64.42, -59.10)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
Data after dropout or use of rescue therapy was censored.
CI = confidence interval; EASI = eczema area and severity index; LSM = least squares mean; SE = standard error; N = number of subjects included in the analysis model; N1 = number of subjects at risk/eligible at the timepoint; N2 = number of subjects included in the analysis and with valid score at the timepoint; OD = observed data.
Mixed Model Repeated Measure (MMRM) contained fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix. Compound symmetry covariance matrix was used if the model with unstructured covariance did not converge.
Hedges'g was defined as the LSM difference divided by pooled standard deviation.
PFIZER CONFIDENTIAL SDTM Creation: 09AUG2021 (01:16) Source Data: adea Table Generation: 06SEP2021 (02:56)
Output File: ./nda1_cdisc/B7451050_GBA/adea_mk1_1

Least Squares Mean of Percent Change from Baseline in Total EASI Score at Weeks 2, 4, 8, 12, 16, 20 and 26 - MMRM (FAS, OD)
(Protocol B7451050)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib - Dupilumab		
	LSM	-11.99	
	95% CI	(-15.77, -8.22)	
	Two-sided P-value	<.0001	
	Hedges'g	-0.47	
	95% CI of Hedges'g	(-0.62, -0.32)	
Week 8	N1	343	351
	N2 (%)	336 (98.0)	348 (99.1)
	LSM (SE)	-81.70 (1.25)	-72.46 (1.24)
	95% CI	(-84.16, -79.25)	(-74.89, -70.02)
	Abrocitinib - Dupilumab		
	LSM	-9.25	
	95% CI	(-12.70, -5.79)	
	Two-sided P-value	<.0001	
	Hedges'g	-0.40	
	95% CI of Hedges'g	(-0.55, -0.25)	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
Data after dropout or use of rescue therapy was censored.
CI = confidence interval; EASI = eczema area and severity index; LSM = least squares mean; SE = standard error; N = number of subjects included in the analysis model; N1 = number of subjects at risk/eligible at the timepoint; N2 = number of subjects included in the analysis and with valid score at the timepoint; OD = observed data.
Mixed Model Repeated Measure (MMRM) contained fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix. Compound symmetry covariance matrix was used if the model with unstructured covariance did not converge.
Hedges'g was defined as the LSM difference divided by pooled standard deviation.
PFIZER CONFIDENTIAL SDTM Creation: 09AUG2021 (01:16) Source Data: adea Table Generation: 06SEP2021 (02:56)
Output File: ./nda1_cdisc/B7451050_GBA/adea_mk1_1

Least Squares Mean of Percent Change from Baseline in Total EASI Score at Weeks 2, 4, 8, 12, 16, 20 and 26 - MMRM (FAS, OD)
(Protocol B7451050)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Week 12	N1	332	343
	N2 (%)	329 (99.1)	341 (99.4)
	LSM (SE)	-84.40 (1.05)	-78.05 (1.04)
	95% CI	(-86.46, -82.34)	(-80.09, -76.01)
	Abrocitinib - Dupilumab		
	LSM	-6.35	
	95% CI	(-9.25, -3.44)	
	Two-sided P-value	<.0001	
	Hedges'g	-0.33	
	95% CI of Hedges'g	(-0.48, -0.18)	
Week 16	N1	329	341
	N2 (%)	324 (98.5)	336 (98.5)
	LSM (SE)	-86.39 (1.03)	-81.14 (1.02)
	95% CI	(-88.41, -84.37)	(-83.14, -79.15)
	Abrocitinib - Dupilumab		
	LSM	-5.24	
	95% CI	(-8.09, -2.40)	
	Two-sided P-value	0.0003	
	Hedges'g	-0.28	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
Data after dropout or use of rescue therapy was censored.
CI = confidence interval; EASI = eczema area and severity index; LSM = least squares mean; SE = standard error; N = number of subjects included in the analysis model; N1 = number of subjects at risk/eligible at the timepoint; N2 = number of subjects included in the analysis and with valid score at the timepoint; OD = observed data.
Mixed Model Repeated Measure (MMRM) contained fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix. Compound symmetry covariance matrix was used if the model with unstructured covariance did not converge.
Hedges'g was defined as the LSM difference divided by pooled standard deviation.
PFIZER CONFIDENTIAL SDTM Creation: 09AUG2021 (01:16) Source Data: adea Table Generation: 06SEP2021 (02:56)
Output File: ./nda1_cdisc/B7451050_GBA/adea_mk1_1

Least Squares Mean of Percent Change from Baseline in Total EASI Score at Weeks 2, 4, 8, 12, 16, 20 and 26 - MMRM (FAS, OD)
(Protocol B7451050)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	95% CI of Hedges'g	(-0.44, -0.13)	
Week 20	N1	323	334
	N2 (%)	320 (99.1)	333 (99.7)
	LSM (SE)	-87.40 (0.98)	-83.42 (0.97)
	95% CI	(-89.33, -85.47)	(-85.32, -81.52)
	Abrocitinib - Dupilumab		
	LSM	-3.98	
	95% CI	(-6.69, -1.27)	
	Two-sided P-value	0.0040	
	Hedges'g	-0.23	
	95% CI of Hedges'g	(-0.38, -0.07)	
Week 26	N1	301	324
	N2 (%)	301 (100.0)	324 (100.0)
	LSM (SE)	-87.03 (1.00)	-84.96 (0.98)
	95% CI	(-89.00, -85.05)	(-86.89, -83.02)

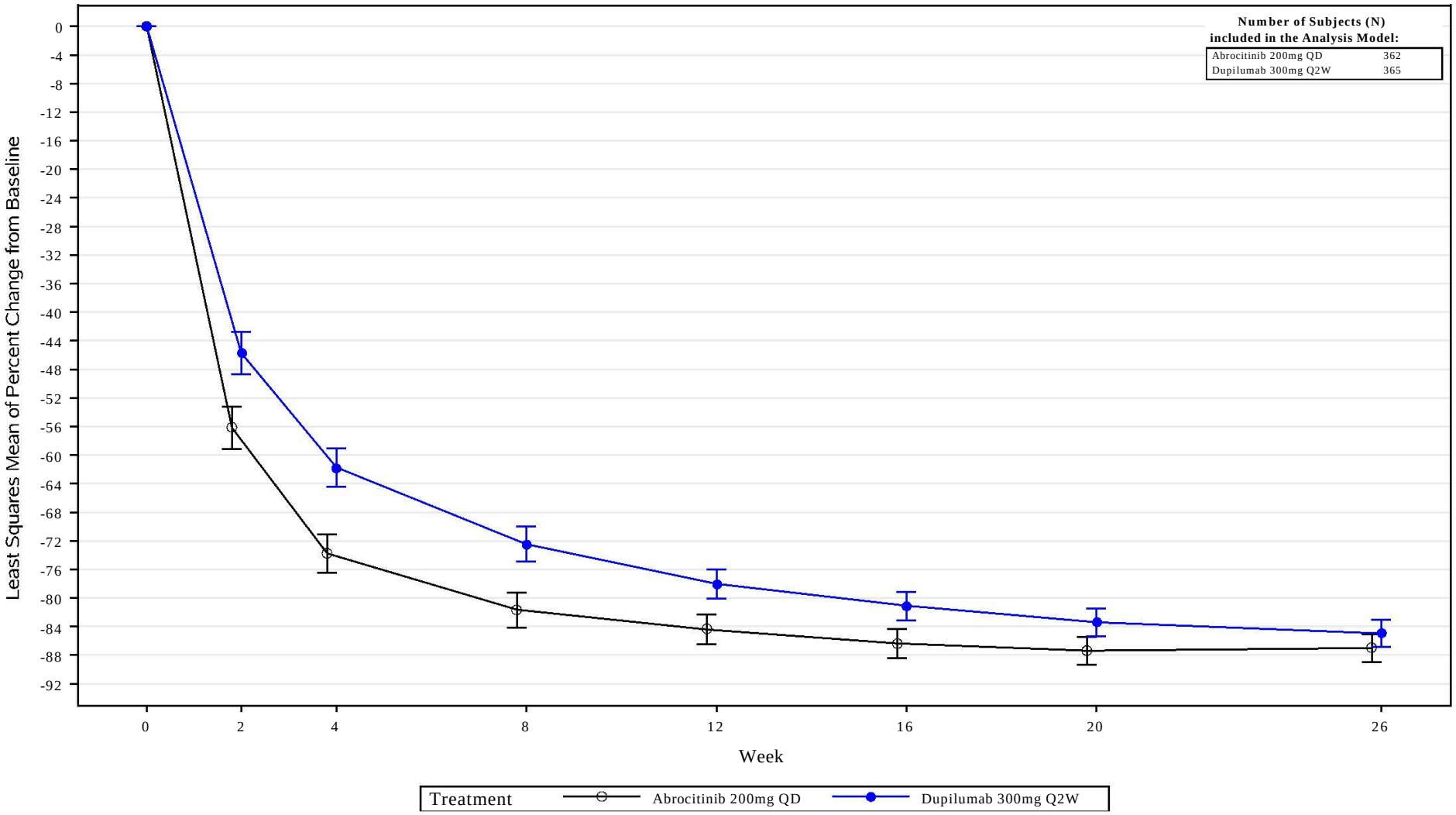
Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
Data after dropout or use of rescue therapy was censored.
CI = confidence interval; EASI = eczema area and severity index; LSM = least squares mean; SE = standard error; N = number of subjects included in the analysis model; N1 = number of subjects at risk/eligible at the timepoint; N2 = number of subjects included in the analysis and with valid score at the timepoint; OD = observed data.
Mixed Model Repeated Measure (MMRM) contained fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix. Compound symmetry covariance matrix was used if the model with unstructured covariance did not converge.
Hedges'g was defined as the LSM difference divided by pooled standard deviation.
PFIZER CONFIDENTIAL SDTM Creation: 09AUG2021 (01:16) Source Data: adea Table Generation: 06SEP2021 (02:56)
Output File: ./nda1_cdisc/B7451050_GBA/adea_mk1_1

Least Squares Mean of Percent Change from Baseline in Total EASI Score at Weeks 2, 4, 8, 12, 16, 20 and 26 - MMRM (FAS, OD)
(Protocol B7451050)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib - Dupilumab		
	LSM	-2.07	
	95% CI	(-4.83, 0.69)	
	Two-sided P-value	0.1408	
	Hedges'g	-0.12	
	95% CI of Hedges'g	(-0.28, 0.04)	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
Data after dropout or use of rescue therapy was censored.
CI = confidence interval; EASI = eczema area and severity index; LSM = least squares mean; SE = standard error; N = number of subjects included in the analysis model; N1 = number of subjects at risk/eligible at the timepoint; N2 = number of subjects included in the analysis and with valid score at the timepoint; OD = observed data.
Mixed Model Repeated Measure (MMRM) contained fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix. Compound symmetry covariance matrix was used if the model with unstructured covariance did not converge.
Hedges'g was defined as the LSM difference divided by pooled standard deviation.

Plot of Least Squares Mean of Percent Change from Baseline in Total EASI Score at Weeks 2, 4, 8, 12, 16, 20 and 26 - MMRM (FAS, OD)
(Protocol B7451050)



Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
Data after dropout or use of rescue therapy was censored.
Mixed Model Repeated Measure (MMRM) contained fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix. Compound symmetry covariance matrix was used if the model with unstructured covariance did not converge.
Vertical line represented 95% confidence interval.
EASI = eczema area and severity index; OD = observed data.
PFIZER CONFIDENTIAL SDTM Creation: 09AUG2021 (01:16) Source Data: adea Table Generation: 05SEP2021 (22:29)
Output File: ./nda1_cdisc/B7451050_GBA/adea_f402

Descriptive Summary of Peak Pruritus Numerical Rating Scale (PP-NRS), Change from Baseline and Percent Change from Baseline up to Week 26 (FAS, OD)

(Protocol B7451050)

		Abrocitinib 200mg QD (N=362)						Dupilumab 300mg Q2W (N=365)					
		n (%)	Mean	Median	SD	Q1	Q3	n (%)	Mean	Median	SD	Q1	Q3
Observed Data	Baseline	362 (100.0)	7.4	8.0	1.6	7.0	8.0	365 (100.0)	7.4	7.0	1.6	6.0	9.0
	Week 2	354 (97.8)	3.8	4.0	2.3	2.0	6.0	355 (97.3)	5.0	5.0	2.2	3.0	7.0
	Week 4	349 (96.4)	3.2	3.0	2.3	1.0	5.0	351 (96.2)	4.2	4.0	2.2	2.0	6.0
	Week 8	345 (95.3)	2.8	2.0	2.3	1.0	4.0	351 (96.2)	3.6	3.0	2.4	2.0	5.0
	Week 12	333 (92.0)	2.6	2.0	2.3	1.0	4.0	347 (95.1)	3.1	3.0	2.2	1.0	5.0
	Week 16	331 (91.4)	2.6	2.0	2.3	1.0	4.0	342 (93.7)	3.0	3.0	2.2	1.0	4.0
	Week 20	326 (90.1)	2.5	2.0	2.2	1.0	4.0	338 (92.6)	2.8	3.0	2.1	1.0	4.0
	Week 26	313 (86.5)	2.3	2.0	2.2	1.0	4.0	328 (89.9)	2.7	2.0	2.1	1.0	4.0
Change from Baseline	Week 2	354 (97.8)	-3.6	-3.0	2.3	-5.0	-2.0	355 (97.3)	-2.3	-2.0	2.1	-4.0	-1.0
	Week 4	349 (96.4)	-4.3	-4.0	2.5	-6.0	-2.0	351 (96.2)	-3.2	-3.0	2.3	-5.0	-2.0
	Week 8	345 (95.3)	-4.7	-5.0	2.5	-6.0	-3.0	351 (96.2)	-3.8	-4.0	2.5	-5.0	-2.0
	Week 12	333 (92.0)	-4.8	-5.0	2.5	-7.0	-3.0	347 (95.1)	-4.2	-4.0	2.3	-6.0	-3.0
	Week 16	331 (91.4)	-4.8	-5.0	2.6	-7.0	-3.0	342 (93.7)	-4.3	-4.0	2.3	-6.0	-3.0
	Week 20	326 (90.1)	-4.9	-5.0	2.5	-7.0	-3.0	338 (92.6)	-4.5	-5.0	2.3	-6.0	-3.0
	Week 26	313 (86.5)	-5.1	-5.0	2.4	-7.0	-4.0	328 (89.9)	-4.6	-5.0	2.4	-6.0	-3.0
Percent Change from Baseline	Week 2	354 (97.8)	-48.2	-50.0	30.0	-71.4	-25.0	355 (97.3)	-31.5	-28.6	27.6	-50.0	-12.5
	Week 4	349 (96.4)	-56.2	-60.0	32.0	-83.3	-33.3	351 (96.2)	-42.9	-42.9	29.0	-66.7	-22.2
	Week 8	345 (95.3)	-62.0	-66.7	31.8	-87.5	-37.5	351 (96.2)	-50.9	-55.6	31.2	-75.0	-30.0
	Week 12	333 (92.0)	-63.9	-71.4	33.0	-87.5	-44.4	347 (95.1)	-57.1	-60.0	29.0	-80.0	-37.5
	Week 16	331 (91.4)	-64.0	-71.4	33.9	-87.5	-50.0	342 (93.7)	-58.7	-62.5	29.2	-83.3	-40.0

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
Data after dropout or use of rescue therapy was censored.
OD = observed data
N = number of subjects in the analysis set
n = number of subjects in the analysis set with observed data at the specified visit

Descriptive Summary of Peak Pruritus Numerical Rating Scale (PP-NRS), Change from Baseline and Percent Change from Baseline up to Week 26 (FAS, OD)
(Protocol B7451050)

		Abrocitinib 200mg QD (N=362)						Dupilumab 300mg Q2W (N=365)					
		n (%)	Mean	Median	SD	Q1	Q3	n (%)	Mean	Median	SD	Q1	Q3
Percent Change from Baseline	Week 20	326 (90.1)	-65.6	-71.4	31.2	-88.9	-44.4	338 (92.6)	-60.8	-64.6	28.7	-83.3	-44.4
	Week 26	313 (86.5)	-68.2	-75.0	31.1	-88.9	-50.0	328 (89.9)	-62.8	-71.4	29.0	-85.7	-44.4

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
Data after dropout or use of rescue therapy was censored.
OD = observed data
N = number of subjects in the analysis set
n = number of subjects in the analysis set with observed data at the specified visit

Least Squares Mean of Change from Baseline in Peak Pruritus Numerical Rating Scale (PP-NRS) up to Week 26 - MMRM (FAS, OD)
(Protocol B7451050)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	N	362	365
Week 2	N1	354	355
	N2 (%)	354 (100.0)	355 (100.0)
	LSM (SE)	-3.60 (0.11)	-2.37 (0.11)
	95% CI	(-3.82, -3.38)	(-2.59, -2.15)
	Abrocitinib - Dupilumab		
	LSM	-1.23	
	95% CI	(-1.54, -0.92)	
	Two-sided P-value	<.0001	
	Hedges'g	-0.58	
	95% CI of Hedges'g	(-0.73, -0.43)	
Week 4	N1	350	352
	N2 (%)	349 (99.7)	351 (99.7)
	LSM (SE)	-4.24 (0.12)	-3.23 (0.12)
	95% CI	(-4.47, -4.01)	(-3.46, -3.00)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
Data after dropout or use of rescue therapy was censored.
CI = confidence interval; LSM = least squares mean; SE = standard error; N = number of subjects included in the analysis model; N1 = number of subjects at risk/eligible at the timepoint; N2 = number of subjects included in the analysis and with valid score at the timepoint; OD = observed data.
Mixed Model Repeated Measure (MMRM) contained fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix. Compound symmetry covariance matrix was used if the model with unstructured covariance did not converge.
Hedges'g was defined as the LSM difference divided by pooled standard deviation.
PFIZER CONFIDENTIAL SDTM Creation: 09AUG2021 (01:16) Source Data: adnr Table Generation: 06SEP2021 (02:56)
Output File: ./nda1_cdisc/B7451050_GBA/adnr_s101_1

Least Squares Mean of Change from Baseline in Peak Pruritus Numerical Rating Scale (PP-NRS) up to Week 26 - MMRM (FAS, OD)
(Protocol B7451050)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib - Dupilumab		
	LSM	-1.01	
	95% CI	(-1.33, -0.68)	
	Two-sided P-value	<.0001	
	Hedges'g	-0.46	
	95% CI of Hedges'g	(-0.61, -0.31)	
Week 8	N1	345	351
	N2 (%)	345 (100.0)	351 (100.0)
	LSM (SE)	-4.63 (0.12)	-3.81 (0.12)
	95% CI	(-4.87, -4.39)	(-4.05, -3.58)
	Abrocitinib - Dupilumab		
	LSM	-0.81	
	95% CI	(-1.15, -0.48)	
	Two-sided P-value	<.0001	
	Hedges'g	-0.36	
	95% CI of Hedges'g	(-0.51, -0.21)	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
Data after dropout or use of rescue therapy was censored.
CI = confidence interval; LSM = least squares mean; SE = standard error; N = number of subjects included in the analysis model; N1 = number of subjects at risk/eligible at the timepoint; N2 = number of subjects included in the analysis and with valid score at the timepoint; OD = observed data.
Mixed Model Repeated Measure (MMRM) contained fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix. Compound symmetry covariance matrix was used if the model with unstructured covariance did not converge.
Hedges'g was defined as the LSM difference divided by pooled standard deviation.

Least Squares Mean of Change from Baseline in Peak Pruritus Numerical Rating Scale (PP-NRS) up to Week 26 - MMRM (FAS, OD)
(Protocol B7451050)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Week 12	N1	334	347
	N2 (%)	333 (99.7)	347 (100.0)
	LSM (SE)	-4.74 (0.12)	-4.24 (0.12)
	95% CI	(-4.97, -4.51)	(-4.47, -4.01)
	Abrocitinib - Dupilumab		
	LSM	-0.50	
	95% CI	(-0.82, -0.17)	
	Two-sided P-value	0.0029	
	Hedges'g	-0.23	
	95% CI of Hedges'g	(-0.38, -0.08)	
Week 16	N1	331	343
	N2 (%)	331 (100.0)	342 (99.7)
	LSM (SE)	-4.76 (0.12)	-4.33 (0.12)
	95% CI	(-5.00, -4.53)	(-4.56, -4.10)
	Abrocitinib - Dupilumab		
	LSM	-0.43	
	95% CI	(-0.76, -0.10)	
	Two-sided P-value	0.0109	
	Hedges'g	-0.20	
	95% CI of Hedges'g	(-0.35, -0.05)	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
Data after dropout or use of rescue therapy was censored.
CI = confidence interval; LSM = least squares mean; SE = standard error; N = number of subjects included in the analysis model; N1 = number of subjects at risk/eligible at the timepoint; N2 = number of subjects included in the analysis and with valid score at the timepoint; OD = observed data.
Mixed Model Repeated Measure (MMRM) contained fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix. Compound symmetry covariance matrix was used if the model with unstructured covariance did not converge.
Hedges'g was defined as the LSM difference divided by pooled standard deviation.
PFIZER CONFIDENTIAL SDTM Creation: 09AUG2021 (01:16) Source Data: adnr Table Generation: 06SEP2021 (02:56)
Output File: ./nda1_cdisc/B7451050_GBA/adnr_s101_1

Least Squares Mean of Change from Baseline in Peak Pruritus Numerical Rating Scale (PP-NRS) up to Week 26 - MMRM (FAS, OD)
(Protocol B7451050)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Week 20	N1	326	338
	N2 (%)	326 (100.0)	338 (100.0)
	LSM (SE)	-4.83 (0.12)	-4.50 (0.12)
	95% CI	(-5.05, -4.60)	(-4.73, -4.27)
	Abrocitinib - Dupilumab		
	LSM	-0.32	
	95% CI	(-0.65, 0.00)	
	Two-sided P-value	0.0497	
	Hedges'g	-0.15	
	95% CI of Hedges'g	(-0.30, 0.00)	
Week 26	N1	313	328
	N2 (%)	313 (100.0)	328 (100.0)
	LSM (SE)	-4.92 (0.12)	-4.65 (0.12)
	95% CI	(-5.15, -4.68)	(-4.88, -4.41)
	Abrocitinib - Dupilumab		
	LSM	-0.27	
	95% CI	(-0.60, 0.06)	
	Two-sided P-value	0.1068	
	Hedges'g	-0.13	

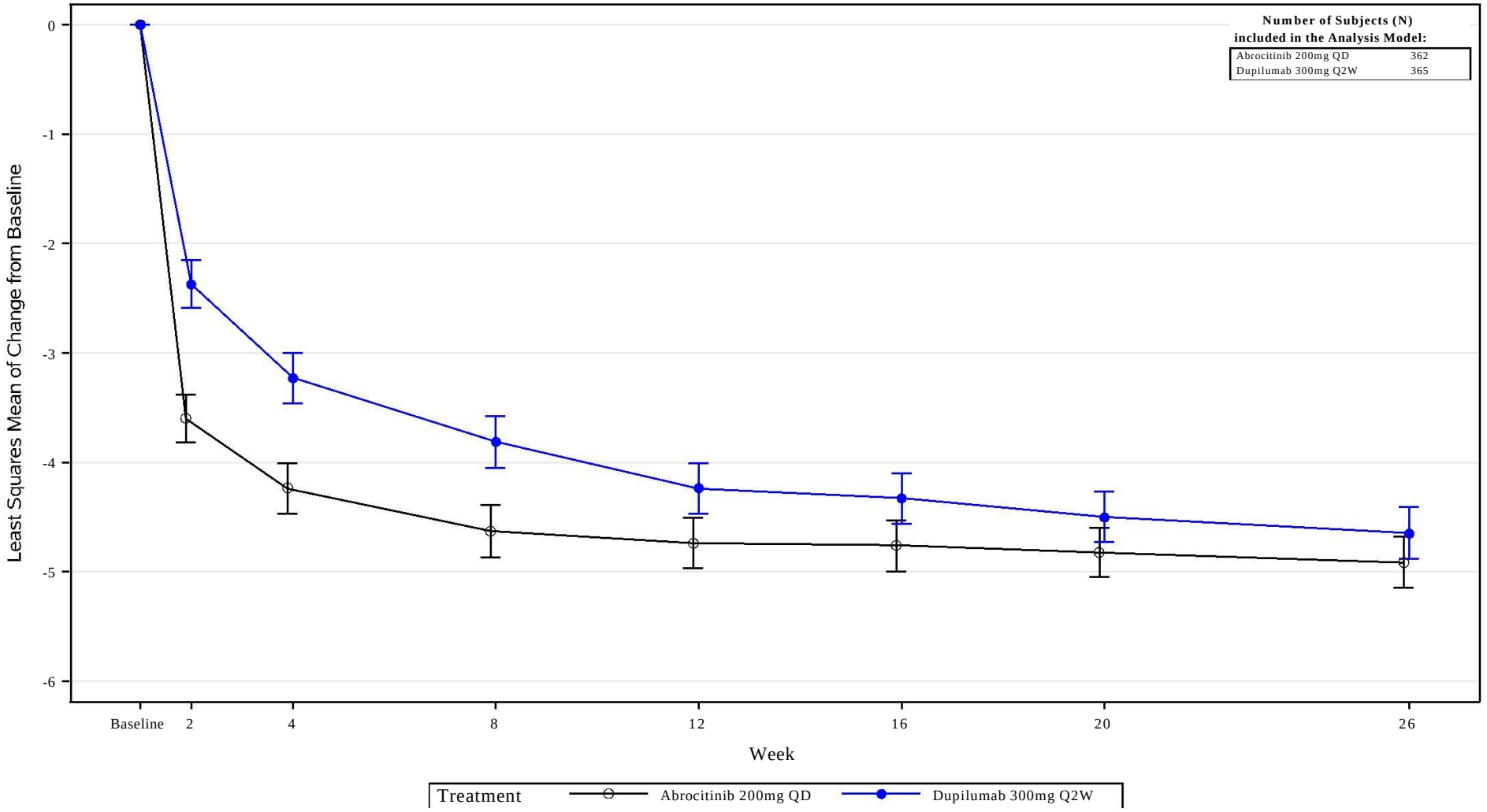
Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
Data after dropout or use of rescue therapy was censored.
CI = confidence interval; LSM = least squares mean; SE = standard error; N = number of subjects included in the analysis model; N1 = number of subjects at risk/eligible at the timepoint; N2 = number of subjects included in the analysis and with valid score at the timepoint; OD = observed data.
Mixed Model Repeated Measure (MMRM) contained fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix. Compound symmetry covariance matrix was used if the model with unstructured covariance did not converge.
Hedges'g was defined as the LSM difference divided by pooled standard deviation.
PFIZER CONFIDENTIAL SDTM Creation: 09AUG2021 (01:16) Source Data: adnr Table Generation: 06SEP2021 (02:56)
Output File: ./nda1_cdisc/B7451050_GBA/adnr_s101_1

Least Squares Mean of Change from Baseline in Peak Pruritus Numerical Rating Scale (PP-NRS) up to Week 26 - MMRM (FAS, OD)
(Protocol B7451050)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	95% CI of Hedges'g	(-0.28, 0.03)	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
Data after dropout or use of rescue therapy was censored.
CI = confidence interval; LSM = least squares mean; SE = standard error; N = number of subjects included in the analysis model; N1 = number of subjects at risk/eligible at the timepoint; N2 = number of subjects included in the analysis and with valid score at the timepoint; OD = observed data.
Mixed Model Repeated Measure (MMRM) contained fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix. Compound symmetry covariance matrix was used if the model with unstructured covariance did not converge.
Hedges'g was defined as the LSM difference divided by pooled standard deviation.

Plot of Least Squares Mean of Change from Baseline in Peak Pruritus Numerical Rating Scale (PP-NRS) at Weeks 2, 4, 8, 12, 16, 20 and 26 - MMRM (FAS, OD)
(Protocol B7451050)



Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
Data after dropout or use of rescue therapy was censored.
Mixed Model Repeated Measure (MMRM) contained fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix. Compound symmetry covariance matrix was used if the model with unstructured covariance did not converge.
Vertical line represented 95% confidence interval.
OD = observed data.
PFIZER CONFIDENTIAL SDTM Creation: 09AUG2021 (01:16) Source Data: adnr Table Generation: 05SEP2021 (22:29)
Output File: ./nda1_cdisc/B7451050_GBA/adnr_f402

Descriptive Summary of DLQI, Absolute Values, Change from Baseline and Percent Change from Baseline up to Week 26 (FAS, OD)
(Protocol B7451050)

		Abrocitinib 200mg QD (N=362)						Dupilumab 300mg Q2W (N=365)					
		n (%)	Mean	Median	SD	Q1	Q3	n (%)	Mean	Median	SD	Q1	Q3
Observed Data	Baseline	361 (99.7)	14.0	14.0	6.8	9.0	19.0	363 (99.5)	14.2	14.0	6.3	9.0	19.0
	Week 2	347 (95.9)	5.4	4.0	5.1	2.0	8.0	351 (96.2)	7.4	6.0	5.1	3.0	11.0
	Week 12	329 (90.9)	3.5	2.0	4.0	1.0	4.0	341 (93.4)	4.3	2.0	4.7	1.0	6.0
	Week 16	325 (89.8)	3.2	2.0	3.9	1.0	4.0	338 (92.6)	4.0	2.5	4.3	1.0	6.0
	Week 20	320 (88.4)	3.3	2.0	4.0	1.0	5.0	333 (91.2)	3.8	2.0	4.1	1.0	5.0
	Week 26	303 (83.7)	3.6	2.0	4.7	1.0	5.0	325 (89.0)	4.0	2.0	4.5	1.0	6.0
Change from Baseline	Week 2	346 (95.6)	-8.6	-8.0	6.1	-12.0	-4.0	349 (95.6)	-6.6	-6.0	5.9	-10.0	-3.0
	Week 12	328 (90.6)	-10.7	-10.0	6.7	-15.0	-6.0	339 (92.9)	-9.6	-9.0	6.1	-13.0	-6.0
	Week 16	324 (89.5)	-10.8	-10.0	6.7	-15.0	-6.0	336 (92.1)	-9.9	-9.0	6.0	-13.0	-6.0
	Week 20	319 (88.1)	-10.9	-10.0	6.7	-15.0	-6.0	331 (90.7)	-10.1	-9.0	6.1	-14.0	-6.0
	Week 26	302 (83.4)	-10.5	-11.0	6.6	-15.0	-5.0	323 (88.5)	-10.0	-10.0	6.2	-14.0	-6.0
Percent Change from Baseline	Week 2	345 (95.3)	-58.3	-66.7	40.4	-84.2	-42.1	349 (95.6)	-42.6	-50.0	38.6	-70.6	-25.0
	Week 12	327 (90.3)	-70.6	-83.3	63.5	-93.8	-62.5	339 (92.9)	-66.6	-77.8	34.7	-90.0	-50.0
	Week 16	323 (89.2)	-73.1	-85.0	40.1	-95.0	-61.9	336 (92.1)	-68.6	-77.4	31.9	-90.0	-56.4
	Week 20	319 (88.1)	-73.2	-85.0	38.7	-95.2	-66.7	331 (90.7)	-69.0	-80.0	38.3	-90.9	-60.0
	Week 26	301 (83.1)	-72.7	-84.6	44.1	-95.8	-66.7	323 (88.5)	-68.5	-80.0	37.6	-90.9	-56.5

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
DLQI = dermatology life quality index; OD = observed data. Data after dropout or use of rescue therapy was censored.
N = number of subjects in the analysis set.
n = number of subjects in the analysis set with observed data at the specified visit.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (01:50) Source Data: adli Table Generation: 12SEP2021 (23:49)
Output File: ./nda1_cdisc/B7451050_GBA/adli_s_g

Least Squares Mean of Change from Baseline in DLQI at Weeks 2, 12, 16, 20 and 26 - MMRM (FAS, OD)
(Protocol B7451050)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	N	361	363
Week 2	N1	349	351
	N2 (%)	346 (99.1)	349 (99.4)
	LSM (SE)	-8.63 (0.24)	-6.67 (0.24)
	95% CI	(-9.11, -8.16)	(-7.15, -6.20)
	Abrocitinib - Dupilumab		
	LSM	-1.96	
	95% CI	(-2.64, -1.29)	
	Two-sided P-value	<.0001	
	Hedges'g	-0.43	
	95% CI of Hedges'g	(-0.58, -0.28)	
Week 12	N1	331	341
	N2 (%)	328 (99.1)	339 (99.4)
	LSM (SE)	-10.69 (0.22)	-9.69 (0.22)
	95% CI	(-11.13, -10.25)	(-10.12, -9.25)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; DLQI = Dermatology Life Quality Index; LSM = least squares mean;SE = Standard Error; N = number of subjects included in the analysis model;
N1 = number of subjects at risk/eligible at the timepoint; N2 = number of subjects included in the analysis and with valid score at the timepoint.
OD = observed data. Data after dropout or use of rescue therapy was censored.
Mixed Model Repeated Measure (MMRM) contained fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.
Hedges'g was defined as the LSM difference divided by pooled standard deviation.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (01:50) Source Data: adli Table Generation: 12SEP2021 (23:19)
Output File: ./nda1_cdisc/B7451050_GBA/adli_s201

Least Squares Mean of Change from Baseline in DLQI at Weeks 2, 12, 16, 20 and 26 - MMRM (FAS, OD)
(Protocol B7451050)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib - Dupilumab		
	LSM	-1.00	
	95% CI	(-1.62, -0.38)	
	Two-sided P-value	0.0016	
	Hedges'g	-0.25	
	95% CI of Hedges'g	(-0.40, -0.09)	
Week 16	N1	328	339
	N2 (%)	324 (98.8)	336 (99.1)
	LSM (SE)	-10.80 (0.22)	-10.04 (0.21)
	95% CI	(-11.22, -10.38)	(-10.46, -9.62)
	Abrocitinib - Dupilumab		
	LSM	-0.76	
	95% CI	(-1.35, -0.16)	
	Two-sided P-value	0.0126	
	Hedges'g	-0.19	
	95% CI of Hedges'g	(-0.35, -0.04)	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; DLQI = Dermatology Life Quality Index; LSM = least squares mean;SE = Standard Error; N = number of subjects included in the analysis model;
N1 = number of subjects at risk/eligible at the timepoint; N2 = number of subjects included in the analysis and with valid score at the timepoint.
OD = observed data. Data after dropout or use of rescue therapy was censored.
Mixed Model Repeated Measure (MMRM) contained fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.
Hedges'g was defined as the LSM difference divided by pooled standard deviation.

Least Squares Mean of Change from Baseline in DLQI at Weeks 2, 12, 16, 20 and 26 - MMRM (FAS, OD)
(Protocol B7451050)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Week 20	N1	322	333
	N2 (%)	319 (99.1)	331 (99.4)
	LSM (SE)	-10.77 (0.22)	-10.13 (0.21)
	95% CI	(-11.19, -10.34)	(-10.55, -9.71)
	Abrocitinib - Dupilumab		
	LSM	-0.64	
	95% CI	(-1.23, -0.04)	
	Two-sided P-value	0.0376	
	Hedges'g	-0.16	
	95% CI of Hedges'g	(-0.32, -0.01)	
Week 26	N1	302	323
	N2 (%)	302 (100.0)	323 (100.0)
	LSM (SE)	-10.34 (0.24)	-10.04 (0.24)
	95% CI	(-10.82, -9.86)	(-10.51, -9.57)
	Abrocitinib - Dupilumab		
	LSM	-0.30	
	95% CI	(-0.97, 0.37)	
	Two-sided P-value	0.3814	
	Hedges'g	-0.07	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; DLQI = Dermatology Life Quality Index; LSM = least squares mean;SE = Standard Error; N = number of subjects included in the analysis model;
N1 = number of subjects at risk/eligible at the timepoint; N2 = number of subjects included in the analysis and with valid score at the timepoint.
OD = observed data. Data after dropout or use of rescue therapy was censored.
Mixed Model Repeated Measure (MMRM) contained fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.
Hedges'g was defined as the LSM difference divided by pooled standard deviation.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (01:50) Source Data: adli Table Generation: 12SEP2021 (23:19)
Output File: ./nda1_cdisc/B7451050_GBA/adli_s201

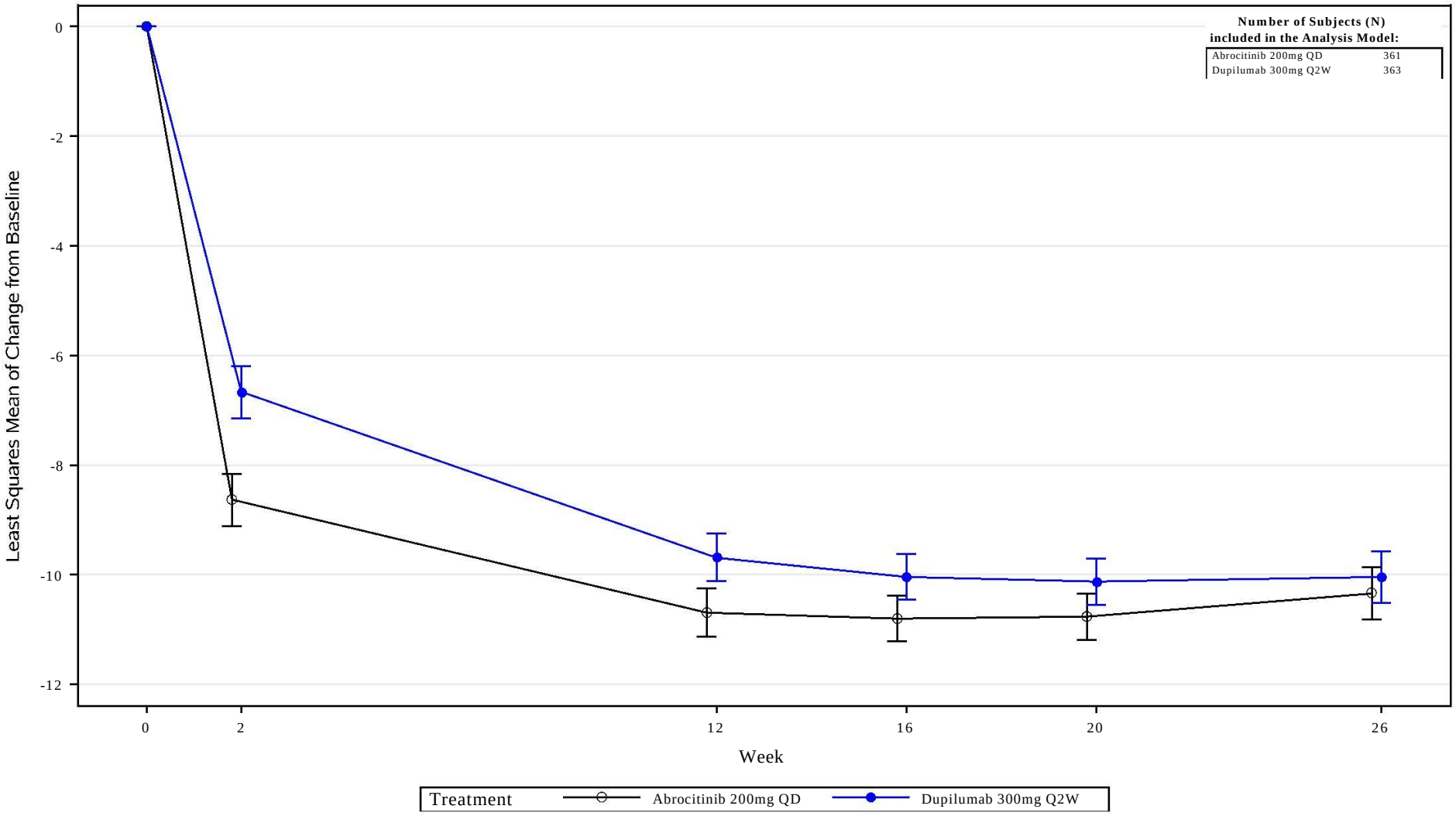
Least Squares Mean of Change from Baseline in DLQI at Weeks 2, 12, 16, 20 and 26 - MMRM (FAS, OD)
(Protocol B7451050)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	95% CI of Hedges'g	(-0.23, 0.09)	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; DLQI = Dermatology Life Quality Index; LSM = least squares mean;SE = Standard Error; N = number of subjects included in the analysis model;
N1 = number of subjects at risk/eligible at the timepoint; N2 = number of subjects included in the analysis and with valid score at the timepoint.
OD = observed data. Data after dropout or use of rescue therapy was censored.
Mixed Model Repeated Measure (MMRM) contained fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.
Hedges'g was defined as the LSM difference divided by pooled standard deviation.

Plot of Least Squares Mean of Change from Baseline in DLQI - MMRM (FAS, OD)
(Protocol B7451050)

Parameter: DLQI Score



Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
Vertical line represented 95% confidence interval.
DLQI = dermatology life quality index; OD = observed data.Data after dropout or use of rescue therapy was censored.
Mixed Model Repeated Measure (MMRM) contained fixed factors of treatment, visit, treatment by visit interaction,
baseline disease severity, baseline value and an unstructured covariance matrix.
PFIZER CONFIDENTIAL SDTM Creation: 22JUN2021 (01:49) Source Data: adli Table Generation: 14SEP2021 (23:40)
Output File: ./nda1_cdisc/B7451050_GBA/adli_f201_1

Descriptive Summary of EQ-5D VAS Score, Absolute Values, Change from Baseline and Percent Change from Baseline up to Week 26 (FAS, OD)
(Protocol B7451050)

		Abrocitinib 200mg QD (N=362)						Dupilumab 300mg Q2W (N=365)					
		n (%)	Mean	Median	SD	Q1	Q3	n (%)	Mean	Median	SD	Q1	Q3
Observed Data	Baseline	362 (100.0)	68.4	72.0	19.5	59.0	80.0	364 (99.7)	67.7	70.0	18.3	58.5	80.0
	Week 12	329 (90.9)	80.5	83.0	15.3	75.0	90.0	341 (93.4)	79.5	81.0	13.4	70.0	90.0
	Week 16	323 (89.2)	80.8	83.0	14.9	75.0	90.0	337 (92.3)	78.5	81.0	15.9	70.0	90.0
	Week 26	303 (83.7)	81.8	85.0	15.3	75.0	92.0	324 (88.8)	82.5	85.0	13.5	76.0	91.0
Change from Baseline	Week 12	329 (90.9)	12.1	10.0	20.3	0.0	20.0	340 (93.2)	11.7	10.0	18.5	0.0	20.0
	Week 16	323 (89.2)	12.2	9.0	20.2	0.0	22.0	336 (92.1)	10.6	10.0	18.2	0.0	20.0
	Week 26	303 (83.7)	13.4	10.0	20.9	1.0	24.0	323 (88.5)	14.6	12.0	18.0	3.0	25.0
Percent Change from Baseline	Week 12	328 (90.6)	32.0	12.6	73.1	0.0	34.4	340 (93.2)	32.1	13.0	82.8	0.0	33.3
	Week 16	322 (89.0)	31.4	11.1	68.8	0.0	36.4	336 (92.1)	26.7	12.5	64.7	0.0	33.3
	Week 26	302 (83.4)	33.8	13.9	73.1	1.3	40.0	323 (88.5)	34.7	15.4	69.5	3.7	41.7

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
EQ-5D VAS Score =EuroQuol Quality of Life 5-Dimension Visual Analog Scale Score; OD = observed data. Data after dropout or use of rescue therapy was censored.
N = number of subjects in the analysis set.
n = number of subjects in the analysis set with observed data at the specified visit.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (01:50) Source Data: ade5 Table Generation: 12SEP2021 (23:49)
Output File: ./nda1_cdisc/B7451050_GBA/ade5_s_g

Least Squares Mean of Change from Baseline in EQ-5D VAS Score at Weeks 12, 16 and 26 - MMRM (FAS, OD)
(Protocol B7451050)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	N	362	364
Week 12	N1	331	342
	N2 (%)	329 (99.4)	340 (99.4)
	LSM (SE)	12.37 (0.74)	11.55 (0.73)
	95% CI	(10.92, 13.82)	(10.12, 12.98)
	Abrocitinib - Dupilumab		
	LSM	0.82	
	95% CI	(-1.22, 2.86)	
	Two-sided P-value	0.4310	
	Hedges'g	0.06	
	95% CI of Hedges'g	(-0.09, 0.21)	
Week 16	N1	328	338
	N2 (%)	323 (98.5)	336 (99.4)
	LSM (SE)	12.57 (0.79)	10.47 (0.78)
	95% CI	(11.02, 14.12)	(8.95, 12.00)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; EQ-5D VAS Score = EuroQuol Quality of Life 5-Dimension Visual Analog Scale Score; SE = Standard Error; LSM = least squares mean;
N = number of subjects included in the analysis model;
N1 = number of subjects at risk/eligible at the timepoint; N2 = number of subjects included in the analysis and with valid score at the timepoint.
OD = observed data. Data after dropout or use of rescue therapy was censored.
Mixed Model Repeated Measure (MMRM) contained fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.
Hedges'g was defined as the LSM difference divided by pooled standard deviation.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (01:50) Source Data: ade5 Table Generation: 12SEP2021 (23:19)
Output File: ./nda1_cdisc/B7451050_GBA/ade5_mk1_1

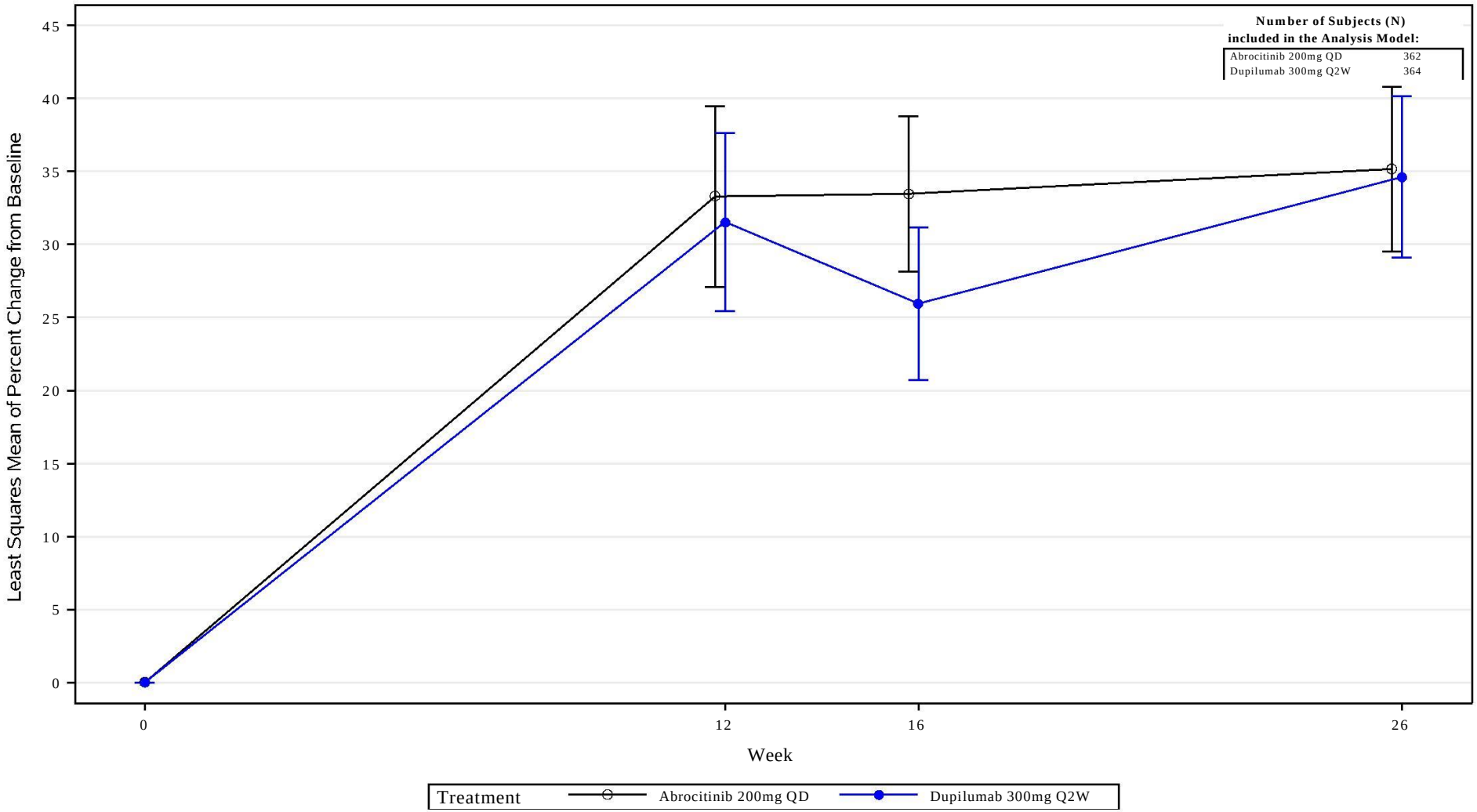
Least Squares Mean of Change from Baseline in EQ-5D VAS Score at Weeks 12, 16 and 26 - MMRM (FAS, OD)
(Protocol B7451050)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib - Dupilumab		
	LSM	2.09	
	95% CI	(-0.08, 4.27)	
	Two-sided P-value	0.0592	
	Hedges'g	0.15	
	95% CI of Hedges'g	(-0.01, 0.30)	
Week 26	N1	303	323
	N2 (%)	303 (100.0)	323 (100.0)
	LSM (SE)	13.48 (0.76)	14.30 (0.75)
	95% CI	(11.98, 14.99)	(12.84, 15.76)
	Abrocitinib - Dupilumab		
	LSM	-0.82	
	95% CI	(-2.91, 1.28)	
	Two-sided P-value	0.4450	
	Hedges'g	-0.06	
	95% CI of Hedges'g	(-0.22, 0.10)	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; EQ-5D VAS Score = EuroQuol Quality of Life 5-Dimension Visual Analog Scale Score; SE = Standard Error; LSM = least squares mean;
N = number of subjects included in the analysis model;
N1 = number of subjects at risk/eligible at the timepoint; N2 = number of subjects included in the analysis and with valid score at the timepoint.
OD = observed data. Data after dropout or use of rescue therapy was censored.
Mixed Model Repeated Measure (MMRM) contained fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.
Hedges'g was defined as the LSM difference divided by pooled standard deviation.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (01:50) Source Data: ade5 Table Generation: 12SEP2021 (23:19)
Output File: ./nda1_cdisc/B7451050_GBA/ade5_mk1_1

Plot of Least Squares Mean of Percent Change from Baseline in EQ-5D VAS Score up to Week 26 (FAS, OD)
(Protocol B7451050)

Parameter: EQ-5D VAS Score



Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
Vertical line represented 95% confidence interval.
EQ-5D VAS Score = EuroQuol Quality of Life 5-Dimension Visual Analog Scale Score; OD = observed data. Data after dropout or use of rescue therapy was censored.
Mixed Model Repeated Measure (MMRM) contained fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (01:50) Source Data: ade5 Table Generation: 13SEP2021 (01:30)
Output File: ./nda1_cdisc/B7451050_GBA/ade5_f_1

Descriptive Summary of POEM, Absolute Values, Change from Baseline and Percent Change from Baseline up to Week 26 (FAS, OD)
(Protocol B7451050)

Parameter: Total Score

		Abrocitinib 200mg QD (N=362)						Dupilumab 300mg Q2W (N=365)					
		n (%)	Mean	Median	SD	Q1	Q3	n (%)	Mean	Median	SD	Q1	Q3
Observed Data	Baseline	362 (100.0)	20.4	21.0	5.8	17.0	25.0	365 (100.0)	20.9	21.0	5.3	18.0	25.0
	Week 12	327 (90.3)	6.3	4.0	6.1	2.0	9.0	341 (93.4)	8.0	6.0	6.2	3.0	11.0
	Week 16	323 (89.2)	6.2	4.0	5.8	2.0	9.0	337 (92.3)	7.8	7.0	5.7	4.0	11.0
	Week 26	303 (83.7)	6.5	5.0	6.4	1.0	10.0	322 (88.2)	7.2	6.0	5.8	3.0	10.0
Change from Baseline	Week 12	327 (90.3)	-14.0	-15.0	7.0	-19.0	-9.0	341 (93.4)	-12.7	-13.0	6.9	-18.0	-8.0
	Week 16	323 (89.2)	-14.1	-15.0	6.8	-19.0	-9.0	337 (92.3)	-12.9	-13.0	6.8	-18.0	-8.0
	Week 26	303 (83.7)	-13.7	-14.0	7.3	-19.0	-9.0	322 (88.2)	-13.5	-14.0	6.6	-18.0	-9.0
Percent Change from Baseline	Week 12	324 (89.5)	-66.5	-77.8	70.5	-91.7	-54.5	341 (93.4)	-59.9	-68.4	33.5	-82.4	-44.4
	Week 16	320 (88.4)	-67.0	-76.9	60.8	-91.1	-53.6	337 (92.3)	-61.1	-65.2	27.9	-81.0	-46.4
	Week 26	300 (82.9)	-65.7	-76.5	58.4	-91.7	-52.6	322 (88.2)	-64.5	-71.4	27.0	-84.0	-47.8

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
POEM = patient-oriented eczema measure; OD = observed data. Data after dropout or use of rescue therapy was censored.
N = number of subjects in the analysis set.
n = number of subjects in the analysis set with observed data at the specified visit.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (03:25) Source Data: adpm Table Generation: 05SEP2021 (10:05)
Output File: ./nda1_cdisc/B7451050_GBA/adpm_s_g

Least Squares Mean of Change from Baseline in POEM Total Score at Weeks 12, 16 and 26 - MMRM (FAS, OD)
(Protocol B7451050)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	N	362	365
Week 12	N1	331	343
	N2 (%)	327 (98.8)	341 (99.4)
	LSM (SE)	-14.23 (0.33)	-12.63 (0.32)
	95% CI	(-14.87, -13.59)	(-13.26, -12.01)
	Abrocitinib - Dupilumab		
	LSM	-1.60	
	95% CI	(-2.49, -0.70)	
	Two-sided P-value	0.0005	
	Hedges'g	-0.27	
	95% CI of Hedges'g	(-0.42, -0.12)	
Week 16	N1	326	338
	N2 (%)	323 (99.1)	337 (99.7)
	LSM (SE)	-14.22 (0.31)	-12.83 (0.30)
	95% CI	(-14.83, -13.62)	(-13.43, -12.24)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; POEM = patient-oriented eczema measure; LSM = least squares mean; SE = Standard Error; N = number of subjects included in the analysis model; N1 = number of subjects at risk/eligible at the timepoint; N2 = number of subjects included in the analysis and with valid score at the timepoint.
OD = observed data. Data after dropout or use of rescue therapy was censored.
Mixed Model Repeated Measure (MMRM) contained fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.
Hedges'g was defined as the LSM difference divided by pooled standard deviation.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (03:25) Source Data: adpm Table Generation: 02SEP2021 (23:49)
Output File: ./nda1_cdisc/B7451050_GBA/adpm_s201_gba

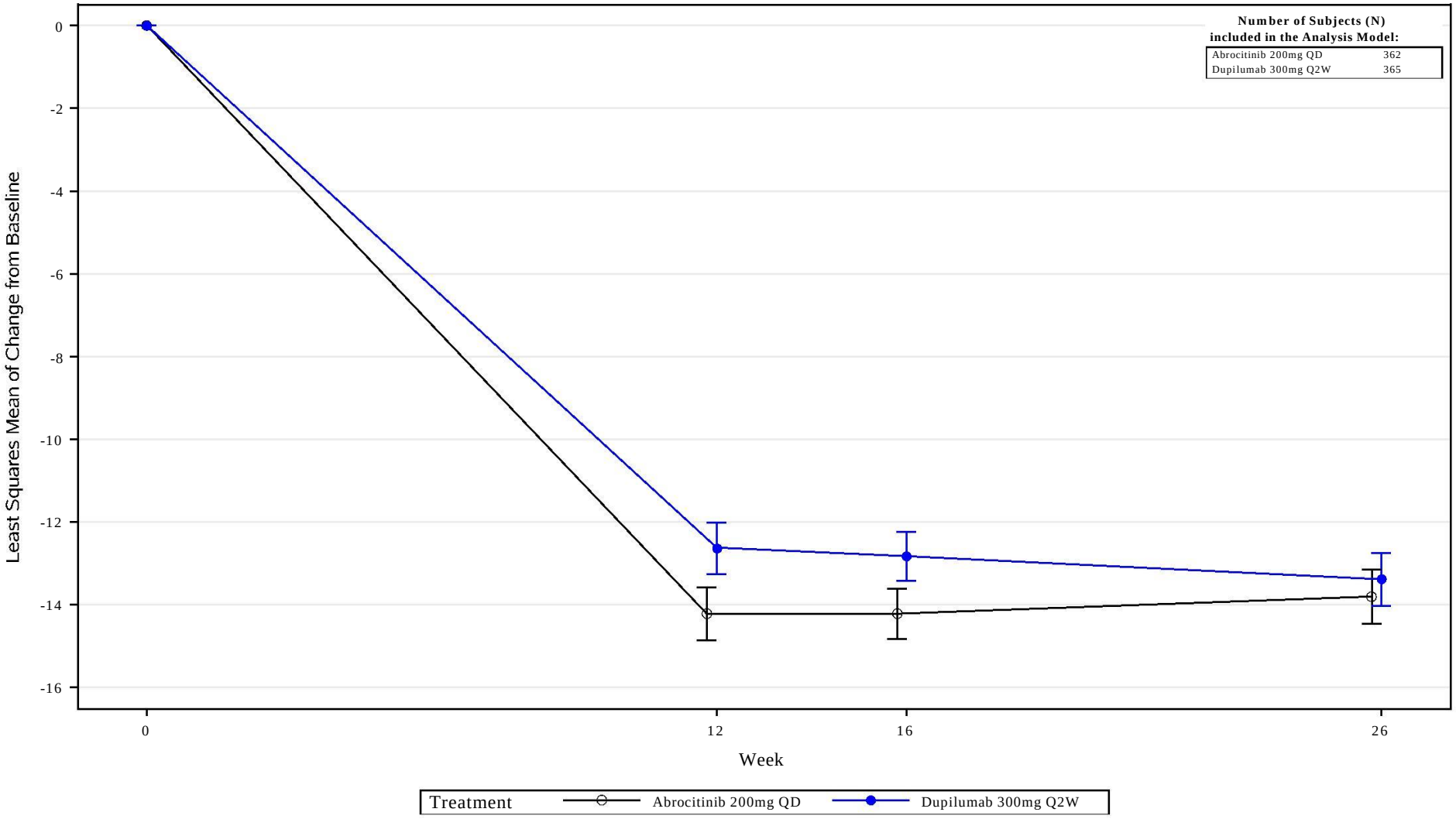
Least Squares Mean of Change from Baseline in POEM Total Score at Weeks 12, 16 and 26 - MMRM (FAS, OD)
(Protocol B7451050)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib - Dupilumab		
	LSM	-1.39	
	95% CI	(-2.24, -0.54)	
	Two-sided P-value	0.0013	
	Hedges'g	-0.25	
	95% CI of Hedges'g	(-0.40, -0.10)	
Week 26	N1	303	322
	N2 (%)	303 (100.0)	322 (100.0)
	LSM (SE)	-13.81 (0.33)	-13.39 (0.33)
	95% CI	(-14.47, -13.15)	(-14.03, -12.75)
	Abrocitinib - Dupilumab		
	LSM	-0.42	
	95% CI	(-1.34, 0.50)	
	Two-sided P-value	0.3684	
	Hedges'g	-0.07	
	95% CI of Hedges'g	(-0.23, 0.09)	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
CI = confidence interval; POEM = patient-oriented eczema measure; LSM = least squares mean; SE = Standard Error; N = number of subjects included in the analysis model; N1 = number of subjects at risk/eligible at the timepoint; N2 = number of subjects included in the analysis and with valid score at the timepoint.
OD = observed data. Data after dropout or use of rescue therapy was censored.
Mixed Model Repeated Measure (MMRM) contained fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.
Hedges'g was defined as the LSM difference divided by pooled standard deviation.

Plot of Least Squares Mean of Change from Baseline in POEM - MMRM (FAS, OD)
(Protocol B7451050)

Parameter: Total Score



Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
Vertical line represented 95% confidence interval.
POEM = patient-oriented eczema measure; OD = observed data. Data after dropout or use of rescue therapy was censored.
Mixed Model Repeated Measure (MMRM) contained fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix.
PFIZER CONFIDENTIAL SDTM Creation: 06AUG2021 (03:25) Source Data: adpm Table Generation: 05SEP2021 (09:35)
Output File: ./nda1_cdisc/B7451050_GBA/adpm_f201

Descriptive Summary of SCORAD Total Score, Change from Baseline and Percent Change from Baseline up to Week 26 (FAS, OD)
(Protocol B7451050)

		Abrocitinib 200mg QD (N=362)						Dupilumab 300mg Q2W (N=365)					
		n (%)	Mean	Median	SD	Q1	Q3	n (%)	Mean	Median	SD	Q1	Q3
Observed Data	Baseline	362 (100.0)	67.8	66.4	12.8	58.9	76.8	365 (100.0)	66.8	65.2	12.7	58.0	75.1
	Week 2	349 (96.4)	38.0	37.8	17.5	25.2	49.4	350 (95.9)	44.4	44.9	18.0	30.4	56.6
	Week 4	340 (93.9)	27.5	25.7	15.8	17.5	35.8	351 (96.2)	35.7	33.8	17.1	23.0	47.4
	Week 8	335 (92.5)	22.9	21.6	15.2	12.1	30.9	348 (95.3)	29.4	27.3	15.6	18.6	39.2
	Week 12	328 (90.6)	20.9	19.3	14.7	10.7	29.3	341 (93.4)	26.1	24.6	14.8	16.1	33.7
	Week 16	324 (89.5)	19.4	18.0	14.9	8.0	26.9	336 (92.1)	23.5	21.2	14.7	14.3	31.2
	Week 20	319 (88.1)	18.3	16.4	14.8	7.2	25.8	333 (91.2)	21.6	19.4	14.7	11.9	30.0
	Week 26	300 (82.9)	18.0	16.4	14.8	5.6	25.7	323 (88.5)	20.9	18.9	14.6	11.5	28.4
Change from Baseline	Week 2	349 (96.4)	-30.0	-29.5	15.2	-40.8	-18.8	350 (95.9)	-22.4	-20.2	16.5	-34.1	-10.5
	Week 4	340 (93.9)	-40.6	-40.5	15.7	-51.0	-30.7	351 (96.2)	-31.0	-29.9	15.9	-41.1	-19.4
	Week 8	335 (92.5)	-45.0	-45.0	16.8	-57.3	-34.8	348 (95.3)	-37.2	-36.7	16.8	-49.1	-25.5
	Week 12	328 (90.6)	-46.9	-47.5	17.6	-57.8	-35.3	341 (93.4)	-40.7	-39.5	16.5	-51.9	-30.3
	Week 16	324 (89.5)	-48.6	-48.9	16.9	-58.8	-38.0	336 (92.1)	-43.3	-43.2	17.5	-53.9	-32.0
	Week 20	319 (88.1)	-49.7	-50.6	17.5	-60.6	-38.4	333 (91.2)	-45.1	-43.9	17.4	-55.9	-34.2
	Week 26	300 (82.9)	-50.0	-50.4	17.3	-60.6	-39.1	323 (88.5)	-45.8	-46.4	17.4	-57.0	-33.8
Percent Change from Baseline	Week 2	349 (96.4)	-44.6	-45.3	22.4	-59.7	-27.0	350 (95.9)	-33.5	-31.1	24.0	-51.5	-15.3
	Week 4	340 (93.9)	-59.8	-61.7	21.3	-73.9	-47.9	351 (96.2)	-46.9	-46.5	22.5	-63.5	-30.1
	Week 8	335 (92.5)	-66.2	-68.6	22.4	-81.2	-54.8	348 (95.3)	-55.7	-56.8	22.5	-72.5	-41.6
	Week 12	328 (90.6)	-68.7	-70.0	21.8	-84.7	-56.4	341 (93.4)	-60.7	-62.2	21.0	-76.1	-49.3
	Week 16	324 (89.5)	-71.4	-73.0	21.0	-88.1	-59.6	336 (92.1)	-64.4	-67.3	21.2	-78.9	-52.9

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
Data after dropout or use of rescue therapy was censored.
SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set; n = number of subjects in the analysis set with observed data at the specified visit;
OD = observed data.
PFIZER CONFIDENTIAL SDTM Creation: 09AUG2021 (01:16) Source Data: adda Table Generation: 15SEP2021 (02:28)
Output File: ./nda1_cdisc/B7451050_GBA/adda_s_g_1

Descriptive Summary of SCORAD Total Score, Change from Baseline and Percent Change from Baseline up to Week 26 (FAS, OD)
(Protocol B7451050)

		Abrocitinib 200mg QD (N=362)						Dupilumab 300mg Q2W (N=365)					
		n (%)	**Mean**	**Median**	**SD**	**Q1**	**Q3**	**n (%)**	**Mean**	**Median**	**SD**	**Q1**	**Q3**
Percent Change from Baseline	Week 20	319 (88.1)	-72.9	-75.6	21.4	-89.7	-60.9	333 (91.2)	-67.3	-70.0	21.2	-81.6	-54.7
	Week 26	300 (82.9)	-73.4	-75.9	21.3	-91.6	-62.4	323 (88.5)	-68.3	-70.3	21.3	-83.2	-57.5

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
Data after dropout or use of rescue therapy was censored.
SCORAD = scoring atopic dermatitis; N = number of subjects in the analysis set; n = number of subjects in the analysis set with observed data at the specified visit;
OD = observed data.

Least Squares Mean of Percent Change from Baseline in SCORAD Total Score - MMRM (FAS, OD)
(Protocol B7451050)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	N	362	365
Week 2	N1	350	353
	N2 (%)	349 (99.7)	350 (99.2)
	LSM (SE)	-44.52 (1.24)	-33.47 (1.24)
	95% CI	(-46.96, -42.09)	(-35.90, -31.05)
	Abrocitinib - Dupilumab		
	LSM	-11.05	
	95% CI	(-14.49, -7.61)	
	Two-sided P-value	<.0001	
	Hedges'g	-0.48	
	95% CI of Hedges'g	(-0.63, -0.33)	
Week 4	N1	349	352
	N2 (%)	340 (97.4)	351 (99.7)
	LSM (SE)	-59.58 (1.18)	-46.83 (1.17)
	95% CI	(-61.90, -57.27)	(-49.13, -44.53)

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
Data after dropout or use of rescue therapy was censored.
CI = confidence interval; SCORAD = scoring atopic dermatitis; LSM = least squares mean; SE = standard error; N = number of subjects included in the analysis model; N1 = number of subjects at risk/eligible at the timepoint; N2 = number of subjects included in the analysis and with valid score at the timepoint; OD = observed data.
Mixed Model Repeated Measure (MMRM) contained fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix. Compound symmetry covariance matrix was used if the model with unstructured covariance did not converge.
Hedges'g was defined as the LSM difference divided by pooled standard deviation.
PFIZER CONFIDENTIAL SDTM Creation: 09AUG2021 (01:16) Source Data: adda Table Generation: 06SEP2021 (02:56)
Output File: ./nda1_cdisc/B7451050_GBA/adda_s101_1

Least Squares Mean of Percent Change from Baseline in SCORAD Total Score - MMRM (FAS, OD)
(Protocol B7451050)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	Abrocitinib - Dupilumab		
	LSM	-12.75	
	95% CI	(-16.02, -9.49)	
	Two-sided P-value	<.0001	
	Hedges'g	-0.58	
	95% CI of Hedges'g	(-0.74, -0.43)	
Week 8	N1	342	351
	N2 (%)	335 (98.0)	348 (99.1)
	LSM (SE)	-65.84 (1.22)	-55.64 (1.20)
	95% CI	(-68.23, -63.45)	(-58.00, -53.27)
	Abrocitinib - Dupilumab		
	LSM	-10.20	
	95% CI	(-13.57, -6.84)	
	Two-sided P-value	<.0001	
	Hedges'g	-0.46	
	95% CI of Hedges'g	(-0.61, -0.30)	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
Data after dropout or use of rescue therapy was censored.
CI = confidence interval; SCORAD = scoring atopic dermatitis; LSM = least squares mean; SE = standard error; N = number of subjects included in the analysis model; N1 = number of subjects at risk/eligible at the timepoint; N2 = number of subjects included in the analysis and with valid score at the timepoint; OD = observed data.
Mixed Model Repeated Measure (MMRM) contained fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix. Compound symmetry covariance matrix was used if the model with unstructured covariance did not converge.
Hedges'g was defined as the LSM difference divided by pooled standard deviation.

Least Squares Mean of Percent Change from Baseline in SCORAD Total Score - MMRM (FAS, OD)
(Protocol B7451050)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Week 12	N1	331	343
	N2 (%)	328 (99.1)	341 (99.4)
	LSM (SE)	-67.90 (1.17)	-60.59 (1.16)
	95% CI	(-70.20, -65.60)	(-62.86, -58.32)
	Abrocitinib - Dupilumab		
	LSM	-7.31	
	95% CI	(-10.54, -4.08)	
	Two-sided P-value	<.0001	
	Hedges'g	-0.34	
	95% CI of Hedges'g	(-0.50, -0.19)	
Week 16	N1	328	341
	N2 (%)	324 (98.8)	336 (98.5)
	LSM (SE)	-70.58 (1.16)	-64.44 (1.14)
	95% CI	(-72.85, -68.31)	(-66.67, -62.20)
	Abrocitinib - Dupilumab		
	LSM	-6.14	
	95% CI	(-9.33, -2.96)	
	Two-sided P-value	0.0002	
	Hedges'g	-0.29	
	95% CI of Hedges'g	(-0.45, -0.14)	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
Data after dropout or use of rescue therapy was censored.
CI = confidence interval; SCORAD = scoring atopic dermatitis; LSM = least squares mean; SE = standard error; N = number of subjects included in the analysis model; N1 = number of subjects at risk/eligible at the timepoint; N2 = number of subjects included in the analysis and with valid score at the timepoint; OD = observed data.
Mixed Model Repeated Measure (MMRM) contained fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix. Compound symmetry covariance matrix was used if the model with unstructured covariance did not converge.
Hedges'g was defined as the LSM difference divided by pooled standard deviation.
PFIZER CONFIDENTIAL SDTM Creation: 09AUG2021 (01:16) Source Data: adda Table Generation: 06SEP2021 (02:56)
Output File: ./nda1_cdisc/B7451050_GBA/adda_s101_1

Least Squares Mean of Percent Change from Baseline in SCORAD Total Score - MMRM (FAS, OD)
(Protocol B7451050)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
Week 20	N1	322	334
	N2 (%)	319 (99.1)	333 (99.7)
	LSM (SE)	-71.78 (1.19)	-66.84 (1.17)
	95% CI	(-74.11, -69.45)	(-69.13, -64.54)
	Abrocitinib - Dupilumab		
	LSM	-4.94	
	95% CI	(-8.22, -1.67)	
	Two-sided P-value	0.0031	
	Hedges'g	-0.23	
	95% CI of Hedges'g	(-0.39, -0.08)	
Week 26	N1	300	323
	N2 (%)	300 (100.0)	323 (100.0)
	LSM (SE)	-71.47 (1.23)	-68.21 (1.20)
	95% CI	(-73.88, -69.06)	(-70.57, -65.86)
	Abrocitinib - Dupilumab		
	LSM	-3.26	
	95% CI	(-6.63, 0.11)	
	Two-sided P-value	0.0578	
	Hedges'g	-0.15	

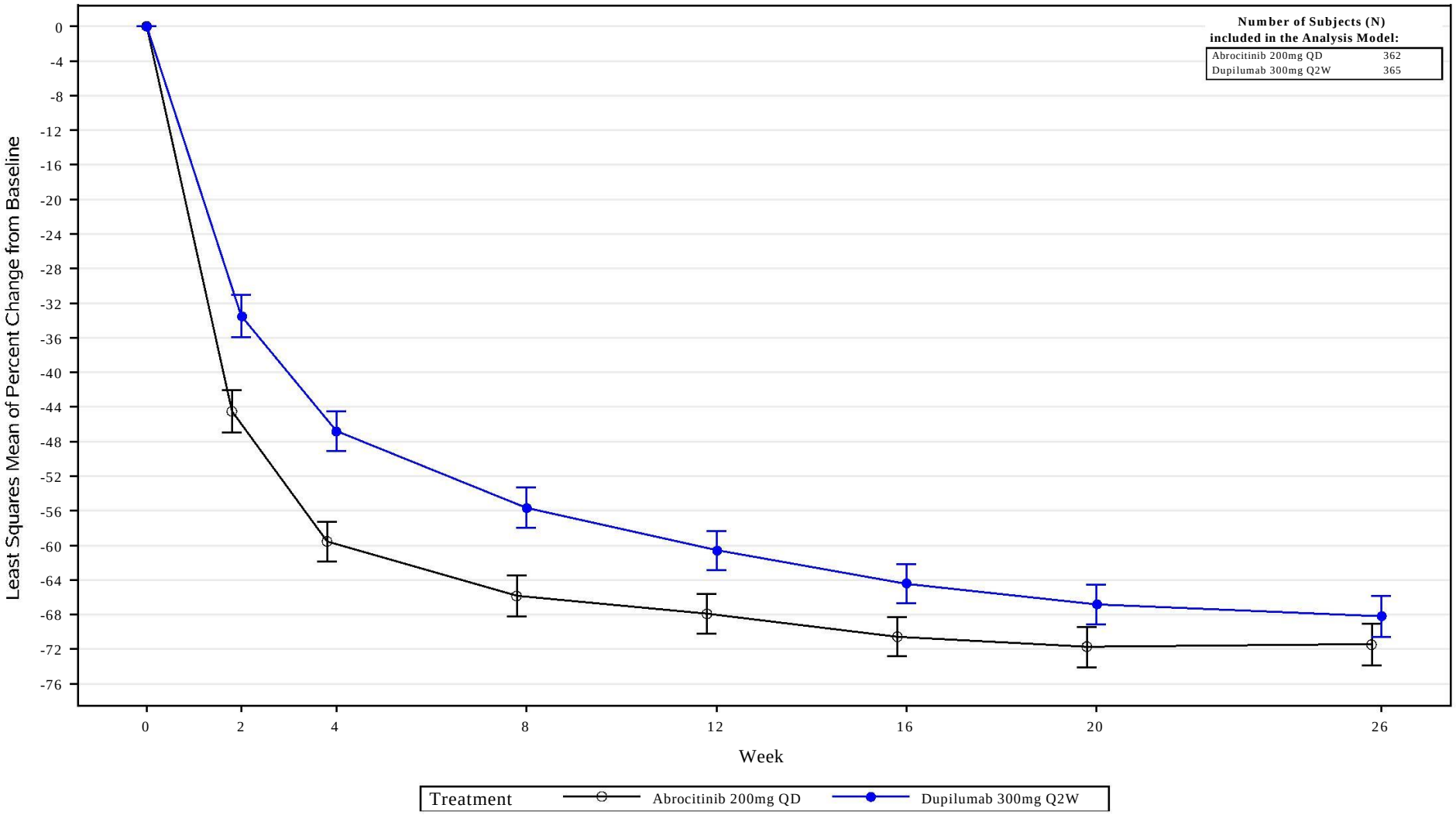
Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
Data after dropout or use of rescue therapy was censored.
CI = confidence interval; SCORAD = scoring atopic dermatitis; LSM = least squares mean; SE = standard error; N = number of subjects included in the analysis model; N1 = number of subjects at risk/eligible at the timepoint; N2 = number of subjects included in the analysis and with valid score at the timepoint; OD = observed data.
Mixed Model Repeated Measure (MMRM) contained fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix. Compound symmetry covariance matrix was used if the model with unstructured covariance did not converge.
Hedges'g was defined as the LSM difference divided by pooled standard deviation.
PFIZER CONFIDENTIAL SDTM Creation: 09AUG2021 (01:16) Source Data: adda Table Generation: 06SEP2021 (02:56)
Output File: ./nda1_cdisc/B7451050_GBA/adda_s101_1

Least Squares Mean of Percent Change from Baseline in SCORAD Total Score - MMRM (FAS, OD)
(Protocol B7451050)

		Abrocitinib 200mg QD	Dupilumab 300mg Q2W
	95% CI of Hedges'g	(-0.31, 0.01)	

Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
Data after dropout or use of rescue therapy was censored.
CI = confidence interval; SCORAD = scoring atopic dermatitis; LSM = least squares mean; SE = standard error; N = number of subjects included in the analysis model; N1 = number of subjects at risk/eligible at the timepoint; N2 = number of subjects included in the analysis and with valid score at the timepoint; OD = observed data.
Mixed Model Repeated Measure (MMRM) contained fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix. Compound symmetry covariance matrix was used if the model with unstructured covariance did not converge.
Hedges'g was defined as the LSM difference divided by pooled standard deviation.

Plot of Least Squares Mean of Percent Change from Baseline in SCORAD Total Score - MMRM (FAS, OD)
(Protocol B7451050)



Full Analysis Set (FAS) was defined as all randomized subjects who received at least one dose of study medication.
Baseline was defined as the measurement collected on or prior to Day 1.
Data after dropout or use of rescue therapy was censored.
Mixed Model Repeated Measure (MMRM) contained fixed factors of treatment, visit, treatment by visit interaction, baseline disease severity, baseline value and an unstructured covariance matrix. Compound symmetry covariance matrix was used if the model with unstructured covariance did not converge.
Vertical line represented 95% confidence interval.
SCORAD = scoring atopic dermatitis; OD = observed data.
PFIZER CONFIDENTIAL SDTM Creation: 09AUG2021 (01:16) Source Data: adda Table Generation: 06SEP2021 (05:51)
Output File: ./nda1_cdisc/B7451050_GBA/adda_f101_1

Responderanalysen JADE TEEN (Woche 12)

Binary Outcome Analysis: SCORAD-75 response at week 12 - Full Analysis Set Safety Population
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Week 12									
Full Analysis Set Safety Population	93	32 (34.4%) (24.9%, 45.0%)	96	12 (12.5%) (6.6%, 20.8%)	3.58 (1.71, 7.48)	2.71 (1.50, 4.90)	21.8% (10.0%, 33.6%)	0.0004+*	--
Baseline Disease Severity									
Week 12									
Moderate baseline disease (IGA=3)	61	20 (32.8%) (21.3%, 46.0%)	57	9 (15.8%) (7.5%, 27.9%)	2.60 (1.07, 6.34)	2.08 (1.03, 4.18)	17.0% (1.9%, 32.1%)	0.0352*	0.3459
Severe baseline disease (IGA=4)	32	12 (37.5%) (21.1%, 56.3%)	39	3 (7.7%) (1.6%, 20.9%)	7.20 (1.81, 28.57)	4.88 (1.50, 15.80)	29.8% (11.1%, 48.6%)	0.0031*	
Gender									
Week 12									
Male	56	22 (39.3%) (26.5%, 53.2%)	44	5 (11.4%) (3.8%, 24.6%)	5.05 (1.72, 14.78)	3.46 (1.42, 8.39)	27.9% (12.1%, 43.8%)	0.0028*	0.2167
Female	37	10 (27.0%) (13.8%, 44.1%)	52	7 (13.5%) (5.6%, 25.8%)	2.38 (0.81, 6.99)	2.01 (0.84, 4.79)	13.6% (-3.5%, 30.6%)	0.1702	

Notes:
Number of subjects: Full Analysis Set Safety Population
Analysis on overall population is calculated based on stratified CMH (Cochran-Mantel-Haenszel) models, for OR, RR, and RD, stratified by by disease activity (moderate, severe) at enrollment.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: SCORAD-75 response at week 12 - Full Analysis Set Safety Population
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Region									
Week 12									
US/Canada/Australia	28	7 (25.0%) (10.7%, 44.9%)	33	9 (27.3%) (13.3%, 45.5%)	0.89 (0.28, 2.80)	0.92 (0.39, 2.14)	-2.3% (-24.4%, 19.8%)	1.0000	0.0464*
Europe	28	10 (35.7%) (18.6%, 55.9%)	27	0 (0.0%)	31.22 (1.72, 565.97)	20.28 (1.25, 329.82)	34.4% (16.3%, 52.6%)	0.0007*	
Asia	28	13 (46.4%) (27.5%, 66.1%)	29	2 (6.9%) (0.8%, 22.8%)	11.70 (2.32, 58.94)	6.73 (1.67, 27.17)	39.5% (18.9%, 60.2%)	0.0008*	
Latin America	9	2 (22.2%) (2.8%, 60.0%)	7	1 (14.3%) (0.4%, 57.9%)	1.71 (0.12, 23.94)	1.56 (0.17, 13.87)	7.9% (-29.6%, 45.5%)	1.0000	
Weight Subgroup									
Week 12									
<= Median Value	46	17 (37.0%) (23.2%, 52.5%)	53	7 (13.2%) (5.5%, 25.3%)	3.85 (1.42, 10.42)	2.80 (1.27, 6.14)	23.7% (7.1%, 40.4%)	0.0091*	0.7273
> Median Value	47	15 (31.9%) (19.1%, 47.1%)	43	5 (11.6%) (3.9%, 25.1%)	3.56 (1.17, 10.88)	2.74 (1.09, 6.91)	20.3% (3.9%, 36.7%)	0.0242*	
Age Subgroup									
Week 12									
<= Median Value	56	19 (33.9%) (21.8%, 47.8%)	60	8 (13.3%) (5.9%, 24.6%)	3.34 (1.32, 8.44)	2.54 (1.21, 5.34)	20.6% (5.5%, 35.7%)	0.0147*	0.7994
> Median Value	37	13 (35.1%) (20.2%, 52.5%)	36	4 (11.1%) (3.1%, 26.1%)	4.33 (1.25, 14.96)	3.16 (1.14, 8.79)	24.0% (5.5%, 42.5%)	0.0252*	

Notes:
Number of subjects: Full Analysis Set Safety Population
Analysis on overall population is calculated based on stratified CMH (Cochran-Mantel-Haenszel) models, for OR, RR, and RD, stratified by by disease activity (moderate, severe) at enrollment.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: SCORAD-90 response at week 12 - Full Analysis Set Safety Population
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Week 12									
Full Analysis Set Safety Population	93	11 (11.8%) (6.1%, 20.2%)	96	4 (4.2%) (1.1%, 10.3%)	3.00 (0.92, 9.80)	2.75 (0.91, 8.29)	7.5% (-0.2%, 15.2%)	0.0591+	--
Baseline Disease Severity									
Week 12									
Moderate baseline disease (IGA=3)	61	8 (13.1%) (5.8%, 24.2%)	57	3 (5.3%) (1.1%, 14.6%)	2.72 (0.68, 10.80)	2.49 (0.70, 8.93)	7.9% (-2.4%, 18.1%)	0.2071	0.8706
Severe baseline disease (IGA=4)	32	3 (9.4%) (2.0%, 25.0%)	39	1 (2.6%) (0.1%, 13.5%)	3.93 (0.39, 39.77)	3.66 (0.40, 33.48)	6.8% (-4.4%, 18.1%)	0.3207	
Gender									
Week 12									
Male	56	9 (16.1%) (7.6%, 28.3%)	44	2 (4.5%) (0.6%, 15.5%)	4.02 (0.82, 19.67)	3.54 (0.80, 15.54)	11.5% (0.1%, 22.9%)	0.1061	0.1836
Female	37	2 (5.4%) (0.7%, 18.2%)	52	2 (3.8%) (0.5%, 13.2%)	1.43 (0.19, 10.63)	1.41 (0.21, 9.53)	1.6% (-7.4%, 10.5%)	1.0000	

Notes:
Number of subjects: Full Analysis Set Safety Population
Analysis on overall population is calculated based on stratified CMH (Cochran-Mantel-Haenszel) models, for OR, RR, and RD, stratified by by disease activity (moderate, severe) at enrollment.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: SCORAD-90 response at week 12 - Full Analysis Set Safety Population
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Region									
Week 12									
US/Canada/Australia	28	2 (7.1%) (0.9%, 23.5%)	33	3 (9.1%) (1.9%, 24.3%)	0.77 (0.12, 4.96)	0.79 (0.14, 4.37)	-1.9% (-15.6%, 11.7%)	1.0000	0.1135
Europe	28	4 (14.3%) (4.0%, 32.7%)	27	0 (0.0%)	10.10 (0.52, 197.31)	8.69 (0.49, 154.06)	13.7% (-0.3%, 27.8%)	0.1115	
Asia	28	5 (17.9%) (6.1%, 36.9%)	29	0 (0.0%)	13.81 (0.73, 262.60)	11.38 (0.66, 196.67)	17.3% (2.3%, 32.3%)	0.0235*	
Latin America	9	0 (0.0%)	7	1 (14.3%) (0.4%, 57.9%)	0.23 (0.01, 6.52)	0.27 (0.01, 5.70)	-13.8% (-44.0%, 16.5%)	0.4375	
Weight Subgroup									
Week 12									
<= Median Value	46	4 (8.7%) (2.4%, 20.8%)	53	1 (1.9%) (0.0%, 10.1%)	4.95 (0.53, 46.00)	4.61 (0.53, 39.78)	6.8% (-2.1%, 15.7%)	0.1802	0.8482
> Median Value	47	7 (14.9%) (6.2%, 28.3%)	43	3 (7.0%) (1.5%, 19.1%)	2.33 (0.56, 9.67)	2.13 (0.59, 7.74)	7.9% (-4.8%, 20.6%)	0.3202	
Age Subgroup									
Week 12									
<= Median Value	56	6 (10.7%) (4.0%, 21.9%)	60	2 (3.3%) (0.4%, 11.5%)	3.48 (0.67, 18.02)	3.21 (0.68, 15.27)	7.4% (-1.9%, 16.7%)	0.1527	0.9259
> Median Value	37	5 (13.5%) (4.5%, 28.8%)	36	2 (5.6%) (0.7%, 18.7%)	2.66 (0.48, 14.68)	2.43 (0.50, 11.74)	8.0% (-5.4%, 21.3%)	0.4297	

Notes:
Number of subjects: Full Analysis Set Safety Population
Analysis on overall population is calculated based on stratified CMH (Cochran-Mantel-Haenszel) models, for OR, RR, and RD, stratified by by disease activity (moderate, severe) at enrollment.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: SCORAD-100 response at week 12 - Full Analysis Set Safety Population
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Week 12									
Full Analysis Set Safety Population	93	3 (3.2%) (0.7%, 9.1%)	96	1 (1.0%) (0.0%, 5.7%)	2.90 (0.29, 28.68)	2.80 (0.30, 26.18)	2.0% (-2.1%, 6.1%)	0.3447+	--
Baseline Disease Severity									
Week 12									
Moderate baseline disease (IGA=3)	61	3 (4.9%) (1.0%, 13.7%)	57	1 (1.8%) (0.0%, 9.4%)	2.90 (0.29, 28.68)	2.80 (0.30, 26.18)	3.2% (-3.2%, 9.6%)	0.6194	0.5059
Severe baseline disease (IGA=4)	32	0 (0.0%)	39	0 (0.0%)	1.22 (0.02, 62.95)	1.21 (0.02, 59.45)	0.3% (-5.1%, 5.7%)	NE	
Gender									
Week 12									
Male	56	3 (5.4%) (1.1%, 14.9%)	44	0 (0.0%)	5.82 (0.29, 115.75)	5.53 (0.29, 104.25)	5.0% (-1.9%, 12.0%)	0.2533	0.1699
Female	37	0 (0.0%)	52	1 (1.9%) (0.0%, 10.3%)	0.46 (0.02, 11.55)	0.46 (0.02, 11.11)	-1.5% (-7.3%, 4.2%)	1.0000	

Notes:
Number of subjects: Full Analysis Set Safety Population
Analysis on overall population is calculated based on stratified CMH (Cochran-Mantel-Haenszel) models, for OR, RR, and RD, stratified by by disease activity (moderate, severe) at enrollment.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: SCORAD-100 response at week 12 - Full Analysis Set Safety Population
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Region									
Week 12									
US/Canada/Australia	28	1 (3.6%) (0.1%, 18.3%)	33	1 (3.0%) (0.1%, 15.8%)	1.19 (0.07, 19.86)	1.18 (0.08, 17.99)	0.5% (-8.5%, 9.6%)	1.0000	0.9486
Europe	28	1 (3.6%) (0.1%, 18.3%)	27	0 (0.0%)	3.00 (0.12, 76.91)	2.90 (0.12, 68.15)	3.4% (-6.0%, 12.8%)	1.0000	
Asia	28	1 (3.6%) (0.1%, 18.3%)	29	0 (0.0%)	3.22 (0.13, 82.38)	3.10 (0.13, 73.12)	3.5% (-5.8%, 12.8%)	0.4912	
Latin America	9	0 (0.0%)	7	0 (0.0%)	0.79 (0.01, 44.65)	0.80 (0.02, 36.05)	-1.3% (-22.8%, 20.3%)	NE	
Weight Subgroup									
Week 12									
<= Median Value	46	2 (4.3%) (0.5%, 14.8%)	53	0 (0.0%)	6.01 (0.28, 128.50)	5.74 (0.28, 116.67)	4.4% (-2.5%, 11.3%)	0.2134	0.3183
> Median Value	47	1 (2.1%) (0.1%, 11.3%)	43	1 (2.3%) (0.1%, 12.3%)	0.91 (0.06, 15.06)	0.91 (0.06, 14.18)	-0.2% (-6.3%, 5.9%)	1.0000	
Age Subgroup									
Week 12									
<= Median Value	56	2 (3.6%) (0.4%, 12.3%)	60	1 (1.7%) (0.0%, 8.9%)	2.19 (0.19, 24.79)	2.14 (0.20, 22.98)	1.9% (-3.9%, 7.7%)	0.6089	0.8841
> Median Value	37	1 (2.7%) (0.1%, 14.2%)	36	0 (0.0%)	3.00 (0.12, 76.09)	2.92 (0.12, 69.43)	2.6% (-4.6%, 9.8%)	1.0000	

Notes:
Number of subjects: Full Analysis Set Safety Population
Analysis on overall population is calculated based on stratified CMH (Cochran-Mantel-Haenszel) models, for OR, RR, and RD, stratified by by disease activity (moderate, severe) at enrollment.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: EASI-75 response at week 12 - Full Analysis Set Safety Population
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Week 12									
Full Analysis Set Safety Population	94	67 (71.3%) (61.0%, 80.1%)	96	39 (40.6%) (30.7%, 51.1%)	3.46 (1.89, 6.31)	1.71 (1.31, 2.24)	29.7% (16.2%, 43.3%)	<0.0001+*	--
Baseline Disease Severity									
Week 12									
Moderate baseline disease (IGA=3)	61	43 (70.5%) (57.4%, 81.5%)	57	31 (54.4%) (40.7%, 67.6%)	2.00 (0.94, 4.28)	1.30 (0.97, 1.73)	16.1% (-1.2%, 33.4%)	0.0874	0.0873
Severe baseline disease (IGA=4)	33	24 (72.7%) (54.5%, 86.7%)	39	8 (20.5%) (9.3%, 36.5%)	10.33 (3.47, 30.77)	3.55 (1.85, 6.81)	52.2% (32.4%, 72.0%)	<0.0001*	
Gender									
Week 12									
Male	56	40 (71.4%) (57.8%, 82.7%)	44	14 (31.8%) (18.6%, 47.6%)	5.36 (2.27, 12.65)	2.24 (1.41, 3.57)	39.6% (21.5%, 57.8%)	0.0001*	0.4468
Female	38	27 (71.1%) (54.1%, 84.6%)	52	25 (48.1%) (34.0%, 62.4%)	2.65 (1.09, 6.44)	1.48 (1.04, 2.09)	23.0% (3.2%, 42.8%)	0.0332*	

Notes:
Number of subjects: Full Analysis Set Safety Population
Analysis on overall population is calculated based on stratified CMH (Cochran-Mantel-Haenszel) models, for OR, RR, and RD, stratified by by disease activity (moderate, severe) at enrollment.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: EASI-75 response at week 12 - Full Analysis Set Safety Population
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Region									
Week 12									
US/Canada/Australia	28	20 (71.4%) (51.3%, 86.8%)	33	20 (60.6%) (42.1%, 77.1%)	1.63 (0.55, 4.77)	1.18 (0.82, 1.69)	10.8% (-12.8%, 34.4%)	0.4269	0.0303*
Europe	29	22 (75.9%) (56.5%, 89.7%)	27	5 (18.5%) (6.3%, 38.1%)	13.83 (3.80, 50.28)	4.10 (1.81, 9.28)	57.3% (36.0%, 78.7%)	<0.0001*	
Asia	28	22 (78.6%) (59.0%, 91.7%)	29	11 (37.9%) (20.7%, 57.7%)	6.00 (1.86, 19.40)	2.07 (1.25, 3.43)	40.6% (17.3%, 63.9%)	0.0030*	
Latin America	9	3 (33.3%) (7.5%, 70.1%)	7	3 (42.9%) (9.9%, 81.6%)	0.67 (0.09, 5.13)	0.78 (0.22, 2.74)	-9.5% (-57.4%, 38.4%)	1.0000	
Weight Subgroup									
Week 12									
<= Median Value	46	35 (76.1%) (61.2%, 87.4%)	53	22 (41.5%) (28.1%, 55.9%)	4.48 (1.88, 10.71)	1.83 (1.28, 2.62)	34.6% (16.5%, 52.7%)	0.0006*	0.4191
> Median Value	48	32 (66.7%) (51.6%, 79.6%)	43	17 (39.5%) (25.0%, 55.6%)	3.06 (1.30, 7.20)	1.69 (1.11, 2.57)	27.1% (7.3%, 46.9%)	0.0120*	
Age Subgroup									
Week 12									
<= Median Value	57	40 (70.2%) (56.6%, 81.6%)	60	25 (41.7%) (29.1%, 55.1%)	3.29 (1.53, 7.08)	1.68 (1.19, 2.38)	28.5% (11.3%, 45.7%)	0.0028*	0.7006
> Median Value	37	27 (73.0%) (55.9%, 86.2%)	36	14 (38.9%) (23.1%, 56.5%)	4.24 (1.58, 11.39)	1.88 (1.19, 2.95)	34.1% (12.7%, 55.5%)	0.0047*	

Notes:
Number of subjects: Full Analysis Set Safety Population
Analysis on overall population is calculated based on stratified CMH (Cochran-Mantel-Haenszel) models, for OR, RR, and RD, stratified by by disease activity (moderate, severe) at enrollment.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: EASI-90 response at week 12 - Full Analysis Set Safety Population
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Week 12									
Full Analysis Set Safety Population	94	46 (48.9%) (38.5%, 59.5%)	96	17 (17.7%) (10.7%, 26.8%)	4.40 (2.26, 8.54)	2.72 (1.69, 4.37)	30.8% (18.2%, 43.5%)	<0.0001+*	--
Baseline Disease Severity									
Week 12									
Moderate baseline disease (IGA=3)	61	31 (50.8%) (37.7%, 63.9%)	57	12 (21.1%) (11.4%, 33.9%)	3.88 (1.72, 8.72)	2.41 (1.38, 4.23)	29.8% (13.4%, 46.2%)	0.0011*	0.9846
Severe baseline disease (IGA=4)	33	15 (45.5%) (28.1%, 63.6%)	39	5 (12.8%) (4.3%, 27.4%)	5.67 (1.77, 18.12)	3.55 (1.44, 8.72)	32.6% (12.7%, 52.6%)	0.0033*	
Gender									
Week 12									
Male	56	29 (51.8%) (38.0%, 65.3%)	44	7 (15.9%) (6.6%, 30.1%)	5.68 (2.17, 14.87)	3.26 (1.58, 6.72)	35.9% (18.9%, 52.8%)	0.0003*	0.4307
Female	38	17 (44.7%) (28.6%, 61.7%)	52	10 (19.2%) (9.6%, 32.5%)	3.40 (1.33, 8.71)	2.33 (1.20, 4.50)	25.5% (6.4%, 44.6%)	0.0113*	

Notes:
Number of subjects: Full Analysis Set Safety Population
Analysis on overall population is calculated based on stratified CMH (Cochran-Mantel-Haenszel) models, for OR, RR, and RD, stratified by by disease activity (moderate, severe) at enrollment.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: EASI-90 response at week 12 - Full Analysis Set Safety Population
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Region									
Week 12									
US/Canada/Australia	28	12 (42.9%) (24.5%, 62.8%)	33	10 (30.3%) (15.6%, 48.7%)	1.73 (0.60, 4.95)	1.41 (0.72, 2.77)	12.6% (-11.6%, 36.7%)	0.4231	0.2462
Europe	29	15 (51.7%) (32.5%, 70.6%)	27	2 (7.4%) (0.9%, 24.3%)	13.39 (2.67, 67.27)	6.98 (1.76, 27.73)	44.3% (23.6%, 65.0%)	0.0004*	
Asia	28	16 (57.1%) (37.2%, 75.5%)	29	4 (13.8%) (3.9%, 31.7%)	8.33 (2.28, 30.39)	4.14 (1.58, 10.87)	43.3% (21.1%, 65.6%)	0.0008*	
Latin America	9	3 (33.3%) (7.5%, 70.1%)	7	1 (14.3%) (0.4%, 57.9%)	3.00 (0.24, 37.67)	2.33 (0.30, 17.88)	19.0% (-21.2%, 59.3%)	0.5846	
Weight Subgroup									
Week 12									
<= Median Value	46	23 (50.0%) (34.9%, 65.1%)	53	8 (15.1%) (6.7%, 27.6%)	5.63 (2.18, 14.52)	3.31 (1.64, 6.68)	34.9% (17.5%, 52.3%)	0.0002*	0.6171
> Median Value	48	23 (47.9%) (33.3%, 62.8%)	43	9 (20.9%) (10.0%, 36.0%)	3.48 (1.37, 8.79)	2.29 (1.19, 4.39)	27.0% (8.3%, 45.6%)	0.0087*	
Age Subgroup									
Week 12									
<= Median Value	57	27 (47.4%) (34.0%, 61.0%)	60	12 (20.0%) (10.8%, 32.3%)	3.60 (1.59, 8.16)	2.37 (1.33, 4.21)	27.4% (10.9%, 43.8%)	0.0030*	0.5035
> Median Value	37	19 (51.4%) (34.4%, 68.1%)	36	5 (13.9%) (4.7%, 29.5%)	6.54 (2.09, 20.54)	3.70 (1.55, 8.84)	37.5% (17.8%, 57.1%)	0.0010*	

Notes:
Number of subjects: Full Analysis Set Safety Population
Analysis on overall population is calculated based on stratified CMH (Cochran-Mantel-Haenszel) models, for OR, RR, and RD, stratified by by disease activity (moderate, severe) at enrollment.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: EASI-100 response at week 12 - Full Analysis Set Safety Population
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Week 12									
Full Analysis Set Safety Population	94	8 (8.5%) (3.7%, 16.1%)	96	2 (2.1%) (0.3%, 7.3%)	4.16 (0.85, 20.30)	3.79 (0.85, 17.01)	6.1% (-0.2%, 12.4%)	0.0590+	--
Baseline Disease Severity									
Week 12									
Moderate baseline disease (IGA=3)	61	7 (11.5%) (4.7%, 22.2%)	57	2 (3.5%) (0.4%, 12.1%)	3.56 (0.71, 17.94)	3.27 (0.71, 15.10)	8.0% (-1.3%, 17.3%)	0.1650	0.4321
Severe baseline disease (IGA=4)	33	1 (3.0%) (0.1%, 15.8%)	39	0 (0.0%)	3.65 (0.14, 92.55)	3.53 (0.15, 83.84)	3.2% (-4.6%, 10.9%)	0.4583	
Gender									
Week 12									
Male	56	6 (10.7%) (4.0%, 21.9%)	44	0 (0.0%)	11.46 (0.63, 209.14)	10.26 (0.59, 177.39)	10.3% (1.5%, 19.1%)	0.0332*	0.1811
Female	38	2 (5.3%) (0.6%, 17.7%)	52	2 (3.8%) (0.5%, 13.2%)	1.39 (0.19, 10.33)	1.37 (0.20, 9.29)	1.4% (-7.4%, 10.2%)	1.0000	

Notes:
Number of subjects: Full Analysis Set Safety Population
Analysis on overall population is calculated based on stratified CMH (Cochran-Mantel-Haenszel) models, for OR, RR, and RD, stratified by by disease activity (moderate, severe) at enrollment.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: EASI-100 response at week 12 - Full Analysis Set Safety Population
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Region									
Week 12									
US/Canada/Australia	28	1 (3.6%) (0.1%, 18.3%)	33	2 (6.1%) (0.7%, 20.2%)	0.57 (0.05, 6.69)	0.59 (0.06, 6.16)	-2.5% (-13.1%, 8.2%)	1.0000	0.2550
Europe	29	4 (13.8%) (3.9%, 31.7%)	27	0 (0.0%)	9.71 (0.50, 189.38)	8.40 (0.47, 149.04)	13.2% (-0.5%, 26.9%)	0.1124	
Asia	28	3 (10.7%) (2.3%, 28.2%)	29	0 (0.0%)	8.10 (0.40, 164.32)	7.24 (0.39, 134.12)	10.4% (-2.3%, 23.1%)	0.1120	
Latin America	9	0 (0.0%)	7	0 (0.0%)	0.79 (0.01, 44.65)	0.80 (0.02, 36.05)	-1.3% (-22.8%, 20.3%)	NE	
Weight Subgroup									
Week 12									
<= Median Value	46	5 (10.9%) (3.6%, 23.6%)	53	1 (1.9%) (0.0%, 10.1%)	6.34 (0.71, 56.42)	5.76 (0.70, 47.54)	9.0% (-0.7%, 18.7%)	0.0937	0.4285
> Median Value	48	3 (6.3%) (1.3%, 17.2%)	43	1 (2.3%) (0.1%, 12.3%)	2.80 (0.28, 27.98)	2.69 (0.29, 24.88)	3.9% (-4.3%, 12.1%)	0.6189	
Age Subgroup									
Week 12									
<= Median Value	57	5 (8.8%) (2.9%, 19.3%)	60	2 (3.3%) (0.4%, 11.5%)	2.79 (0.52, 14.99)	2.63 (0.53, 13.02)	5.4% (-3.2%, 14.1%)	0.2640	0.7276
> Median Value	37	3 (8.1%) (1.7%, 21.9%)	36	0 (0.0%)	7.41 (0.37, 148.68)	6.82 (0.36, 127.44)	7.9% (-2.1%, 17.8%)	0.2397	

Notes:
Number of subjects: Full Analysis Set Safety Population
Analysis on overall population is calculated based on stratified CMH (Cochran-Mantel-Haenszel) models, for OR, RR, and RD, stratified by by disease activity (moderate, severe) at enrollment.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Achieving 0-2 in POEM total score at week 12 - Full Analysis Set Safety Population
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Week 12									
Full Analysis Set Safety Population	94	18 (19.1%) (11.8%, 28.6%)	95	6 (6.3%) (2.4%, 13.2%)	3.59 (1.35, 9.54)	3.08 (1.27, 7.45)	13.0% (3.7%, 22.3%)	0.0077+*	--
Baseline Disease Severity									
Week 12									
Moderate baseline disease (IGA=3)	61	11 (18.0%) (9.4%, 30.0%)	56	3 (5.4%) (1.1%, 14.9%)	3.89 (1.02, 14.75)	3.37 (0.99, 11.45)	12.7% (1.4%, 24.0%)	0.0460*	0.9046
Severe baseline disease (IGA=4)	33	7 (21.2%) (9.0%, 38.9%)	39	3 (7.7%) (1.6%, 20.9%)	3.23 (0.76, 13.68)	2.76 (0.77, 9.82)	13.5% (-2.7%, 29.8%)	0.1698	
Gender									
Week 12									
Male	56	11 (19.6%) (10.2%, 32.4%)	44	4 (9.1%) (2.5%, 21.7%)	2.44 (0.72, 8.29)	2.16 (0.74, 6.33)	10.6% (-2.9%, 24.0%)	0.1683	0.7260
Female	38	7 (18.4%) (7.7%, 34.3%)	51	2 (3.9%) (0.5%, 13.5%)	5.53 (1.08, 28.37)	4.70 (1.03, 21.36)	14.5% (1.1%, 27.9%)	0.0343*	

Notes:
Number of subjects: Full Analysis Set Safety Population
Number of subjects: Full Analysis Set Safety Population, excluding subjects with baseline POEM 0-2.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Achieving 0-2 in POEM total score at week 12 - Full Analysis Set Safety Population
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Region									
Week 12									
US/Canada/Australia	28	5 (17.9%) (6.1%, 36.9%)	32	6 (18.8%) (7.2%, 36.4%)	0.94 (0.25, 3.50)	0.95 (0.33, 2.78)	-0.9% (-20.5%, 18.7%)	1.0000	0.1239
Europe	29	8 (27.6%) (12.7%, 47.2%)	27	0 (0.0%)	21.74 (1.19, 398.13)	15.87 (0.96, 262.30)	26.5% (9.7%, 43.4%)	0.0046*	
Asia	28	5 (17.9%) (6.1%, 36.9%)	29	0 (0.0%)	13.81 (0.73, 262.60)	11.38 (0.66, 196.67)	17.3% (2.3%, 32.3%)	0.0235*	
Latin America	9	0 (0.0%)	7	0 (0.0%)	0.79 (0.01, 44.65)	0.80 (0.02, 36.05)	-1.3% (-22.8%, 20.3%)	NE	
Weight Subgroup									
Week 12									
<= Median Value	46	8 (17.4%) (7.8%, 31.4%)	52	0 (0.0%)	23.18 (1.30, 413.93)	19.17 (1.14, 323.23)	17.1% (5.8%, 28.4%)	0.0017*	0.3671
> Median Value	48	10 (20.8%) (10.5%, 35.0%)	43	6 (14.0%) (5.3%, 27.9%)	1.62 (0.54, 4.92)	1.49 (0.59, 3.76)	6.9% (-8.6%, 22.3%)	0.4230	
Age Subgroup									
Week 12									
<= Median Value	57	13 (22.8%) (12.7%, 35.8%)	59	5 (8.5%) (2.8%, 18.7%)	3.19 (1.06, 9.64)	2.69 (1.03, 7.06)	14.3% (1.3%, 27.3%)	0.0413*	0.6253
> Median Value	37	5 (13.5%) (4.5%, 28.8%)	36	1 (2.8%) (0.1%, 14.5%)	5.47 (0.61, 49.35)	4.86 (0.60, 39.63)	10.7% (-1.5%, 23.0%)	0.1992	

Notes:
Number of subjects: Full Analysis Set Safety Population
Number of subjects: Full Analysis Set Safety Population, excluding subjects with baseline POEM 0-2.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Achieving 0 in POEM total score at week 12 - Full Analysis Set Safety Population
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Week 12									
Full Analysis Set Safety Population	94	6 (6.4%) (2.4%, 13.4%)	95	4 (4.2%) (1.2%, 10.4%)	1.52 (0.41, 5.54)	1.48 (0.44, 5.04)	2.1% (-4.3%, 8.5%)	0.5272+	--
Baseline Disease Severity									
Week 12									
Moderate baseline disease (IGA=3)	61	4 (6.6%) (1.8%, 15.9%)	56	3 (5.4%) (1.1%, 14.9%)	1.24 (0.26, 5.80)	1.22 (0.29, 5.23)	1.2% (-7.4%, 9.8%)	1.0000	0.7282
Severe baseline disease (IGA=4)	33	2 (6.1%) (0.7%, 20.2%)	39	1 (2.6%) (0.1%, 13.5%)	2.45 (0.21, 28.32)	2.36 (0.22, 24.91)	3.5% (-6.0%, 13.0%)	0.5900	
Gender									
Week 12									
Male	56	3 (5.4%) (1.1%, 14.9%)	44	2 (4.5%) (0.6%, 15.5%)	1.19 (0.19, 7.44)	1.18 (0.21, 6.75)	0.8% (-7.7%, 9.3%)	1.0000	0.6328
Female	38	3 (7.9%) (1.7%, 21.4%)	51	2 (3.9%) (0.5%, 13.5%)	2.10 (0.33, 13.24)	2.01 (0.35, 11.46)	4.0% (-6.1%, 14.1%)	0.6473	

Notes:
Number of subjects: Full Analysis Set Safety Population
Number of subjects: Full Analysis Set Safety Population, excluding subjects with baseline POEM 0.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Achieving 0 in POEM total score at week 12 - Full Analysis Set Safety Population
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Region									
Week 12									
US/Canada/Australia	28	2 (7.1%) (0.9%, 23.5%)	32	4 (12.5%) (3.5%, 29.0%)	0.54 (0.09, 3.19)	0.57 (0.11, 2.89)	-5.4% (-20.3%, 9.6%)	0.6754	0.4377
Europe	29	1 (3.4%) (0.1%, 17.8%)	27	0 (0.0%)	2.89 (0.11, 74.15)	2.80 (0.12, 65.93)	3.2% (-6.0%, 12.4%)	1.0000	
Asia	28	3 (10.7%) (2.3%, 28.2%)	29	0 (0.0%)	8.10 (0.40, 164.32)	7.24 (0.39, 134.12)	10.4% (-2.3%, 23.1%)	0.1120	
Latin America	9	0 (0.0%)	7	0 (0.0%)	0.79 (0.01, 44.65)	0.80 (0.02, 36.05)	-1.3% (-22.8%, 20.3%)	NE	
Weight Subgroup									
Week 12									
<= Median Value	46	2 (4.3%) (0.5%, 14.8%)	52	0 (0.0%)	5.90 (0.28, 126.13)	5.64 (0.28, 114.49)	4.4% (-2.5%, 11.3%)	0.2178	0.4530
> Median Value	48	4 (8.3%) (2.3%, 20.0%)	43	4 (9.3%) (2.6%, 22.1%)	0.89 (0.21, 3.78)	0.90 (0.24, 3.36)	-1.0% (-12.7%, 10.7%)	1.0000	
Age Subgroup									
Week 12									
<= Median Value	57	2 (3.5%) (0.4%, 12.1%)	59	3 (5.1%) (1.1%, 14.1%)	0.68 (0.11, 4.22)	0.69 (0.12, 3.98)	-1.6% (-8.9%, 5.8%)	1.0000	0.1579
> Median Value	37	4 (10.8%) (3.0%, 25.4%)	36	1 (2.8%) (0.1%, 14.5%)	4.24 (0.45, 39.94)	3.89 (0.46, 33.17)	8.0% (-3.3%, 19.4%)	0.3575	

Notes:
Number of subjects: Full Analysis Set Safety Population
Number of subjects: Full Analysis Set Safety Population, excluding subjects with baseline POEM 0.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Achieving 0-1 in CDLQI total score at week 12 - Full Analysis Set Safety Population
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Week 12									
Full Analysis Set Safety Population	94	21 (22.3%) (14.4%, 32.1%)	96	13 (13.5%) (7.4%, 22.0%)	1.78 (0.83, 3.83)	1.59 (0.85, 2.98)	8.2% (-2.6%, 19.0%)	0.1382+	--
Baseline Disease Severity									
Week 12									
Moderate baseline disease (IGA=3)	61	16 (26.2%) (15.8%, 39.1%)	57	10 (17.5%) (8.7%, 29.9%)	1.67 (0.69, 4.07)	1.50 (0.74, 3.02)	8.7% (-6.1%, 23.5%)	0.2757	0.8366
Severe baseline disease (IGA=4)	33	5 (15.2%) (5.1%, 31.9%)	39	3 (7.7%) (1.6%, 20.9%)	2.14 (0.47, 9.74)	1.97 (0.51, 7.63)	7.5% (-7.4%, 22.3%)	0.4563	
Gender									
Week 12									
Male	56	11 (19.6%) (10.2%, 32.4%)	44	4 (9.1%) (2.5%, 21.7%)	2.44 (0.72, 8.29)	2.16 (0.74, 6.33)	10.6% (-2.9%, 24.0%)	0.1683	0.9548
Female	38	10 (26.3%) (13.4%, 43.1%)	52	9 (17.3%) (8.2%, 30.3%)	1.71 (0.62, 4.73)	1.52 (0.68, 3.38)	9.0% (-8.4%, 26.4%)	0.3113	

Notes:
Number of subjects: Full Analysis Set Safety Population
Number of subjects: Full Analysis Set Safety Population, excluding subjects with baseline DLQI 0-1.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Achieving 0-1 in CDLQI total score at week 12 - Full Analysis Set Safety Population
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Region									
Week 12									
US/Canada/Australia	28	6 (21.4%) (8.3%, 41.0%)	33	6 (18.2%) (7.0%, 35.5%)	1.23 (0.35, 4.34)	1.18 (0.43, 3.25)	3.2% (-16.9%, 23.4%)	0.7590	0.0577
Europe	29	10 (34.5%) (17.9%, 54.3%)	27	1 (3.7%) (0.1%, 19.0%)	13.68 (1.61, 116.20)	9.31 (1.28, 67.95)	30.8% (12.1%, 49.5%)	0.0056*	
Asia	28	5 (17.9%) (6.1%, 36.9%)	29	6 (20.7%) (8.0%, 39.7%)	0.83 (0.22, 3.12)	0.86 (0.30, 2.51)	-2.8% (-23.3%, 17.6%)	1.0000	
Latin America	9	0 (0.0%)	7	0 (0.0%)	0.79 (0.01, 44.65)	0.80 (0.02, 36.05)	-1.3% (-22.8%, 20.3%)	NE	
Weight Subgroup									
Week 12									
<= Median Value	46	9 (19.6%) (9.4%, 33.9%)	53	7 (13.2%) (5.5%, 25.3%)	1.60 (0.54, 4.70)	1.48 (0.60, 3.66)	6.4% (-8.3%, 21.0%)	0.4241	0.6557
> Median Value	48	12 (25.0%) (13.6%, 39.6%)	43	6 (14.0%) (5.3%, 27.9%)	2.06 (0.70, 6.07)	1.79 (0.74, 4.36)	11.0% (-5.0%, 27.1%)	0.2917	
Age Subgroup									
Week 12									
<= Median Value	57	12 (21.1%) (11.4%, 33.9%)	60	9 (15.0%) (7.1%, 26.6%)	1.51 (0.58, 3.92)	1.40 (0.64, 3.08)	6.1% (-7.9%, 20.0%)	0.4729	0.5333
> Median Value	37	9 (24.3%) (11.8%, 41.2%)	36	4 (11.1%) (3.1%, 26.1%)	2.57 (0.71, 9.27)	2.19 (0.74, 6.48)	13.2% (-4.0%, 30.4%)	0.2210	

Notes:
Number of subjects: Full Analysis Set Safety Population
Number of subjects: Full Analysis Set Safety Population, excluding subjects with baseline DLQI 0-1.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: PP-NRS total score 4-point improvement at week 12 - Full Analysis Set Safety Population
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Week 12									
Full Analysis Set Safety Population	90	41 (45.6%) (35.0%, 56.4%)	96	25 (26.0%) (17.6%, 36.0%)	2.34 (1.26, 4.33)	1.73 (1.15, 2.61)	19.1% (5.5%, 32.6%)	0.0067+*	--
Baseline Disease Severity									
Week 12									
Moderate baseline disease (IGA=3)	58	30 (51.7%) (38.2%, 65.0%)	57	15 (26.3%) (15.5%, 39.7%)	3.00 (1.37, 6.56)	1.97 (1.19, 3.24)	25.4% (8.2%, 42.6%)	0.0073*	0.1868
Severe baseline disease (IGA=4)	32	11 (34.4%) (18.6%, 53.2%)	39	10 (25.6%) (13.0%, 42.1%)	1.52 (0.55, 4.23)	1.34 (0.65, 2.75)	8.7% (-12.7%, 30.1%)	0.4459	
Gender									
Week 12									
Male	53	26 (49.1%) (35.1%, 63.2%)	44	13 (29.5%) (16.8%, 45.2%)	2.30 (0.99, 5.33)	1.66 (0.97, 2.83)	19.5% (0.5%, 38.6%)	0.0627	0.7702
Female	37	15 (40.5%) (24.8%, 57.9%)	52	12 (23.1%) (12.5%, 36.8%)	2.27 (0.91, 5.70)	1.76 (0.93, 3.30)	17.5% (-2.1%, 37.0%)	0.1024	

Notes:
Number of subjects: Full Analysis Set Safety Population
Number of subjects: Full Analysis Set Safety Population, excluding subjects with baseline PP-NRS score <4.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: PP-NRS total score 4-point improvement at week 12 - Full Analysis Set Safety Population
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Region									
Week 12									
US/Canada/Australia	26	14 (53.8%) (33.4%, 73.4%)	33	16 (48.5%) (30.8%, 66.5%)	1.24 (0.44, 3.47)	1.11 (0.67, 1.83)	5.4% (-20.3%, 31.0%)	0.7948	0.5058
Europe	28	13 (46.4%) (27.5%, 66.1%)	27	2 (7.4%) (0.9%, 24.3%)	10.83 (2.14, 54.77)	6.27 (1.56, 25.21)	39.0% (18.1%, 60.0%)	0.0019*	
Asia	28	12 (42.9%) (24.5%, 62.8%)	29	7 (24.1%) (10.3%, 43.5%)	2.36 (0.76, 7.32)	1.78 (0.82, 3.85)	18.7% (-5.3%, 42.8%)	0.1665	
Latin America	8	2 (25.0%) (3.2%, 65.1%)	7	0 (0.0%)	5.77 (0.23, 143.37)	4.44 (0.25, 79.42)	21.5% (-12.2%, 55.3%)	0.4667	
Weight Subgroup									
Week 12									
<= Median Value	44	21 (47.7%) (32.5%, 63.3%)	53	11 (20.8%) (10.8%, 34.1%)	3.49 (1.43, 8.48)	2.30 (1.25, 4.23)	27.0% (8.6%, 45.3%)	0.0087*	0.2980
> Median Value	46	20 (43.5%) (28.9%, 58.9%)	43	14 (32.6%) (19.1%, 48.5%)	1.59 (0.67, 3.78)	1.34 (0.78, 2.30)	10.9% (-9.1%, 31.0%)	0.3830	
Age Subgroup									
Week 12									
<= Median Value	54	28 (51.9%) (37.8%, 65.7%)	60	18 (30.0%) (18.8%, 43.2%)	2.51 (1.17, 5.42)	1.73 (1.09, 2.75)	21.9% (4.2%, 39.5%)	0.0221*	0.5223
> Median Value	36	13 (36.1%) (20.8%, 53.8%)	36	7 (19.4%) (8.2%, 36.0%)	2.34 (0.80, 6.82)	1.86 (0.84, 4.11)	16.7% (-3.7%, 37.0%)	0.1877	

Notes:
Number of subjects: Full Analysis Set Safety Population
Number of subjects: Full Analysis Set Safety Population, excluding subjects with baseline PP-NRS score <4.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Achieving 0-1 in PP-NRS total score at week 12 - Full Analysis Set Safety Population
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Week 12									
Full Analysis Set Safety Population	94	18 (19.1%) (11.8%, 28.6%)	96	10 (10.4%) (5.1%, 18.3%)	2.03 (0.88, 4.67)	1.83 (0.89, 3.77)	8.7% (-1.4%, 18.7%)	0.0935+	--
Baseline Disease Severity									
Week 12									
Moderate baseline disease (IGA=3)	61	12 (19.7%) (10.6%, 31.8%)	57	6 (10.5%) (4.0%, 21.5%)	2.08 (0.72, 5.98)	1.87 (0.75, 4.65)	9.1% (-3.6%, 21.9%)	0.2051	0.9027
Severe baseline disease (IGA=4)	33	6 (18.2%) (7.0%, 35.5%)	39	4 (10.3%) (2.9%, 24.2%)	1.94 (0.50, 7.58)	1.77 (0.55, 5.75)	7.9% (-8.3%, 24.2%)	0.4962	
Gender									
Week 12									
Male	56	12 (21.4%) (11.6%, 34.4%)	44	5 (11.4%) (3.8%, 24.6%)	2.13 (0.69, 6.58)	1.89 (0.72, 4.95)	10.1% (-4.2%, 24.3%)	0.2834	0.6841
Female	38	6 (15.8%) (6.0%, 31.3%)	52	5 (9.6%) (3.2%, 21.0%)	1.76 (0.50, 6.27)	1.64 (0.54, 4.99)	6.2% (-7.9%, 20.3%)	0.5170	

Notes:
Number of subjects: Full Analysis Set Safety Population
Analysis on overall population is calculated based on stratified CMH (Cochran-Mantel-Haenszel) models, for OR, RR, and RD, stratified by by disease activity (moderate, severe) at enrollment.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Achieving 0-1 in PP-NRS total score at week 12 - Full Analysis Set Safety Population
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Region									
Week 12									
US/Canada/Australia	28	8 (28.6%) (13.2%, 48.7%)	33	9 (27.3%) (13.3%, 45.5%)	1.07 (0.35, 3.28)	1.05 (0.47, 2.35)	1.3% (-21.3%, 23.9%)	1.0000	0.8159
Europe	29	5 (17.2%) (5.8%, 35.8%)	27	0 (0.0%)	12.35 (0.65, 234.92)	10.27 (0.59, 177.29)	16.5% (1.9%, 31.2%)	0.0522	
Asia	28	4 (14.3%) (4.0%, 32.7%)	29	1 (3.4%) (0.1%, 17.8%)	4.67 (0.49, 44.64)	4.14 (0.49, 34.82)	10.8% (-3.7%, 25.4%)	0.1936	
Latin America	9	1 (11.1%) (0.3%, 48.2%)	7	0 (0.0%)	2.65 (0.09, 75.29)	2.40 (0.11, 51.32)	8.8% (-19.0%, 36.5%)	1.0000	
Weight Subgroup									
Week 12									
<= Median Value	46	8 (17.4%) (7.8%, 31.4%)	53	4 (7.5%) (2.1%, 18.2%)	2.58 (0.72, 9.21)	2.30 (0.74, 7.16)	9.8% (-3.2%, 22.9%)	0.2162	0.8132
> Median Value	48	10 (20.8%) (10.5%, 35.0%)	43	6 (14.0%) (5.3%, 27.9%)	1.62 (0.54, 4.92)	1.49 (0.59, 3.76)	6.9% (-8.6%, 22.3%)	0.4230	
Age Subgroup									
Week 12									
<= Median Value	57	12 (21.1%) (11.4%, 33.9%)	60	9 (15.0%) (7.1%, 26.6%)	1.51 (0.58, 3.92)	1.40 (0.64, 3.08)	6.1% (-7.9%, 20.0%)	0.4729	0.5179
> Median Value	37	6 (16.2%) (6.2%, 32.0%)	36	1 (2.8%) (0.1%, 14.5%)	6.77 (0.77, 59.42)	5.84 (0.74, 46.11)	13.4% (0.4%, 26.5%)	0.1070	

Notes:
Number of subjects: Full Analysis Set Safety Population
Analysis on overall population is calculated based on stratified CMH (Cochran-Mantel-Haenszel) models, for OR, RR, and RD, stratified by by disease activity (moderate, severe) at enrollment.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: EQ-5D VAS 15-point improvement at week 12 - Full Analysis Set Safety Population
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Week 12									
Full Analysis Set Safety Population	75	41 (54.7%) (42.7%, 66.2%)	73	32 (43.8%) (32.2%, 55.9%)	1.53 (0.80, 2.93)	1.24 (0.89, 1.73)	10.7% (-5.4%, 26.8%)	0.1990+	--
Baseline Disease Severity									
Week 12									
Moderate baseline disease (IGA=3)	47	25 (53.2%) (38.1%, 67.9%)	40	19 (47.5%) (31.5%, 63.9%)	1.26 (0.54, 2.92)	1.12 (0.73, 1.71)	5.7% (-15.4%, 26.7%)	0.6694	0.4882
Severe baseline disease (IGA=4)	28	16 (57.1%) (37.2%, 75.5%)	33	13 (39.4%) (22.9%, 57.9%)	2.05 (0.74, 5.71)	1.45 (0.85, 2.47)	17.7% (-7.0%, 42.5%)	0.2037	
Gender									
Week 12									
Male	46	26 (56.5%) (41.1%, 71.1%)	33	16 (48.5%) (30.8%, 66.5%)	1.38 (0.56, 3.39)	1.17 (0.76, 1.80)	8.0% (-14.2%, 30.3%)	0.5022	0.8854
Female	29	15 (51.7%) (32.5%, 70.6%)	40	16 (40.0%) (24.9%, 56.7%)	1.61 (0.61, 4.22)	1.29 (0.77, 2.17)	11.7% (-12.0%, 35.4%)	0.4624	

Notes:
Number of subjects: Full Analysis Set Safety Population
Number of subjects: Full Analysis Set Safety Population, excluding subjects with baseline EQ5D-VAS >85.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: EQ-5D VAS 15-point improvement at week 12 - Full Analysis Set Safety Population
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Region									
Week 12									
US/Canada/Australia	18	8 (44.4%) (21.5%, 69.2%)	21	12 (57.1%) (34.0%, 78.2%)	0.60 (0.17, 2.14)	0.78 (0.41, 1.47)	-12.7% (-43.9%, 18.5%)	0.5273	0.1577
Europe	24	12 (50.0%) (29.1%, 70.9%)	24	11 (45.8%) (25.6%, 67.2%)	1.18 (0.38, 3.67)	1.09 (0.60, 1.97)	4.2% (-24.1%, 32.4%)	1.0000	
Asia	26	17 (65.4%) (44.3%, 82.8%)	23	7 (30.4%) (13.2%, 52.9%)	4.32 (1.30, 14.34)	2.15 (1.09, 4.23)	34.9% (8.7%, 61.2%)	0.0222*	
Latin America	7	4 (57.1%) (18.4%, 90.1%)	5	2 (40.0%) (5.3%, 85.3%)	2.00 (0.19, 20.61)	1.43 (0.41, 4.99)	17.1% (-39.3%, 73.6%)	1.0000	
Weight Subgroup									
Week 12									
<= Median Value	38	21 (55.3%) (38.3%, 71.4%)	41	17 (41.5%) (26.3%, 57.9%)	1.74 (0.72, 4.25)	1.33 (0.84, 2.12)	13.8% (-8.0%, 35.6%)	0.2635	0.7077
> Median Value	37	20 (54.1%) (36.9%, 70.5%)	32	15 (46.9%) (29.1%, 65.3%)	1.33 (0.52, 3.44)	1.15 (0.72, 1.85)	7.2% (-16.4%, 30.8%)	0.6324	
Age Subgroup									
Week 12									
<= Median Value	43	21 (48.8%) (33.3%, 64.5%)	42	17 (40.5%) (25.6%, 56.7%)	1.40 (0.59, 3.31)	1.21 (0.75, 1.95)	8.4% (-12.7%, 29.4%)	0.5151	0.6272
> Median Value	32	20 (62.5%) (43.7%, 78.9%)	31	15 (48.4%) (30.2%, 66.9%)	1.78 (0.65, 4.85)	1.29 (0.82, 2.03)	14.1% (-10.2%, 38.4%)	0.3152	

Notes:
Number of subjects: Full Analysis Set Safety Population
Number of subjects: Full Analysis Set Safety Population, excluding subjects with baseline EQ5D-VAS >85.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Stratified Cochran-Mantel-Haenszel p-value presented for overall analysis, stratified by by disease activity (moderate, severe) at enrollment.
[*] p-value <0.05
CMH: Cochran-Mantel-Haenszel; NE: not estimable; OR: odds ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events-Total mortality (TEAE leading to death) - Safety Set
JADE TEEN (PF-04965842) - 2023 datacut

No adverse events of this type occurred

Binary Outcome Analysis: Adverse Events-Any Treatment Emergent Adverse Events - Safety Set
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Safety Set	94	59 (62.8%) (52.2%, 72.5%)	96	50 (52.1%) (41.6%, 62.4%)	1.55 (0.87, 2.77)	1.21 (0.94, 1.54)	10.7% (-3.3%, 24.7%)	0.1341+	--
Baseline Disease Severity									
Moderate baseline disease (IGA=3)	61	37 (60.7%) (47.3%, 72.9%)	57	30 (52.6%) (39.0%, 66.0%)	1.39 (0.67, 2.88)	1.15 (0.84, 1.58)	8.0% (-9.8%, 25.9%)	0.4578	0.5912
Severe baseline disease (IGA=4)	33	22 (66.7%) (48.2%, 82.0%)	39	20 (51.3%) (34.8%, 67.6%)	1.90 (0.73, 4.95)	1.30 (0.88, 1.92)	15.4% (-7.1%, 37.9%)	0.2336	
Gender									
Male	56	32 (57.1%) (43.2%, 70.3%)	44	22 (50.0%) (34.6%, 65.4%)	1.33 (0.60, 2.95)	1.14 (0.79, 1.66)	7.1% (-12.5%, 26.8%)	0.5464	0.3850
Female	38	27 (71.1%) (54.1%, 84.6%)	52	28 (53.8%) (39.5%, 67.8%)	2.10 (0.87, 5.11)	1.32 (0.96, 1.82)	17.2% (-2.6%, 37.0%)	0.1267	
Region									
US/Canada/Australia	28	12 (42.9%) (24.5%, 62.8%)	33	12 (36.4%) (20.4%, 54.9%)	1.31 (0.47, 3.68)	1.18 (0.63, 2.19)	6.5% (-18.1%, 31.1%)	0.7929	0.8874
Europe	29	20 (69.0%) (49.2%, 84.7%)	27	16 (59.3%) (38.8%, 77.6%)	1.53 (0.51, 4.59)	1.16 (0.78, 1.73)	9.7% (-15.3%, 34.7%)	0.5785	
Asia	28	22 (78.6%) (59.0%, 91.7%)	29	19 (65.5%) (45.7%, 82.1%)	1.93 (0.59, 6.30)	1.20 (0.86, 1.66)	13.1% (-10.0%, 36.1%)	0.3786	
Latin America	9	5 (55.6%) (21.2%, 86.3%)	7	3 (42.9%) (9.9%, 81.6%)	1.67 (0.23, 12.22)	1.30 (0.46, 3.65)	12.7% (-36.3%, 61.7%)	1.0000	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events-Any Treatment Emergent Adverse Events - Safety Set
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Weight Subgroup									
<= Median Value	46	28 (60.9%) (45.4%, 74.9%)	53	31 (58.5%) (44.1%, 71.9%)	1.10 (0.49, 2.47)	1.04 (0.75, 1.44)	2.4% (-17.0%, 21.7%)	0.8398	0.2466
> Median Value	48	31 (64.6%) (49.5%, 77.8%)	43	19 (44.2%) (29.1%, 60.1%)	2.30 (0.99, 5.36)	1.46 (0.98, 2.17)	20.4% (0.3%, 40.5%)	0.0601	
Age Subgroup									
<= Median Value	57	35 (61.4%) (47.6%, 74.0%)	60	33 (55.0%) (41.6%, 67.9%)	1.30 (0.62, 2.72)	1.12 (0.82, 1.52)	6.4% (-11.4%, 24.2%)	0.5746	0.4677
> Median Value	37	24 (64.9%) (47.5%, 79.8%)	36	17 (47.2%) (30.4%, 64.5%)	2.06 (0.81, 5.28)	1.37 (0.90, 2.09)	17.6% (-4.8%, 40.1%)	0.1601	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events-Severe Treatment Emergent Adverse Events - Safety Set
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Safety Set	94	2 (2.1%) (0.3%, 7.5%)	96	2 (2.1%) (0.3%, 7.3%)	1.02 (0.14, 7.41)	1.02 (0.15, 7.10)	0.0% (-4.0%, 4.1%)	0.9830+	--
Baseline Disease Severity									
Moderate baseline disease (IGA=3)	61	2 (3.3%) (0.4%, 11.3%)	57	1 (1.8%) (0.0%, 9.4%)	1.90 (0.17, 21.52)	1.87 (0.17, 20.05)	1.5% (-4.1%, 7.1%)	1.0000	0.4155
Severe baseline disease (IGA=4)	33	0 (0.0%)	39	1 (2.6%) (0.1%, 13.5%)	0.38 (0.02, 9.72)	0.39 (0.02, 9.32)	-2.3% (-9.4%, 4.9%)	1.0000	
Gender									
Male	56	0 (0.0%)	44	0 (0.0%)	0.79 (0.02, 40.48)	0.79 (0.02, 39.02)	-0.2% (-4.1%, 3.7%)	NE	0.7330
Female	38	2 (5.3%) (0.6%, 17.7%)	52	2 (3.8%) (0.5%, 13.2%)	1.39 (0.19, 10.33)	1.37 (0.20, 9.29)	1.4% (-7.4%, 10.2%)	1.0000	
Region									
US/Canada/Australia	28	1 (3.6%) (0.1%, 18.3%)	33	1 (3.0%) (0.1%, 15.8%)	1.19 (0.07, 19.86)	1.18 (0.08, 17.99)	0.5% (-8.5%, 9.6%)	1.0000	0.7489
Europe	29	0 (0.0%)	27	1 (3.7%) (0.1%, 19.0%)	0.30 (0.01, 7.67)	0.31 (0.01, 7.33)	-3.7% (-13.2%, 5.8%)	0.4821	
Asia	28	1 (3.6%) (0.1%, 18.3%)	29	0 (0.0%)	3.22 (0.13, 82.38)	3.10 (0.13, 73.12)	3.5% (-5.8%, 12.8%)	0.4912	
Latin America	9	0 (0.0%)	7	0 (0.0%)	0.79 (0.01, 44.65)	0.80 (0.02, 36.05)	-1.3% (-22.8%, 20.3%)	NE	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events-Severe Treatment Emergent Adverse Events - Safety Set
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Weight Subgroup									
<= Median Value	46	0 (0.0%)	53	2 (3.8%) (0.5%, 13.0%)	0.22 (0.01, 4.73)	0.23 (0.01, 4.67)	-3.6% (-9.9%, 2.8%)	0.4974	0.1132
> Median Value	48	2 (4.2%) (0.5%, 14.3%)	43	0 (0.0%)	4.68 (0.22, 100.20)	4.49 (0.22, 90.99)	4.0% (-2.9%, 10.9%)	0.4960	
Age Subgroup									
<= Median Value	57	1 (1.8%) (0.0%, 9.4%)	60	2 (3.3%) (0.4%, 11.5%)	0.52 (0.05, 5.87)	0.53 (0.05, 5.65)	-1.6% (-7.3%, 4.1%)	1.0000	0.3688
> Median Value	37	1 (2.7%) (0.1%, 14.2%)	36	0 (0.0%)	3.00 (0.12, 76.09)	2.92 (0.12, 69.43)	2.6% (-4.6%, 9.8%)	1.0000	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events-Serious Treatment Emergent Adverse Events - Safety Set
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Safety Set	94	1 (1.1%) (0.0%, 5.8%)	96	2 (2.1%) (0.3%, 7.3%)	0.51 (0.05, 5.67)	0.51 (0.05, 5.54)	-1.0% (-4.5%, 2.5%)	0.5714+	--
Baseline Disease Severity									
Moderate baseline disease (IGA=3)	61	1 (1.6%) (0.0%, 8.8%)	57	1 (1.8%) (0.0%, 9.4%)	0.93 (0.06, 15.28)	0.93 (0.06, 14.59)	-0.1% (-4.8%, 4.6%)	1.0000	0.6186
Severe baseline disease (IGA=4)	33	0 (0.0%)	39	1 (2.6%) (0.1%, 13.5%)	0.38 (0.02, 9.72)	0.39 (0.02, 9.32)	-2.3% (-9.4%, 4.9%)	1.0000	
Gender									
Male	56	1 (1.8%) (0.0%, 9.6%)	44	1 (2.3%) (0.1%, 12.0%)	0.78 (0.05, 12.86)	0.79 (0.05, 12.21)	-0.5% (-6.1%, 5.1%)	1.0000	0.7967
Female	38	0 (0.0%)	52	1 (1.9%) (0.0%, 10.3%)	0.45 (0.02, 11.25)	0.45 (0.02, 10.83)	-1.5% (-7.2%, 4.1%)	1.0000	
Region									
US/Canada/Australia	28	1 (3.6%) (0.1%, 18.3%)	33	1 (3.0%) (0.1%, 15.8%)	1.19 (0.07, 19.86)	1.18 (0.08, 17.99)	0.5% (-8.5%, 9.6%)	1.0000	0.9113
Europe	29	0 (0.0%)	27	1 (3.7%) (0.1%, 19.0%)	0.30 (0.01, 7.67)	0.31 (0.01, 7.33)	-3.7% (-13.2%, 5.8%)	0.4821	
Asia	28	0 (0.0%)	29	0 (0.0%)	1.04 (0.02, 53.95)	1.03 (0.02, 50.42)	0.1% (-6.5%, 6.6%)	NE	
Latin America	9	0 (0.0%)	7	0 (0.0%)	0.79 (0.01, 44.65)	0.80 (0.02, 36.05)	-1.3% (-22.8%, 20.3%)	NE	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events-Serious Treatment Emergent Adverse Events - Safety Set
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Weight Subgroup									
<= Median Value	46	0 (0.0%)	53	1 (1.9%) (0.0%, 10.1%)	0.38 (0.01, 9.47)	0.38 (0.02, 9.18)	-1.7% (-7.0%, 3.6%)	1.0000	0.7219
> Median Value	48	1 (2.1%) (0.1%, 11.1%)	43	1 (2.3%) (0.1%, 12.3%)	0.89 (0.05, 14.74)	0.90 (0.06, 13.89)	-0.2% (-6.3%, 5.8%)	1.0000	
Age Subgroup									
<= Median Value	57	1 (1.8%) (0.0%, 9.4%)	60	1 (1.7%) (0.0%, 8.9%)	1.05 (0.06, 17.25)	1.05 (0.07, 16.43)	0.1% (-4.6%, 4.8%)	1.0000	0.5154
> Median Value	37	0 (0.0%)	36	1 (2.8%) (0.1%, 14.5%)	0.32 (0.01, 8.00)	0.32 (0.01, 7.71)	-2.7% (-10.1%, 4.6%)	0.4932	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events-Treatment Emergent Adverse Events leading to therapy discontinuation - Safety Set
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Safety Set	94	2 (2.1%) (0.3%, 7.5%)	96	2 (2.1%) (0.3%, 7.3%)	1.02 (0.14, 7.41)	1.02 (0.15, 7.10)	0.0% (-4.0%, 4.1%)	0.9830+	--
Baseline Disease Severity									
Moderate baseline disease (IGA=3)	61	2 (3.3%) (0.4%, 11.3%)	57	0 (0.0%)	4.83 (0.23, 102.84)	4.68 (0.23, 95.39)	3.2% (-2.3%, 8.6%)	0.4963	0.1295
Severe baseline disease (IGA=4)	33	0 (0.0%)	39	2 (5.1%) (0.6%, 17.3%)	0.22 (0.01, 4.83)	0.24 (0.01, 4.73)	-4.8% (-13.3%, 3.7%)	0.4965	
Gender									
Male	56	2 (3.6%) (0.4%, 12.3%)	44	1 (2.3%) (0.1%, 12.0%)	1.59 (0.14, 18.16)	1.57 (0.15, 16.77)	1.3% (-5.3%, 7.9%)	1.0000	0.5289
Female	38	0 (0.0%)	52	1 (1.9%) (0.0%, 10.3%)	0.45 (0.02, 11.25)	0.45 (0.02, 10.83)	-1.5% (-7.2%, 4.1%)	1.0000	
Region									
US/Canada/Australia	28	0 (0.0%)	33	0 (0.0%)	1.18 (0.02, 61.15)	1.17 (0.02, 57.26)	0.3% (-6.0%, 6.5%)	NE	0.4550
Europe	29	0 (0.0%)	27	0 (0.0%)	0.93 (0.02, 48.62)	0.93 (0.02, 45.47)	-0.1% (-6.8%, 6.6%)	NE	
Asia	28	0 (0.0%)	29	2 (6.9%) (0.8%, 22.8%)	0.19 (0.01, 4.20)	0.21 (0.01, 4.13)	-6.6% (-17.6%, 4.4%)	0.4912	
Latin America	9	2 (22.2%) (2.8%, 60.0%)	7	0 (0.0%)	5.00 (0.20, 122.74)	4.00 (0.22, 72.01)	18.8% (-12.9%, 50.4%)	0.4750	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events-Treatment Emergent Adverse Events leading to therapy discontinuation - Safety Set
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Weight Subgroup									
<= Median Value	46	1 (2.2%) (0.1%, 11.5%)	53	2 (3.8%) (0.5%, 13.0%)	0.57 (0.05, 6.46)	0.58 (0.05, 6.15)	-1.6% (-8.2%, 5.0%)	1.0000	0.4345
> Median Value	48	1 (2.1%) (0.1%, 11.1%)	43	0 (0.0%)	2.75 (0.11, 69.24)	2.69 (0.11, 64.43)	1.9% (-3.8%, 7.7%)	1.0000	
Age Subgroup									
<= Median Value	57	1 (1.8%) (0.0%, 9.4%)	60	2 (3.3%) (0.4%, 11.5%)	0.52 (0.05, 5.87)	0.53 (0.05, 5.65)	-1.6% (-7.3%, 4.1%)	1.0000	0.3688
> Median Value	37	1 (2.7%) (0.1%, 14.2%)	36	0 (0.0%)	3.00 (0.12, 76.09)	2.92 (0.12, 69.43)	2.6% (-4.6%, 9.8%)	1.0000	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events-Any Treatment Emergent Adverse Events excluding progression events - Safety Set
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Safety Set	94	59 (62.8%) (52.2%, 72.5%)	96	50 (52.1%) (41.6%, 62.4%)	1.55 (0.87, 2.77)	1.21 (0.94, 1.54)	10.7% (-3.3%, 24.7%)	0.1341+	--
Baseline Disease Severity									
Moderate baseline disease (IGA=3)	61	37 (60.7%) (47.3%, 72.9%)	57	30 (52.6%) (39.0%, 66.0%)	1.39 (0.67, 2.88)	1.15 (0.84, 1.58)	8.0% (-9.8%, 25.9%)	0.4578	0.5912
Severe baseline disease (IGA=4)	33	22 (66.7%) (48.2%, 82.0%)	39	20 (51.3%) (34.8%, 67.6%)	1.90 (0.73, 4.95)	1.30 (0.88, 1.92)	15.4% (-7.1%, 37.9%)	0.2336	
Gender									
Male	56	32 (57.1%) (43.2%, 70.3%)	44	22 (50.0%) (34.6%, 65.4%)	1.33 (0.60, 2.95)	1.14 (0.79, 1.66)	7.1% (-12.5%, 26.8%)	0.5464	0.3850
Female	38	27 (71.1%) (54.1%, 84.6%)	52	28 (53.8%) (39.5%, 67.8%)	2.10 (0.87, 5.11)	1.32 (0.96, 1.82)	17.2% (-2.6%, 37.0%)	0.1267	
Region									
US/Canada/Australia	28	12 (42.9%) (24.5%, 62.8%)	33	12 (36.4%) (20.4%, 54.9%)	1.31 (0.47, 3.68)	1.18 (0.63, 2.19)	6.5% (-18.1%, 31.1%)	0.7929	0.8874
Europe	29	20 (69.0%) (49.2%, 84.7%)	27	16 (59.3%) (38.8%, 77.6%)	1.53 (0.51, 4.59)	1.16 (0.78, 1.73)	9.7% (-15.3%, 34.7%)	0.5785	
Asia	28	22 (78.6%) (59.0%, 91.7%)	29	19 (65.5%) (45.7%, 82.1%)	1.93 (0.59, 6.30)	1.20 (0.86, 1.66)	13.1% (-10.0%, 36.1%)	0.3786	
Latin America	9	5 (55.6%) (21.2%, 86.3%)	7	3 (42.9%) (9.9%, 81.6%)	1.67 (0.23, 12.22)	1.30 (0.46, 3.65)	12.7% (-36.3%, 61.7%)	1.0000	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events-Any Treatment Emergent Adverse Events excluding progression events - Safety Set
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Weight Subgroup									
<= Median Value	46	28 (60.9%) (45.4%, 74.9%)	53	31 (58.5%) (44.1%, 71.9%)	1.10 (0.49, 2.47)	1.04 (0.75, 1.44)	2.4% (-17.0%, 21.7%)	0.8398	0.2466
> Median Value	48	31 (64.6%) (49.5%, 77.8%)	43	19 (44.2%) (29.1%, 60.1%)	2.30 (0.99, 5.36)	1.46 (0.98, 2.17)	20.4% (0.3%, 40.5%)	0.0601	
Age Subgroup									
<= Median Value	57	35 (61.4%) (47.6%, 74.0%)	60	33 (55.0%) (41.6%, 67.9%)	1.30 (0.62, 2.72)	1.12 (0.82, 1.52)	6.4% (-11.4%, 24.2%)	0.5746	0.4677
> Median Value	37	24 (64.9%) (47.5%, 79.8%)	36	17 (47.2%) (30.4%, 64.5%)	2.06 (0.81, 5.28)	1.37 (0.90, 2.09)	17.6% (-4.8%, 40.1%)	0.1601	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events-Severe Treatment Emergent Adverse Events excluding progression events - Safety Set
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Safety Set	94	2 (2.1%) (0.3%, 7.5%)	96	2 (2.1%) (0.3%, 7.3%)	1.02 (0.14, 7.41)	1.02 (0.15, 7.10)	0.0% (-4.0%, 4.1%)	0.9830+	--
Baseline Disease Severity									
Moderate baseline disease (IGA=3)	61	2 (3.3%) (0.4%, 11.3%)	57	1 (1.8%) (0.0%, 9.4%)	1.90 (0.17, 21.52)	1.87 (0.17, 20.05)	1.5% (-4.1%, 7.1%)	1.0000	0.4155
Severe baseline disease (IGA=4)	33	0 (0.0%)	39	1 (2.6%) (0.1%, 13.5%)	0.38 (0.02, 9.72)	0.39 (0.02, 9.32)	-2.3% (-9.4%, 4.9%)	1.0000	
Gender									
Male	56	0 (0.0%)	44	0 (0.0%)	0.79 (0.02, 40.48)	0.79 (0.02, 39.02)	-0.2% (-4.1%, 3.7%)	NE	0.7330
Female	38	2 (5.3%) (0.6%, 17.7%)	52	2 (3.8%) (0.5%, 13.2%)	1.39 (0.19, 10.33)	1.37 (0.20, 9.29)	1.4% (-7.4%, 10.2%)	1.0000	
Region									
US/Canada/Australia	28	1 (3.6%) (0.1%, 18.3%)	33	1 (3.0%) (0.1%, 15.8%)	1.19 (0.07, 19.86)	1.18 (0.08, 17.99)	0.5% (-8.5%, 9.6%)	1.0000	0.7489
Europe	29	0 (0.0%)	27	1 (3.7%) (0.1%, 19.0%)	0.30 (0.01, 7.67)	0.31 (0.01, 7.33)	-3.7% (-13.2%, 5.8%)	0.4821	
Asia	28	1 (3.6%) (0.1%, 18.3%)	29	0 (0.0%)	3.22 (0.13, 82.38)	3.10 (0.13, 73.12)	3.5% (-5.8%, 12.8%)	0.4912	
Latin America	9	0 (0.0%)	7	0 (0.0%)	0.79 (0.01, 44.65)	0.80 (0.02, 36.05)	-1.3% (-22.8%, 20.3%)	NE	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events-Severe Treatment Emergent Adverse Events excluding progression events - Safety Set
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Weight Subgroup									
<= Median Value	46	0 (0.0%)	53	2 (3.8%) (0.5%, 13.0%)	0.22 (0.01, 4.73)	0.23 (0.01, 4.67)	-3.6% (-9.9%, 2.8%)	0.4974	0.1132
> Median Value	48	2 (4.2%) (0.5%, 14.3%)	43	0 (0.0%)	4.68 (0.22, 100.20)	4.49 (0.22, 90.99)	4.0% (-2.9%, 10.9%)	0.4960	
Age Subgroup									
<= Median Value	57	1 (1.8%) (0.0%, 9.4%)	60	2 (3.3%) (0.4%, 11.5%)	0.52 (0.05, 5.87)	0.53 (0.05, 5.65)	-1.6% (-7.3%, 4.1%)	1.0000	0.3688
> Median Value	37	1 (2.7%) (0.1%, 14.2%)	36	0 (0.0%)	3.00 (0.12, 76.09)	2.92 (0.12, 69.43)	2.6% (-4.6%, 9.8%)	1.0000	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events-Serious Treatment Emergent Adverse Events excluding progression events - Safety Set
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Safety Set	94	1 (1.1%) (0.0%, 5.8%)	96	2 (2.1%) (0.3%, 7.3%)	0.51 (0.05, 5.67)	0.51 (0.05, 5.54)	-1.0% (-4.5%, 2.5%)	0.5714+	--
Baseline Disease Severity									
Moderate baseline disease (IGA=3)	61	1 (1.6%) (0.0%, 8.8%)	57	1 (1.8%) (0.0%, 9.4%)	0.93 (0.06, 15.28)	0.93 (0.06, 14.59)	-0.1% (-4.8%, 4.6%)	1.0000	0.6186
Severe baseline disease (IGA=4)	33	0 (0.0%)	39	1 (2.6%) (0.1%, 13.5%)	0.38 (0.02, 9.72)	0.39 (0.02, 9.32)	-2.3% (-9.4%, 4.9%)	1.0000	
Gender									
Male	56	1 (1.8%) (0.0%, 9.6%)	44	1 (2.3%) (0.1%, 12.0%)	0.78 (0.05, 12.86)	0.79 (0.05, 12.21)	-0.5% (-6.1%, 5.1%)	1.0000	0.7967
Female	38	0 (0.0%)	52	1 (1.9%) (0.0%, 10.3%)	0.45 (0.02, 11.25)	0.45 (0.02, 10.83)	-1.5% (-7.2%, 4.1%)	1.0000	
Region									
US/Canada/Australia	28	1 (3.6%) (0.1%, 18.3%)	33	1 (3.0%) (0.1%, 15.8%)	1.19 (0.07, 19.86)	1.18 (0.08, 17.99)	0.5% (-8.5%, 9.6%)	1.0000	0.9113
Europe	29	0 (0.0%)	27	1 (3.7%) (0.1%, 19.0%)	0.30 (0.01, 7.67)	0.31 (0.01, 7.33)	-3.7% (-13.2%, 5.8%)	0.4821	
Asia	28	0 (0.0%)	29	0 (0.0%)	1.04 (0.02, 53.95)	1.03 (0.02, 50.42)	0.1% (-6.5%, 6.6%)	NE	
Latin America	9	0 (0.0%)	7	0 (0.0%)	0.79 (0.01, 44.65)	0.80 (0.02, 36.05)	-1.3% (-22.8%, 20.3%)	NE	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events-Serious Treatment Emergent Adverse Events excluding progression events - Safety Set
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Weight Subgroup									
<= Median Value	46	0 (0.0%)	53	1 (1.9%) (0.0%, 10.1%)	0.38 (0.01, 9.47)	0.38 (0.02, 9.18)	-1.7% (-7.0%, 3.6%)	1.0000	0.7219
> Median Value	48	1 (2.1%) (0.1%, 11.1%)	43	1 (2.3%) (0.1%, 12.3%)	0.89 (0.05, 14.74)	0.90 (0.06, 13.89)	-0.2% (-6.3%, 5.8%)	1.0000	
Age Subgroup									
<= Median Value	57	1 (1.8%) (0.0%, 9.4%)	60	1 (1.7%) (0.0%, 8.9%)	1.05 (0.06, 17.25)	1.05 (0.07, 16.43)	0.1% (-4.6%, 4.8%)	1.0000	0.5154
> Median Value	37	0 (0.0%)	36	1 (2.8%) (0.1%, 14.5%)	0.32 (0.01, 8.00)	0.32 (0.01, 7.71)	-2.7% (-10.1%, 4.6%)	0.4932	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events of Special Interest (AESI)-Superinfections - Safety Set
JADE TEEN (PF-04965842) - 2023 datacut

No adverse events of this type occurred

Binary Outcome Analysis: Adverse Events of Special Interest (AESI)-Herpes Zoster - Safety Set
JADE TEEN (PF-04965842) - 2023 datacut

No adverse events of this type occurred

Binary Outcome Analysis: Adverse Events of Special Interest (AESI)-Conjunctivitis - Safety Set
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Safety Set	94	0 (0.0%) .	96	2 (2.1%) (0.3%, 7.3%)	<0.01 (<0.01, NE)	<0.01 (<0.01, NE)	-4.4% (-25.4%, 16.7%)	0.6846+	--
Baseline Disease Severity									
Moderate baseline disease (IGA=3)	61	0 (0.0%) .	57	1 (1.8%) (0.0%, 9.4%)	0.31 (0.01, 7.67)	0.31 (0.01, 7.50)	-1.8% (-6.4%, 2.9%)	0.4831	0.9055
Severe baseline disease (IGA=4)	33	0 (0.0%) .	39	1 (2.6%) (0.1%, 13.5%)	0.38 (0.02, 9.72)	0.39 (0.02, 9.32)	-2.3% (-9.4%, 4.9%)	1.0000	
Gender									
Male	56	0 (0.0%) .	44	1 (2.3%) (0.1%, 12.0%)	0.26 (0.01, 6.45)	0.26 (0.01, 6.31)	-2.5% (-8.2%, 3.3%)	0.4400	0.8254
Female	38	0 (0.0%) .	52	1 (1.9%) (0.0%, 10.3%)	0.45 (0.02, 11.25)	0.45 (0.02, 10.83)	-1.5% (-7.2%, 4.1%)	1.0000	
Region									
US/Canada/Australia	28	0 (0.0%) .	33	0 (0.0%)	1.18 (0.02, 61.15)	1.17 (0.02, 57.26)	0.3% (-6.0%, 6.5%)	NE	0.7289
Europe	29	0 (0.0%) .	27	0 (0.0%)	0.93 (0.02, 48.62)	0.93 (0.02, 45.47)	-0.1% (-6.8%, 6.6%)	NE	
Asia	28	0 (0.0%) .	29	2 (6.9%) (0.8%, 22.8%)	0.19 (0.01, 4.20)	0.21 (0.01, 4.13)	-6.6% (-17.6%, 4.4%)	0.4912	
Latin America	9	0 (0.0%) .	7	0 (0.0%)	0.79 (0.01, 44.65)	0.80 (0.02, 36.05)	-1.3% (-22.8%, 20.3%)	NE	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events of Special Interest (AESI)-Conjunctivitis - Safety Set
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Weight Subgroup									
<= Median Value	46	0 (0.0%) .	53	2 (3.8%) (0.5%, 13.0%)	0.22 (0.01, 4.73)	0.23 (0.01, 4.67)	-3.6% (-9.9%, 2.8%)	0.4974	0.3760
> Median Value	48	0 (0.0%) .	43	0 (0.0%)	0.90 (0.02, 46.17)	0.90 (0.02, 44.31)	-0.1% (-4.3%, 4.1%)	NE	
Age Subgroup									
<= Median Value	57	0 (0.0%) .	60	2 (3.3%) (0.4%, 11.5%)	0.20 (0.01, 4.33)	0.21 (0.01, 4.29)	-3.2% (-8.8%, 2.3%)	0.4960	0.4160
> Median Value	37	0 (0.0%) .	36	0 (0.0%)	0.97 (0.02, 50.37)	0.97 (0.02, 47.80)	-0.0% (-5.2%, 5.2%)	NE	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events of Special Interest (AESI)-Acne (PT) - Safety Set
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Safety Set	94	5 (5.3%) (1.7%, 12.0%)	96	1 (1.0%) (0.0%, 5.7%)	5.34 (0.61, 46.58)	5.11 (0.61, 42.89)	4.3% (-0.7%, 9.2%)	0.0917+	--
Baseline Disease Severity									
Moderate baseline disease (IGA=3)	61	3 (4.9%) (1.0%, 13.7%)	57	1 (1.8%) (0.0%, 9.4%)	2.90 (0.29, 28.68)	2.80 (0.30, 26.18)	3.2% (-3.2%, 9.6%)	0.6194	0.6039
Severe baseline disease (IGA=4)	33	2 (6.1%) (0.7%, 20.2%)	39	0 (0.0%)	6.27 (0.29, 135.37)	5.88 (0.29, 118.36)	6.1% (-3.3%, 15.5%)	0.2066	
Gender									
Male	56	3 (5.4%) (1.1%, 14.9%)	44	0 (0.0%)	5.82 (0.29, 115.75)	5.53 (0.29, 104.25)	5.0% (-1.9%, 12.0%)	0.2533	0.7608
Female	38	2 (5.3%) (0.6%, 17.7%)	52	1 (1.9%) (0.0%, 10.3%)	2.83 (0.25, 32.44)	2.74 (0.26, 29.09)	3.3% (-4.7%, 11.4%)	0.5711	
Region									
US/Canada/Australia	28	0 (0.0%)	33	0 (0.0%)	1.18 (0.02, 61.15)	1.17 (0.02, 57.26)	0.3% (-6.0%, 6.5%)	NE	0.2121
Europe	29	1 (3.4%) (0.1%, 17.8%)	27	0 (0.0%)	2.89 (0.11, 74.15)	2.80 (0.12, 65.93)	3.2% (-6.0%, 12.4%)	1.0000	
Asia	28	4 (14.3%) (4.0%, 32.7%)	29	0 (0.0%)	10.84 (0.56, 211.32)	9.31 (0.52, 165.33)	13.9% (-0.1%, 27.8%)	0.0518	
Latin America	9	0 (0.0%)	7	1 (14.3%) (0.4%, 57.9%)	0.23 (0.01, 6.52)	0.27 (0.01, 5.70)	-13.8% (-44.0%, 16.5%)	0.4375	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events of Special Interest (AESI)-Acne (PT) - Safety Set
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Weight Subgroup									
<= Median Value	46	3 (6.5%) (1.4%, 17.9%)	53	1 (1.9%) (0.0%, 10.1%)	3.63 (0.36, 36.15)	3.46 (0.37, 32.10)	4.6% (-3.4%, 12.7%)	0.3349	0.8956
> Median Value	48	2 (4.2%) (0.5%, 14.3%)	43	0 (0.0%)	4.68 (0.22, 100.20)	4.49 (0.22, 90.99)	4.0% (-2.9%, 10.9%)	0.4960	
Age Subgroup									
<= Median Value	57	4 (7.0%) (1.9%, 17.0%)	60	0 (0.0%)	10.18 (0.54, 193.44)	9.47 (0.52, 171.95)	6.9% (-0.3%, 14.2%)	0.0533	0.1962
> Median Value	37	1 (2.7%) (0.1%, 14.2%)	36	1 (2.8%) (0.1%, 14.5%)	0.97 (0.06, 16.16)	0.97 (0.06, 14.97)	-0.1% (-7.6%, 7.4%)	1.0000	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events of Special Interest (AESI)-Folliculitis (PT) - Safety Set
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Safety Set	94	2 (2.1%) (0.3%, 7.5%)	96	1 (1.0%) (0.0%, 5.7%)	2.07 (0.18, 23.17)	2.04 (0.19, 22.15)	1.1% (-2.5%, 4.6%)	0.5493+	--
Baseline Disease Severity									
Moderate baseline disease (IGA=3)	61	1 (1.6%) (0.0%, 8.8%)	57	0 (0.0%)	2.85 (0.11, 71.43)	2.81 (0.12, 67.52)	1.6% (-2.9%, 6.1%)	1.0000	0.8146
Severe baseline disease (IGA=4)	33	1 (3.0%) (0.1%, 15.8%)	39	1 (2.6%) (0.1%, 13.5%)	1.19 (0.07, 19.75)	1.18 (0.08, 18.17)	0.5% (-7.2%, 8.1%)	1.0000	
Gender									
Male	56	1 (1.8%) (0.0%, 9.6%)	44	1 (2.3%) (0.1%, 12.0%)	0.78 (0.05, 12.86)	0.79 (0.05, 12.21)	-0.5% (-6.1%, 5.1%)	1.0000	0.4201
Female	38	1 (2.6%) (0.1%, 13.8%)	52	0 (0.0%)	4.20 (0.17, 105.95)	4.08 (0.17, 97.43)	2.9% (-3.7%, 9.5%)	0.4222	
Region									
US/Canada/Australia	28	1 (3.6%) (0.1%, 18.3%)	33	0 (0.0%)	3.65 (0.14, 93.32)	3.52 (0.15, 83.07)	3.7% (-5.3%, 12.7%)	0.4590	0.9049
Europe	29	0 (0.0%)	27	0 (0.0%)	0.93 (0.02, 48.62)	0.93 (0.02, 45.47)	-0.1% (-6.8%, 6.6%)	NE	
Asia	28	1 (3.6%) (0.1%, 18.3%)	29	1 (3.4%) (0.1%, 17.8%)	1.04 (0.06, 17.43)	1.04 (0.07, 15.77)	0.1% (-9.4%, 9.7%)	1.0000	
Latin America	9	0 (0.0%)	7	0 (0.0%)	0.79 (0.01, 44.65)	0.80 (0.02, 36.05)	-1.3% (-22.8%, 20.3%)	NE	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events of Special Interest (AESI)-Folliculitis (PT) - Safety Set
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Weight Subgroup									
<= Median Value	46	0 (0.0%)	53	1 (1.9%) (0.0%, 10.1%)	0.38 (0.01, 9.47)	0.38 (0.02, 9.18)	-1.7% (-7.0%, 3.6%)	1.0000	0.1986
> Median Value	48	2 (4.2%) (0.5%, 14.3%)	43	0 (0.0%)	4.68 (0.22, 100.20)	4.49 (0.22, 90.99)	4.0% (-2.9%, 10.9%)	0.4960	
Age Subgroup									
<= Median Value	57	0 (0.0%)	60	1 (1.7%) (0.0%, 8.9%)	0.34 (0.01, 8.64)	0.35 (0.01, 8.43)	-1.6% (-6.2%, 3.0%)	1.0000	0.1649
> Median Value	37	2 (5.4%) (0.7%, 18.2%)	36	0 (0.0%)	5.14 (0.24, 110.89)	4.87 (0.24, 98.02)	5.2% (-3.5%, 13.9%)	0.4932	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events by SOC/PT-Any Treatment Emergent Adverse Events - Infections and infestations [SOC] - Safety Set
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Safety Set	94	34 (36.2%) (26.5%, 46.7%)	96	30 (31.3%) (22.2%, 41.5%)	1.25 (0.68, 2.28)	1.16 (0.78, 1.73)	4.9% (-8.5%, 18.3%)	0.4727+	--
Baseline Disease Severity									
Moderate baseline disease (IGA=3)	61	19 (31.1%) (19.9%, 44.3%)	57	17 (29.8%) (18.4%, 43.4%)	1.06 (0.49, 2.33)	1.04 (0.61, 1.80)	1.3% (-15.3%, 17.9%)	1.0000	0.4245
Severe baseline disease (IGA=4)	33	15 (45.5%) (28.1%, 63.6%)	39	13 (33.3%) (19.1%, 50.2%)	1.67 (0.64, 4.33)	1.36 (0.76, 2.44)	12.1% (-10.4%, 34.6%)	0.3380	
Gender									
Male	56	18 (32.1%) (20.3%, 46.0%)	44	12 (27.3%) (15.0%, 42.8%)	1.26 (0.53, 3.01)	1.18 (0.64, 2.18)	4.9% (-13.1%, 22.8%)	0.6638	0.8071
Female	38	16 (42.1%) (26.3%, 59.2%)	52	18 (34.6%) (22.0%, 49.1%)	1.37 (0.58, 3.25)	1.22 (0.72, 2.06)	7.5% (-12.8%, 27.8%)	0.5141	
Region									
US/Canada/Australia	28	7 (25.0%) (10.7%, 44.9%)	33	6 (18.2%) (7.0%, 35.5%)	1.50 (0.44, 5.13)	1.38 (0.52, 3.62)	6.8% (-13.9%, 27.6%)	0.5471	0.2252
Europe	29	17 (58.6%) (38.9%, 76.5%)	27	10 (37.0%) (19.4%, 57.6%)	2.41 (0.82, 7.06)	1.58 (0.89, 2.82)	21.6% (-4.0%, 47.1%)	0.1194	
Asia	28	10 (35.7%) (18.6%, 55.9%)	29	13 (44.8%) (26.4%, 64.3%)	0.68 (0.24, 1.98)	0.80 (0.42, 1.51)	-9.1% (-34.5%, 16.2%)	0.5919	
Latin America	9	0 (0.0%)	7	1 (14.3%) (0.4%, 57.9%)	0.23 (0.01, 6.52)	0.27 (0.01, 5.70)	-13.8% (-44.0%, 16.5%)	0.4375	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events by SOC/PT-Any Treatment Emergent Adverse Events - Infections and infestations [SOC] - Safety Set
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Weight Subgroup									
<= Median Value	46	13 (28.3%) (16.0%, 43.5%)	53	20 (37.7%) (24.8%, 52.1%)	0.65 (0.28, 1.52)	0.75 (0.42, 1.33)	-9.5% (-27.9%, 9.0%)	0.3941	0.0284*
> Median Value	48	21 (43.8%) (29.5%, 58.8%)	43	10 (23.3%) (11.8%, 38.6%)	2.57 (1.03, 6.37)	1.88 (1.00, 3.53)	20.5% (1.6%, 39.4%)	0.0480*	
Age Subgroup									
<= Median Value	57	18 (31.6%) (19.9%, 45.2%)	60	21 (35.0%) (23.1%, 48.4%)	0.86 (0.40, 1.85)	0.90 (0.54, 1.51)	-3.4% (-20.5%, 13.6%)	0.8446	0.1229
> Median Value	37	16 (43.2%) (27.1%, 60.5%)	36	9 (25.0%) (12.1%, 42.2%)	2.29 (0.84, 6.19)	1.73 (0.88, 3.40)	18.2% (-3.1%, 39.6%)	0.1396	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events by SOC/PT-Any Treatment Emergent Adverse Events - Gastrointestinal disorders [SOC] - Safety Set
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Safety Set	94	22 (23.4%) (15.3%, 33.3%)	96	8 (8.3%) (3.7%, 15.8%)	3.36 (1.41, 8.00)	2.81 (1.32, 5.99)	15.1% (4.9%, 25.3%)	0.003	--
Baseline Disease Severity									
Moderate baseline disease (IGA=3)	61	15 (24.6%) (14.5%, 37.3%)	57	5 (8.8%) (2.9%, 19.3%)	3.39 (1.14, 10.06)	2.80 (1.09, 7.22)	15.8% (2.8%, 28.9%)	0.0274*	0.8087
Severe baseline disease (IGA=4)	33	7 (21.2%) (9.0%, 38.9%)	39	3 (7.7%) (1.6%, 20.9%)	3.23 (0.76, 13.68)	2.76 (0.77, 9.82)	13.5% (-2.7%, 29.8%)	0.1698	
Gender									
Male	56	11 (19.6%) (10.2%, 32.4%)	44	3 (6.8%) (1.4%, 18.7%)	3.34 (0.87, 12.82)	2.88 (0.86, 9.70)	12.8% (0.0%, 25.6%)	0.0848	0.4915
Female	38	11 (28.9%) (15.4%, 45.9%)	52	5 (9.6%) (3.2%, 21.0%)	3.83 (1.20, 12.19)	3.01 (1.14, 7.95)	19.3% (2.8%, 35.8%)	0.0252*	
Region									
US/Canada/Australia	28	6 (21.4%) (8.3%, 41.0%)	33	2 (6.1%) (0.7%, 20.2%)	4.23 (0.78, 22.93)	3.54 (0.77, 16.15)	15.4% (-1.9%, 32.6%)	0.1272	0.2652
Europe	29	4 (13.8%) (3.9%, 31.7%)	27	3 (11.1%) (2.4%, 29.2%)	1.28 (0.26, 6.33)	1.24 (0.31, 5.05)	2.7% (-14.6%, 19.9%)	1.0000	
Asia	28	10 (35.7%) (18.6%, 55.9%)	29	2 (6.9%) (0.8%, 22.8%)	7.50 (1.47, 38.32)	5.18 (1.24, 21.57)	28.8% (8.8%, 48.8%)	0.0099*	
Latin America	9	2 (22.2%) (2.8%, 60.0%)	7	1 (14.3%) (0.4%, 57.9%)	1.71 (0.12, 23.94)	1.56 (0.17, 13.87)	7.9% (-29.6%, 45.5%)	1.0000	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events by SOC/PT-Any Treatment Emergent Adverse Events - Gastrointestinal disorders [SOC] - Safety Set
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Weight Subgroup									
<= Median Value	46	12 (26.1%) (14.3%, 41.1%)	53	4 (7.5%) (2.1%, 18.2%)	4.32 (1.29, 14.55)	3.46 (1.20, 9.98)	18.5% (4.0%, 33.1%)	0.0150*	0.4991
> Median Value	48	10 (20.8%) (10.5%, 35.0%)	43	4 (9.3%) (2.6%, 22.1%)	2.57 (0.74, 8.89)	2.24 (0.76, 6.62)	11.5% (-2.9%, 25.9%)	0.1544	
Age Subgroup									
<= Median Value	57	14 (24.6%) (14.1%, 37.8%)	60	6 (10.0%) (3.8%, 20.5%)	2.93 (1.04, 8.26)	2.46 (1.01, 5.95)	14.6% (1.1%, 28.1%)	0.0492*	0.9383
> Median Value	37	8 (21.6%) (9.8%, 38.2%)	36	2 (5.6%) (0.7%, 18.7%)	4.69 (0.92, 23.86)	3.89 (0.89, 17.10)	16.1% (0.8%, 31.3%)	0.0854	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events by SOC/PT-Any Treatment Emergent Adverse Events - Nervous system disorders [SOC] - Safety Set
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Safety Set	94	14 (14.9%) (8.4%, 23.7%)	96	9 (9.4%) (4.4%, 17.1%)	1.69 (0.69, 4.12)	1.59 (0.72, 3.49)	5.5% (-3.7%, 14.8%)	0.2429+	--
Baseline Disease Severity									
Moderate baseline disease (IGA=3)	61	9 (14.8%) (7.0%, 26.2%)	57	6 (10.5%) (4.0%, 21.5%)	1.47 (0.49, 4.43)	1.40 (0.53, 3.69)	4.2% (-7.7%, 16.2%)	0.5855	0.7462
Severe baseline disease (IGA=4)	33	5 (15.2%) (5.1%, 31.9%)	39	3 (7.7%) (1.6%, 20.9%)	2.14 (0.47, 9.74)	1.97 (0.51, 7.63)	7.5% (-7.4%, 22.3%)	0.4563	
Gender									
Male	56	8 (14.3%) (6.4%, 26.2%)	44	3 (6.8%) (1.4%, 18.7%)	2.28 (0.57, 9.15)	2.10 (0.59, 7.44)	7.5% (-4.3%, 19.3%)	0.3384	0.7567
Female	38	6 (15.8%) (6.0%, 31.3%)	52	6 (11.5%) (4.4%, 23.4%)	1.44 (0.43, 4.86)	1.37 (0.48, 3.92)	4.3% (-10.2%, 18.7%)	0.7548	
Region									
US/Canada/Australia	28	2 (7.1%) (0.9%, 23.5%)	33	3 (9.1%) (1.9%, 24.3%)	0.77 (0.12, 4.96)	0.79 (0.14, 4.37)	-1.9% (-15.6%, 11.7%)	1.0000	0.0313*
Europe	29	1 (3.4%) (0.1%, 17.8%)	27	3 (11.1%) (2.4%, 29.2%)	0.29 (0.03, 2.93)	0.31 (0.03, 2.81)	-7.7% (-21.3%, 5.9%)	0.3434	
Asia	28	8 (28.6%) (13.2%, 48.7%)	29	1 (3.4%) (0.1%, 17.8%)	11.20 (1.30, 96.79)	8.29 (1.11, 62.02)	25.1% (7.1%, 43.1%)	0.0119*	
Latin America	9	3 (33.3%) (7.5%, 70.1%)	7	2 (28.6%) (3.7%, 71.0%)	1.25 (0.15, 10.70)	1.17 (0.26, 5.19)	4.8% (-40.7%, 50.2%)	1.0000	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events by SOC/PT-Any Treatment Emergent Adverse Events - Nervous system disorders [SOC] - Safety Set
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Weight Subgroup									
<= Median Value	46	7 (15.2%) (6.3%, 28.9%)	53	6 (11.3%) (4.3%, 23.0%)	1.41 (0.44, 4.53)	1.34 (0.49, 3.71)	3.9% (-9.5%, 17.3%)	0.7666	0.7085
> Median Value	48	7 (14.6%) (6.1%, 27.8%)	43	3 (7.0%) (1.5%, 19.1%)	2.28 (0.55, 9.43)	2.09 (0.58, 7.58)	7.6% (-5.0%, 20.2%)	0.3233	
Age Subgroup									
<= Median Value	57	6 (10.5%) (4.0%, 21.5%)	60	7 (11.7%) (4.8%, 22.6%)	0.89 (0.28, 2.83)	0.90 (0.32, 2.52)	-1.1% (-12.5%, 10.2%)	1.0000	0.0748
> Median Value	37	8 (21.6%) (9.8%, 38.2%)	36	2 (5.6%) (0.7%, 18.7%)	4.69 (0.92, 23.86)	3.89 (0.89, 17.10)	16.1% (0.8%, 31.3%)	0.0854	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events by SOC/PT-Any Treatment Emergent Adverse Events - Nausea [PT] - Safety Set
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Safety Set	94	17 (18.1%) (10.9%, 27.4%)	96	1 (1.0%) (0.0%, 5.7%)	20.97 (2.73, >99.99)	17.36 (2.36, >99.99)	17.0% (9.0%, 25.1%)	<0.0001+*	--
Baseline Disease Severity									
Moderate baseline disease (IGA=3)	61	11 (18.0%) (9.4%, 30.0%)	57	1 (1.8%) (0.0%, 9.4%)	12.32 (1.54, 98.85)	10.28 (1.37, 77.10)	16.3% (6.0%, 26.5%)	0.0044*	0.8605
Severe baseline disease (IGA=4)	33	6 (18.2%) (7.0%, 35.5%)	39	0 (0.0%)	18.67 (1.01, 345.30)	15.29 (0.89, 261.74)	17.9% (4.2%, 31.5%)	0.0071*	
Gender									
Male	56	8 (14.3%) (6.4%, 26.2%)	44	0 (0.0%)	15.60 (0.87, 278.15)	13.42 (0.80, 226.35)	13.8% (4.1%, 23.5%)	0.0086*	0.3386
Female	38	9 (23.7%) (11.4%, 40.2%)	52	1 (1.9%) (0.0%, 10.3%)	15.83 (1.91, 131.29)	12.32 (1.63, 93.14)	21.8% (7.7%, 35.8%)	0.0016*	
Region									
US/Canada/Australia	28	3 (10.7%) (2.3%, 28.2%)	33	0 (0.0%)	9.20 (0.45, 186.12)	8.21 (0.44, 152.39)	10.6% (-1.9%, 23.1%)	0.0910	0.0582
Europe	29	2 (6.9%) (0.8%, 22.8%)	27	0 (0.0%)	5.00 (0.23, 109.01)	4.67 (0.23, 93.02)	6.5% (-4.5%, 17.6%)	0.4916	
Asia	28	10 (35.7%) (18.6%, 55.9%)	29	0 (0.0%)	33.49 (1.85, 606.14)	21.72 (1.33, 353.95)	34.5% (16.5%, 52.6%)	0.0003*	
Latin America	9	2 (22.2%) (2.8%, 60.0%)	7	1 (14.3%) (0.4%, 57.9%)	1.71 (0.12, 23.94)	1.56 (0.17, 13.87)	7.9% (-29.6%, 45.5%)	1.0000	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events by SOC/PT-Any Treatment Emergent Adverse Events - Nausea [PT] - Safety Set
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Weight Subgroup									
<= Median Value	46	10 (21.7%) (10.9%, 36.4%)	53	0 (0.0%)	30.78 (1.75, 541.83)	24.13 (1.45, 400.74)	21.4% (9.2%, 33.6%)	0.0003*	0.2778
> Median Value	48	7 (14.6%) (6.1%, 27.8%)	43	1 (2.3%) (0.1%, 12.3%)	7.17 (0.84, 60.89)	6.27 (0.80, 48.93)	12.3% (1.3%, 23.2%)	0.0616	
Age Subgroup									
<= Median Value	57	11 (19.3%) (10.0%, 31.9%)	60	1 (1.7%) (0.0%, 8.9%)	14.11 (1.76, 113.28)	11.58 (1.54, 86.83)	17.6% (6.9%, 28.4%)	0.0017*	0.8169
> Median Value	37	6 (16.2%) (6.2%, 32.0%)	36	0 (0.0%)	15.06 (0.82, 278.09)	12.66 (0.74, 216.78)	15.8% (3.2%, 28.3%)	0.0251*	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events by SOC/PT-Any Treatment Emergent Adverse Events - Upper respiratory tract infection [PT] - Safety Set
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Safety Set	94	10 (10.6%) (5.2%, 18.7%)	96	10 (10.4%) (5.1%, 18.3%)	1.02 (0.41, 2.59)	1.02 (0.45, 2.34)	0.2% (-8.5%, 9.0%)	0.9603+	--
Baseline Disease Severity									
Moderate baseline disease (IGA=3)	61	5 (8.2%) (2.7%, 18.1%)	57	4 (7.0%) (1.9%, 17.0%)	1.18 (0.30, 4.64)	1.17 (0.33, 4.14)	1.2% (-8.4%, 10.7%)	1.0000	0.8914
Severe baseline disease (IGA=4)	33	5 (15.2%) (5.1%, 31.9%)	39	6 (15.4%) (5.9%, 30.5%)	0.98 (0.27, 3.57)	0.98 (0.33, 2.94)	-0.2% (-16.9%, 16.4%)	1.0000	
Gender									
Male	56	4 (7.1%) (2.0%, 17.3%)	44	2 (4.5%) (0.6%, 15.5%)	1.62 (0.28, 9.25)	1.57 (0.30, 8.19)	2.6% (-6.5%, 11.7%)	0.6920	0.8279
Female	38	6 (15.8%) (6.0%, 31.3%)	52	8 (15.4%) (6.9%, 28.1%)	1.03 (0.33, 3.26)	1.03 (0.39, 2.71)	0.4% (-14.8%, 15.6%)	1.0000	
Region									
US/Canada/Australia	28	2 (7.1%) (0.9%, 23.5%)	33	0 (0.0%)	6.32 (0.29, 137.37)	5.86 (0.29, 117.23)	7.2% (-3.8%, 18.1%)	0.2066	0.6428
Europe	29	4 (13.8%) (3.9%, 31.7%)	27	5 (18.5%) (6.3%, 38.1%)	0.70 (0.17, 2.95)	0.74 (0.22, 2.49)	-4.7% (-24.0%, 14.6%)	0.7249	
Asia	28	4 (14.3%) (4.0%, 32.7%)	29	5 (17.2%) (5.8%, 35.8%)	0.80 (0.19, 3.35)	0.83 (0.25, 2.77)	-3.0% (-21.9%, 15.9%)	1.0000	
Latin America	9	0 (0.0%)	7	0 (0.0%)	0.79 (0.01, 44.65)	0.80 (0.02, 36.05)	-1.3% (-22.8%, 20.3%)	NE	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Adverse Events by SOC/PT-Any Treatment Emergent Adverse Events - Upper respiratory tract infection [PT] - Safety Set
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Weight Subgroup									
<= Median Value	46	5 (10.9%) (3.6%, 23.6%)	53	7 (13.2%) (5.5%, 25.3%)	0.80 (0.24, 2.72)	0.82 (0.28, 2.42)	-2.3% (-15.1%, 10.5%)	0.7674	0.5153
> Median Value	48	5 (10.4%) (3.5%, 22.7%)	43	3 (7.0%) (1.5%, 19.1%)	1.55 (0.35, 6.91)	1.49 (0.38, 5.88)	3.4% (-8.1%, 15.0%)	0.7174	
Age Subgroup									
<= Median Value	57	5 (8.8%) (2.9%, 19.3%)	60	8 (13.3%) (5.9%, 24.6%)	0.63 (0.19, 2.04)	0.66 (0.23, 1.89)	-4.6% (-15.9%, 6.7%)	0.5598	0.1605
> Median Value	37	5 (13.5%) (4.5%, 28.8%)	36	2 (5.6%) (0.7%, 18.7%)	2.66 (0.48, 14.68)	2.43 (0.50, 11.74)	8.0% (-5.4%, 21.3%)	0.4297	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Selected Adverse Events (PT)-PT Natural killer cell count decreased - Safety Set
JADE TEEN (PF-04965842) - 2023 datacut

No adverse events of this type occurred

Binary Outcome Analysis: Selected Adverse Events (PT)-PT Headache - Safety Set
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Safety Set	94	8 (8.5%) (3.7%, 16.1%)	96	7 (7.3%) (3.0%, 14.4%)	1.18 (0.41, 3.40)	1.17 (0.44, 3.09)	1.2% (-6.5%, 8.9%)	0.7555+	--
Baseline Disease Severity									
Moderate baseline disease (IGA=3)	61	6 (9.8%) (3.7%, 20.2%)	57	5 (8.8%) (2.9%, 19.3%)	1.13 (0.33, 3.94)	1.12 (0.36, 3.47)	1.1% (-9.4%, 11.5%)	1.0000	0.9821
Severe baseline disease (IGA=4)	33	2 (6.1%) (0.7%, 20.2%)	39	2 (5.1%) (0.6%, 17.3%)	1.19 (0.16, 8.97)	1.18 (0.18, 7.94)	0.9% (-9.8%, 11.6%)	1.0000	
Gender									
Male	56	4 (7.1%) (2.0%, 17.3%)	44	1 (2.3%) (0.1%, 12.0%)	3.31 (0.36, 30.71)	3.14 (0.36, 27.13)	4.9% (-3.2%, 12.9%)	0.3808	0.4782
Female	38	4 (10.5%) (2.9%, 24.8%)	52	6 (11.5%) (4.4%, 23.4%)	0.90 (0.24, 3.45)	0.91 (0.28, 3.01)	-1.0% (-14.1%, 12.0%)	1.0000	
Region									
US/Canada/Australia	28	2 (7.1%) (0.9%, 23.5%)	33	3 (9.1%) (1.9%, 24.3%)	0.77 (0.12, 4.96)	0.79 (0.14, 4.37)	-1.9% (-15.6%, 11.7%)	1.0000	0.5578
Europe	29	1 (3.4%) (0.1%, 17.8%)	27	2 (7.4%) (0.9%, 24.3%)	0.45 (0.04, 5.23)	0.47 (0.04, 4.84)	-4.0% (-15.9%, 7.9%)	0.6045	
Asia	28	2 (7.1%) (0.9%, 23.5%)	29	0 (0.0%)	5.57 (0.26, 121.27)	5.17 (0.26, 103.18)	7.0% (-4.2%, 18.1%)	0.2368	
Latin America	9	3 (33.3%) (7.5%, 70.1%)	7	2 (28.6%) (3.7%, 71.0%)	1.25 (0.15, 10.70)	1.17 (0.26, 5.19)	4.8% (-40.7%, 50.2%)	1.0000	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Selected Adverse Events (PT)-PT Headache - Safety Set
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Weight Subgroup									
<= Median Value	46	3 (6.5%) (1.4%, 17.9%)	53	4 (7.5%) (2.1%, 18.2%)	0.85 (0.18, 4.03)	0.86 (0.20, 3.66)	-1.0% (-11.1%, 9.0%)	1.0000	0.5678
> Median Value	48	5 (10.4%) (3.5%, 22.7%)	43	3 (7.0%) (1.5%, 19.1%)	1.55 (0.35, 6.91)	1.49 (0.38, 5.88)	3.4% (-8.1%, 15.0%)	0.7174	
Age Subgroup									
<= Median Value	57	5 (8.8%) (2.9%, 19.3%)	60	5 (8.3%) (2.8%, 18.4%)	1.06 (0.29, 3.87)	1.05 (0.32, 3.44)	0.4% (-9.7%, 10.6%)	1.0000	0.7901
> Median Value	37	3 (8.1%) (1.7%, 21.9%)	36	2 (5.6%) (0.7%, 18.7%)	1.50 (0.24, 9.55)	1.46 (0.26, 8.23)	2.6% (-9.0%, 14.1%)	1.0000	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Selected Adverse Events (PT)-SOC Nervous system disorders - Safety Set
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Safety Set	94	14 (14.9%) (8.4%, 23.7%)	96	9 (9.4%) (4.4%, 17.1%)	1.69 (0.69, 4.12)	1.59 (0.72, 3.49)	5.5% (-3.7%, 14.8%)	0.2429+	--
Baseline Disease Severity									
Moderate baseline disease (IGA=3)	61	9 (14.8%) (7.0%, 26.2%)	57	6 (10.5%) (4.0%, 21.5%)	1.47 (0.49, 4.43)	1.40 (0.53, 3.69)	4.2% (-7.7%, 16.2%)	0.5855	0.7462
Severe baseline disease (IGA=4)	33	5 (15.2%) (5.1%, 31.9%)	39	3 (7.7%) (1.6%, 20.9%)	2.14 (0.47, 9.74)	1.97 (0.51, 7.63)	7.5% (-7.4%, 22.3%)	0.4563	
Gender									
Male	56	8 (14.3%) (6.4%, 26.2%)	44	3 (6.8%) (1.4%, 18.7%)	2.28 (0.57, 9.15)	2.10 (0.59, 7.44)	7.5% (-4.3%, 19.3%)	0.3384	0.7567
Female	38	6 (15.8%) (6.0%, 31.3%)	52	6 (11.5%) (4.4%, 23.4%)	1.44 (0.43, 4.86)	1.37 (0.48, 3.92)	4.3% (-10.2%, 18.7%)	0.7548	
Region									
US/Canada/Australia	28	2 (7.1%) (0.9%, 23.5%)	33	3 (9.1%) (1.9%, 24.3%)	0.77 (0.12, 4.96)	0.79 (0.14, 4.37)	-1.9% (-15.6%, 11.7%)	1.0000	0.0313*
Europe	29	1 (3.4%) (0.1%, 17.8%)	27	3 (11.1%) (2.4%, 29.2%)	0.29 (0.03, 2.93)	0.31 (0.03, 2.81)	-7.7% (-21.3%, 5.9%)	0.3434	
Asia	28	8 (28.6%) (13.2%, 48.7%)	29	1 (3.4%) (0.1%, 17.8%)	11.20 (1.30, 96.79)	8.29 (1.11, 62.02)	25.1% (7.1%, 43.1%)	0.0119*	
Latin America	9	3 (33.3%) (7.5%, 70.1%)	7	2 (28.6%) (3.7%, 71.0%)	1.25 (0.15, 10.70)	1.17 (0.26, 5.19)	4.8% (-40.7%, 50.2%)	1.0000	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Selected Adverse Events (PT)-SOC Nervous system disorders - Safety Set
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Weight Subgroup									
<= Median Value	46	7 (15.2%) (6.3%, 28.9%)	53	6 (11.3%) (4.3%, 23.0%)	1.41 (0.44, 4.53)	1.34 (0.49, 3.71)	3.9% (-9.5%, 17.3%)	0.7666	0.7085
> Median Value	48	7 (14.6%) (6.1%, 27.8%)	43	3 (7.0%) (1.5%, 19.1%)	2.28 (0.55, 9.43)	2.09 (0.58, 7.58)	7.6% (-5.0%, 20.2%)	0.3233	
Age Subgroup									
<= Median Value	57	6 (10.5%) (4.0%, 21.5%)	60	7 (11.7%) (4.8%, 22.6%)	0.89 (0.28, 2.83)	0.90 (0.32, 2.52)	-1.1% (-12.5%, 10.2%)	1.0000	0.0748
> Median Value	37	8 (21.6%) (9.8%, 38.2%)	36	2 (5.6%) (0.7%, 18.7%)	4.69 (0.92, 23.86)	3.89 (0.89, 17.10)	16.1% (0.8%, 31.3%)	0.0854	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Selected Adverse Events (SOC)-SOC Skin and subcutaneous tissue disorders - Safety Set
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Overall									
Safety Set	94	9 (9.6%) (4.5%, 17.4%)	96	7 (7.3%) (3.0%, 14.4%)	1.35 (0.48, 3.78)	1.31 (0.51, 3.38)	2.3% (-5.6%, 10.2%)	0.5712+	--
Baseline Disease Severity									
Moderate baseline disease (IGA=3)	61	6 (9.8%) (3.7%, 20.2%)	57	6 (10.5%) (4.0%, 21.5%)	0.93 (0.28, 3.06)	0.93 (0.32, 2.73)	-0.7% (-11.6%, 10.2%)	1.0000	0.3635
Severe baseline disease (IGA=4)	33	3 (9.1%) (1.9%, 24.3%)	39	1 (2.6%) (0.1%, 13.5%)	3.80 (0.38, 38.41)	3.55 (0.39, 32.49)	6.5% (-4.5%, 17.5%)	0.3266	
Gender									
Male	56	5 (8.9%) (3.0%, 19.6%)	44	3 (6.8%) (1.4%, 18.7%)	1.34 (0.30, 5.94)	1.31 (0.33, 5.18)	2.1% (-8.4%, 12.7%)	1.0000	0.9266
Female	38	4 (10.5%) (2.9%, 24.8%)	52	4 (7.7%) (2.1%, 18.5%)	1.41 (0.33, 6.04)	1.37 (0.37, 5.13)	2.8% (-9.3%, 15.0%)	0.7172	
Region									
US/Canada/Australia	28	1 (3.6%) (0.1%, 18.3%)	33	2 (6.1%) (0.7%, 20.2%)	0.57 (0.05, 6.69)	0.59 (0.06, 6.16)	-2.5% (-13.1%, 8.2%)	1.0000	0.4491
Europe	29	2 (6.9%) (0.8%, 22.8%)	27	1 (3.7%) (0.1%, 19.0%)	1.93 (0.16, 22.55)	1.86 (0.18, 19.38)	3.2% (-8.5%, 14.8%)	1.0000	
Asia	28	6 (21.4%) (8.3%, 41.0%)	29	3 (10.3%) (2.2%, 27.4%)	2.36 (0.53, 10.57)	2.07 (0.57, 7.49)	11.1% (-7.7%, 29.9%)	0.2973	
Latin America	9	0 (0.0%)	7	1 (14.3%) (0.4%, 57.9%)	0.23 (0.01, 6.52)	0.27 (0.01, 5.70)	-13.8% (-44.0%, 16.5%)	0.4375	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Binary Outcome Analysis: Selected Adverse Events (SOC)-SOC Skin and subcutaneous tissue disorders - Safety Set
JADE TEEN (PF-04965842) - 2023 datacut

	PF-04965842 200mg QD		Placebo		Placebo vs. PF-04965842 200mg QD				
Visit / Population	n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH or Logistic Regression p-value [1]	P-val [2] for trt*subgroup interaction
Weight Subgroup									
<= Median Value	46	4 (8.7%) (2.4%, 20.8%)	53	5 (9.4%) (3.1%, 20.7%)	0.91 (0.23, 3.63)	0.92 (0.26, 3.23)	-0.7% (-12.1%, 10.6%)	1.0000	0.4199
> Median Value	48	5 (10.4%) (3.5%, 22.7%)	43	2 (4.7%) (0.6%, 15.8%)	2.38 (0.44, 12.98)	2.24 (0.46, 10.95)	5.8% (-4.9%, 16.5%)	0.4396	
Age Subgroup									
<= Median Value	57	8 (14.0%) (6.3%, 25.8%)	60	4 (6.7%) (1.8%, 16.2%)	2.29 (0.65, 8.06)	2.11 (0.67, 6.61)	7.4% (-3.6%, 18.4%)	0.2317	0.0885
> Median Value	37	1 (2.7%) (0.1%, 14.2%)	36	3 (8.3%) (1.8%, 22.5%)	0.31 (0.03, 3.08)	0.32 (0.04, 2.97)	-5.6% (-16.1%, 4.8%)	0.3575	

Notes:
Number of subjects: Safety Set
Analysis on overall population is calculated based on unstratified models, for OR, RR, and RD, using generalized linear models with logit, log, and identity link, respectively.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.
[+] Unstratified Wald p-value for the risk difference, from a generalized linear model with identity link.
[*] p-value <0.05
NE: not estimable; OR: Odds Ratio; RD: Risk Difference; RR: Relative Risk.

Safety incidence analysis: Treatment Emergent Adverse Events leading to study drug discontinuation, overall and by SOC/PT - Safety Set
JADE TEEN (PF-04965842) - 2023 datacut

System Organ Class (SOC) Preferred Term (PT)	PF-04965842 200mg QD N=94	Placebo N=96	Total Population N=190
Overall	2 (2.1%)	2 (2.1%)	4 (2.1%)
Infections and infestations	0	2 (2.1%)	2 (1.1%)
Upper respiratory tract infection	0	1 (1.0%)	1 (0.5%)
Wound abscess	0	1 (1.0%)	1 (0.5%)
Gastrointestinal disorders	1 (1.1%)	0	1 (0.5%)
Gastrooesophageal reflux disease	1 (1.1%)	0	1 (0.5%)
Nausea	1 (1.1%)	0	1 (0.5%)
Vomiting	1 (1.1%)	0	1 (0.5%)
Nervous system disorders	1 (1.1%)	0	1 (0.5%)
Headache	1 (1.1%)	0	1 (0.5%)

Safety incidence analysis: Severe Treatment Emergent Adverse Events leading to study drug discontinuation, overall and by SOC/PT - Safety Set
JADE TEEN (PF-04965842) - 2023 datacut

System Organ Class (SOC) Preferred Term (PT)	PF-04965842 200mg QD N=94	Placebo N=96	Total Population N=190
Overall	0 (0.0%)	0 (0.0%)	0 (0.0%)

Safety incidence analysis: Serious Treatment Emergent Adverse Events leading to study drug discontinuation, overall and by SOC/PT - Safety Set
JADE TEEN (PF-04965842) - 2023 datacut

System Organ Class (SOC) Preferred Term (PT)	PF-04965842 200mg QD N=94	Placebo N=96	Total Population N=190
Overall	0 (0.0%)	0 (0.0%)	0 (0.0%)

MMRM Analysen JADE TEEN

MMRM models: EASI01-Total EASI Score (Derived) percent change from baseline, Total population - Full Analysis Set Population
JADE TEEN (PF-04965842) - 2023 datacut

Variable / analysis	PF-04965842 200mg QD N=94	Placebo N=96
Baseline		
Return Rate (% subjects with missing data)		
Results at Baseline	0 (0.0%)	0 (0.0%)
Descriptive Results of Actual Values		
N with data	94	96
Mean (SD)	29.52 (12.20)	29.17 (12.68)
p25, median, p75 | Min,Max |	19.8, 25.4, 37.7 | 16, 68 |	19.5, 24.5, 34.9 | 9, 64 |

Full Analysis Set Population
Least Square Means estimates of change from baseline are calculated from a MMRM analysis, using the change from baseline as outcome, study visit as repeated variable, subject as subject effect, and baseline value, baseline disease severity stratum, treatment, study visit and the interaction effect of study visit by treatment as fixed effects.
MMRM: Mixed model for repeated measures; SD: Standard Deviation; SE: Standard Deviation.

MMRM models: EASI01-Total EASI Score (Derived) percent change from baseline, Total population - Full Analysis Set Population
JADE TEEN (PF-04965842) - 2023 datacut

Variable / analysis	PF-04965842 200mg QD N=94	Placebo N=96
Week 2		
Return Rate (% subjects with missing data)		
Results at Week 2	2 (2.1%)	5 (5.2%)
Descriptive Results of Actual Values		
N with data	92	91
Mean (SD)	13.93 (12.13)	20.78 (12.31)
p25, median, p75 | Min,Max |	6.2, 11.0, 16.8 | 0, 59 |	12.9, 17.6, 25.0 | 3, 64 |
Descriptive Results of Change from baseline		
N with data	92	91
Mean (SD)	-54.69 (28.44)	-29.38 (27.22)
p25, median, p75 | Min,Max |	-75.7, -56.6, -41.8 | -98, 29 |	-49.6, -28.5, -10.7 | -84, 39 |
Least Square Means estimates of change from baseline		
Treatment arm estimate (SE), (95% CI)	-54.55 (3.55) (-61.58,-47.53)	-27.56 (3.51) (-34.51,-20.62)
Treatment arm difference (SE), (95% CI), p-value		-26.99 (4.99) (-36.87,-17.10) p<.0001
Hedge G analysis of change from baseline		
Treatment arm difference estimate (95% CI)		-0.62 (-0.92, -0.32)

Full Analysis Set Population
Least Square Means estimates of change from baseline are calculated from a MMRM analysis, using the change from baseline as outcome, study visit as repeated variable, subject as subject effect, and baseline value, baseline disease severity stratum, treatment, study visit and the interaction effect of study visit by treatment as fixed effects.
MMRM: Mixed model for repeated measures; SD: Standard Deviation; SE: Standard Deviation.

MMRM models: EASI01-Total EASI Score (Derived) percent change from baseline, Total population - Full Analysis Set Population
JADE TEEN (PF-04965842) - 2023 datacut

Variable / analysis	PF-04965842 200mg QD N=94	Placebo N=96
Week 4		
Return Rate (% subjects with missing data)		
Results at Week 4	3 (3.2%)	0 (0.0%)
Descriptive Results of Actual Values		
N with data	91	96
Mean (SD)	7.58 (9.34)	16.83 (12.91)
p25, median, p75 | Min,Max |	2.1, 4.3, 10.4 | 0, 54 |	8.2, 13.2, 20.3 | 1, 68 |
Descriptive Results of Change from baseline		
N with data	91	96
Mean (SD)	-75.18 (23.88)	-41.48 (45.08)
p25, median, p75 | Min,Max |	-92.0, -82.7, -66.7 | -100, 0 |	-68.8, -50.2, -24.6 | -93, 300 |
Least Square Means estimates of change from baseline		
Treatment arm estimate (SE), (95% CI)	-74.26 (3.82) (-81.80,-66.71)	-41.71 (3.74) (-49.08,-34.33)
Treatment arm difference (SE), (95% CI), p-value		-32.55 (5.35) (-43.10,-22.00) p<.0001
Hedge G analysis of change from baseline		
Treatment arm difference estimate (95% CI)		-0.61 (-0.91, -0.32)

Full Analysis Set Population
Least Square Means estimates of change from baseline are calculated from a MMRM analysis, using the change from baseline as outcome, study visit as repeated variable, subject as subject effect, and baseline value, baseline disease severity stratum, treatment, study visit and the interaction effect of study visit by treatment as fixed effects.
MMRM: Mixed model for repeated measures; SD: Standard Deviation; SE: Standard Deviation.

MMRM models: EASI01-Total EASI Score (Derived) percent change from baseline, Total population - Full Analysis Set Population
JADE TEEN (PF-04965842) - 2023 datacut

Variable / analysis	PF-04965842 200mg QD N=94	Placebo N=96
Week 8		
Return Rate (% subjects with missing data)		
Results at Week 8	5 (5.3%)	6 (6.3%)
Descriptive Results of Actual Values		
N with data	89	90
Mean (SD)	6.78 (9.26)	12.98 (13.58)
p25, median, p75 | Min,Max |	1.0, 2.9, 8.0 | 0, 52 |	4.2, 9.2, 16.5 | 0, 70 |
Descriptive Results of Change from baseline		
N with data	89	90
Mean (SD)	-78.32 (24.92)	-56.85 (33.17)
p25, median, p75 | Min,Max |	-95.5, -88.1, -71.7 | -100, -2 |	-82.1, -65.7, -39.6 | -99, 48 |
Least Square Means estimates of change from baseline		
Treatment arm estimate (SE), (95% CI)	-77.87 (3.03) (-83.86,-71.89)	-57.56 (2.99) (-63.46,-51.66)
Treatment arm difference (SE), (95% CI), p-value		-20.31 (4.26) (-28.73,-11.90) p<.0001
Hedge G analysis of change from baseline		
Treatment arm difference estimate (95% CI)		-0.63 (-0.93, -0.33)

Full Analysis Set Population
Least Square Means estimates of change from baseline are calculated from a MMRM analysis, using the change from baseline as outcome, study visit as repeated variable, subject as subject effect, and baseline value, baseline disease severity stratum, treatment, study visit and the interaction effect of study visit by treatment as fixed effects.
MMRM: Mixed model for repeated measures; SD: Standard Deviation; SE: Standard Deviation.

MMRM models: EASI01-Total EASI Score (Derived) percent change from baseline, Total population - Full Analysis Set Population
JADE TEEN (PF-04965842) - 2023 datacut

Variable / analysis	PF-04965842 200mg QD N=94	Placebo N=96
Week 12		
Return Rate (% subjects with missing data)		
Results at Week 12	4 (4.3%)	6 (6.3%)
Descriptive Results of Actual Values		
N with data	90	90
Mean (SD)	5.97 (8.69)	11.81 (12.64)
p25, median, p75 | Min,Max |	0.8, 2.6, 6.6 | 0, 46 |	2.8, 7.0, 16.0 | 0, 60 |
Descriptive Results of Change from baseline		
N with data	90	90
Mean (SD)	-80.98 (24.13)	-62.41 (31.16)
p25, median, p75 | Min,Max |	-96.7, -90.2, -74.1 | -100, 50 |	-85.8, -70.8, -44.5 | -100, 24 |
Least Square Means estimates of change from baseline		
Treatment arm estimate (SE), (95% CI)	-80.68 (2.86) (-86.33,-75.02)	-63.65 (2.84) (-69.25,-58.05)
Treatment arm difference (SE), (95% CI), p-value		-17.02 (4.04) (-24.99,-9.06) p<.0001
Hedge G analysis of change from baseline		
Treatment arm difference estimate (95% CI)		-0.63 (-0.93, -0.33)

Full Analysis Set Population
Least Square Means estimates of change from baseline are calculated from a MMRM analysis, using the change from baseline as outcome, study visit as repeated variable, subject as subject effect, and baseline value, baseline disease severity stratum, treatment, study visit and the interaction effect of study visit by treatment as fixed effects.
MMRM: Mixed model for repeated measures; SD: Standard Deviation; SE: Standard Deviation.

MMRM models: EASI01-Total EASI Score (Derived) percent change from baseline, Total population - Full Analysis Set Population
JADE TEEN (PF-04965842) - 2023 datacut

Variable / analysis	PF-04965842 200mg QD N=94	Placebo N=96
Overall post-baseline		
Least Square Means estimates of change from baseline		
Treatment arm average post-baseline estimate (SE), (95% CI)	-71.84 (2.79) (-77.34,-66.34)	-47.62 (2.74) (-53.02,-42.22)
Treatment arm difference (SE), (95% CI), p-value		-24.22 (3.91) (-31.94,-16.50) p<.0001
Hedge G analysis of average post-baseline change		
Treatment arm difference estimate (95% CI)		-0.90 (-1.20, -0.60)

Full Analysis Set Population
Least Square Means estimates of change from baseline are calculated from a MMRM analysis, using the change from baseline as outcome, study visit as repeated variable, subject as subject effect, and baseline value, baseline disease severity stratum, treatment, study visit and the interaction effect of study visit by treatment as fixed effects.
MMRM: Mixed model for repeated measures; SD: Standard Deviation; SE: Standard Deviation.

MMRM models: SCA01-Total Score percent change from baseline, Total population - Full Analysis Set Population
JADE TEEN (PF-04965842) - 2023 datacut

Variable / analysis	PF-04965842 200mg QD N=94	Placebo N=96
Baseline		
Return Rate (% subjects with missing data)		
Results at Baseline	1 (1.1%)	0 (0.0%)
Descriptive Results of Actual Values		
N with data	93	96
Mean (SD)	66.24 (13.33)	68.51 (13.39)
p25, median, p75 | Min,Max |	56.4, 66.1, 76.4 | 32, 94 |	57.9, 68.3, 78.7 | 40, 101 |

Full Analysis Set Population
Least Square Means estimates of change from baseline are calculated from a MMRM analysis, using the change from baseline as outcome, study visit as repeated variable, subject as subject effect, and baseline value, baseline disease severity stratum, treatment, study visit and the interaction effect of study visit by treatment as fixed effects.
MMRM: Mixed model for repeated measures; SD: Standard Deviation; SE: Standard Deviation.

MMRM models: SCA01-Total Score percent change from baseline, Total population - Full Analysis Set Population
JADE TEEN (PF-04965842) - 2023 datacut

Variable / analysis	PF-04965842 200mg QD N=94	Placebo N=96
Week 2		
Return Rate (% subjects with missing data)		
Results at Week 2	2 (2.1%)	3 (3.1%)
Descriptive Results of Actual Values		
N with data	92	93
Mean (SD)	40.81 (19.26)	56.11 (16.97)
p25, median, p75 | Min,Max |	26.5, 38.7, 55.0 | 7, 95 |	47.0, 57.5, 66.1 | 18, 94 |
Descriptive Results of Change from baseline		
N with data	92	93
Mean (SD)	-38.76 (23.78)	-18.50 (19.88)
p25, median, p75 | Min,Max |	-54.1, -38.7, -22.2 | -90, 7 |	-30.1, -16.7, -4.5 | -67, 47 |
Least Square Means estimates of change from baseline		
Treatment arm estimate (SE), (95% CI)	-38.63 (2.30) (-43.16,-34.10)	-18.86 (2.26) (-23.33,-14.39)
Treatment arm difference (SE), (95% CI), p-value		-19.77 (3.23) (-26.15,-13.40) p<.0001
Hedge G analysis of change from baseline		
Treatment arm difference estimate (95% CI)		-0.74 (-1.04, -0.44)

Full Analysis Set Population
Least Square Means estimates of change from baseline are calculated from a MMRM analysis, using the change from baseline as outcome, study visit as repeated variable, subject as subject effect, and baseline value, baseline disease severity stratum, treatment, study visit and the interaction effect of study visit by treatment as fixed effects.
MMRM: Mixed model for repeated measures; SD: Standard Deviation; SE: Standard Deviation.

MMRM models: SCA01-Total Score percent change from baseline, Total population - Full Analysis Set Population
JADE TEEN (PF-04965842) - 2023 datacut

Variable / analysis	PF-04965842 200mg QD N=94	Placebo N=96
Week 4		
Return Rate (% subjects with missing data)		
Results at Week 4	5 (5.3%)	0 (0.0%)
Descriptive Results of Actual Values		
N with data	89	96
Mean (SD)	28.22 (17.88)	47.95 (17.16)
p25, median, p75 | Min,Max |	15.5, 25.0, 35.1 | 0, 82 |	34.8, 47.5, 59.0 | 17, 95 |
Descriptive Results of Change from baseline		
N with data	89	96
Mean (SD)	-57.56 (23.56)	-29.99 (20.95)
p25, median, p75 | Min,Max |	-73.2, -61.3, -42.1 | -100, 5 |	-48.3, -28.9, -16.3 | -73, 24 |
Least Square Means estimates of change from baseline		
Treatment arm estimate (SE), (95% CI)	-56.86 (2.34) (-61.47,-52.25)	-30.14 (2.27) (-34.63,-25.66)
Treatment arm difference (SE), (95% CI), p-value		-26.72 (3.26) (-33.16,-20.28) p<.0001
Hedge G analysis of change from baseline		
Treatment arm difference estimate (95% CI)		-0.74 (-1.04, -0.44)

Full Analysis Set Population
Least Square Means estimates of change from baseline are calculated from a MMRM analysis, using the change from baseline as outcome, study visit as repeated variable, subject as subject effect, and baseline value, baseline disease severity stratum, treatment, study visit and the interaction effect of study visit by treatment as fixed effects.
MMRM: Mixed model for repeated measures; SD: Standard Deviation; SE: Standard Deviation.

MMRM models: SCA01-Total Score percent change from baseline, Total population - Full Analysis Set Population
JADE TEEN (PF-04965842) - 2023 datacut

Variable / analysis	PF-04965842 200mg QD N=94	Placebo N=96
Week 8		
Return Rate (% subjects with missing data)		
Results at Week 8	5 (5.3%)	5 (5.2%)
Descriptive Results of Actual Values		
N with data	89	91
Mean (SD)	24.87 (17.27)	41.24 (20.26)
p25, median, p75 | Min,Max |	13.3, 22.1, 31.6 | 0, 75 |	25.1, 40.1, 51.7 | 6, 99 |
Descriptive Results of Change from baseline		
N with data	89	91
Mean (SD)	-62.40 (24.49)	-39.91 (24.23)
p25, median, p75 | Min,Max |	-78.7, -65.2, -53.3 | -100, 29 |	-56.0, -41.9, -19.6 | -92, 13 |
Least Square Means estimates of change from baseline		
Treatment arm estimate (SE), (95% CI)	-61.98 (2.54) (-66.98,-56.97)	-40.02 (2.49) (-44.93,-35.11)
Treatment arm difference (SE), (95% CI), p-value		-21.95 (3.56) (-28.98,-14.93) p<.0001
Hedge G analysis of change from baseline		
Treatment arm difference estimate (95% CI)		-0.75 (-1.05, -0.45)

Full Analysis Set Population
Least Square Means estimates of change from baseline are calculated from a MMRM analysis, using the change from baseline as outcome, study visit as repeated variable, subject as subject effect, and baseline value, baseline disease severity stratum, treatment, study visit and the interaction effect of study visit by treatment as fixed effects.
MMRM: Mixed model for repeated measures; SD: Standard Deviation; SE: Standard Deviation.

MMRM models: SCA01-Total Score percent change from baseline, Total population - Full Analysis Set Population
JADE TEEN (PF-04965842) - 2023 datacut

Variable / analysis	PF-04965842 200mg QD N=94	Placebo N=96
Week 12		
Return Rate (% subjects with missing data)		
Results at Week 12	5 (5.3%)	7 (7.3%)
Descriptive Results of Actual Values		
N with data	89	89
Mean (SD)	23.55 (17.35)	38.55 (21.17)
p25, median, p75 | Min,Max |	11.6, 18.6, 31.6 | 0, 90 |	23.0, 35.9, 51.9 | 0, 88 |
Descriptive Results of Change from baseline		
N with data	89	89
Mean (SD)	-64.58 (24.88)	-43.19 (28.25)
p25, median, p75 | Min,Max |	-82.1, -67.3, -52.2 | -100, 45 |	-65.3, -42.0, -21.7 | -100, 22 |
Least Square Means estimates of change from baseline		
Treatment arm estimate (SE), (95% CI)	-64.27 (2.78) (-69.76,-58.78)	-44.52 (2.75) (-49.94,-39.09)
Treatment arm difference (SE), (95% CI), p-value		-19.76 (3.91) (-27.48,-12.03) p<.0001
Hedge G analysis of change from baseline		
Treatment arm difference estimate (95% CI)		-0.75 (-1.06, -0.45)

Full Analysis Set Population
Least Square Means estimates of change from baseline are calculated from a MMRM analysis, using the change from baseline as outcome, study visit as repeated variable, subject as subject effect, and baseline value, baseline disease severity stratum, treatment, study visit and the interaction effect of study visit by treatment as fixed effects.
MMRM: Mixed model for repeated measures; SD: Standard Deviation; SE: Standard Deviation.

MMRM models: SCA01-Total Score percent change from baseline, Total population - Full Analysis Set Population
JADE TEEN (PF-04965842) - 2023 datacut

Variable / analysis	PF-04965842 200mg QD N=94	Placebo N=96
Overall post-baseline		
Least Square Means estimates of change from baseline		
Treatment arm average post-baseline estimate (SE), (95% CI)	-55.44 (2.08) (-59.55,-51.32)	-33.39 (2.04) (-37.41,-29.36)
Treatment arm difference (SE), (95% CI), p-value		-22.05 (2.92) (-27.82,-16.29) p<.0001
Hedge G analysis of average post-baseline change		
Treatment arm difference estimate (95% CI)		-1.10 (-1.41, -0.79)

Full Analysis Set Population
Least Square Means estimates of change from baseline are calculated from a MMRM analysis, using the change from baseline as outcome, study visit as repeated variable, subject as subject effect, and baseline value, baseline disease severity stratum, treatment, study visit and the interaction effect of study visit by treatment as fixed effects.
MMRM: Mixed model for repeated measures; SD: Standard Deviation; SE: Standard Deviation.

MMRM models: POEM01-Total Score, Total population - Full Analysis Set Population
JADE TEEN (PF-04965842) - 2023 datacut

Variable / analysis	PF-04965842 200mg QD N=94	Placebo N=96
Baseline		
Return Rate (% subjects with missing data)		
Results at Baseline	0 (0.0%)	1 (1.0%)
Descriptive Results of Actual Values		
N with data	94	95
Mean (SD)	19.20 (6.22)	19.84 (5.87)
p25, median, p75 | Min,Max |	15.0, 20.0, 24.0 | 5, 28 |	16.0, 21.0, 24.0 | 6, 28 |

Full Analysis Set Population
Least Square Means estimates of change from baseline are calculated from a MMRM analysis, using the change from baseline as outcome, study visit as repeated variable, subject as subject effect, and baseline value, baseline disease severity stratum, treatment, study visit and the interaction effect of study visit by treatment as fixed effects.
MMRM: Mixed model for repeated measures; SD: Standard Deviation; SE: Standard Deviation.

MMRM models: POEM01-Total Score, Total population - Full Analysis Set Population
JADE TEEN (PF-04965842) - 2023 datacut

Variable / analysis	PF-04965842 200mg QD N=94	Placebo N=96
Week 2		
Return Rate (% subjects with missing data)		
Results at Week 2	2 (2.1%)	5 (5.2%)
Descriptive Results of Actual Values		
N with data	92	91
Mean (SD)	11.24 (7.32)	16.33 (7.49)
p25, median, p75 | Min,Max |	6.0, 10.0, 16.0 | 0, 28 |	10.0, 17.0, 22.0 | 3, 28 |
Descriptive Results of Change from baseline		
N with data	92	91
Mean (SD)	-8.16 (7.24)	-3.59 (6.29)
p25, median, p75 | Min,Max |	-14.0, -7.0, -3.0 | -25, 4 |	-6.0, -2.0, 0.0 | -24, 10 |
Least Square Means estimates of change from baseline		
Treatment arm estimate (SE), (95% CI)	-8.20 (0.67) (-9.53,-6.88)	-3.42 (0.67) (-4.75,-2.10)
Treatment arm difference (SE), (95% CI), p-value		-4.78 (0.95) (-6.65,-2.90) p<.0001
Hedge G analysis of change from baseline		
Treatment arm difference estimate (95% CI)		-0.56 (-0.86, -0.27)

Full Analysis Set Population
Least Square Means estimates of change from baseline are calculated from a MMRM analysis, using the change from baseline as outcome, study visit as repeated variable, subject as subject effect, and baseline value, baseline disease severity stratum, treatment, study visit and the interaction effect of study visit by treatment as fixed effects.
MMRM: Mixed model for repeated measures; SD: Standard Deviation; SE: Standard Deviation.

MMRM models: POEM01-Total Score, Total population - Full Analysis Set Population
JADE TEEN (PF-04965842) - 2023 datacut

Variable / analysis	PF-04965842 200mg QD N=94	Placebo N=96
Week 4		
Return Rate (% subjects with missing data)		
Results at Week 4	3 (3.2%)	1 (1.0%)
Descriptive Results of Actual Values		
N with data	91	95
Mean (SD)	8.76 (6.53)	14.84 (6.70)
p25, median, p75 | Min,Max |	4.0, 7.0, 12.0 | 0, 28 |	10.0, 15.0, 20.0 | 0, 28 |
Descriptive Results of Change from baseline		
N with data	91	95
Mean (SD)	-10.62 (6.44)	-5.00 (6.07)
p25, median, p75 | Min,Max |	-16.0, -10.0, -6.0 | -26, 2 |	-8.0, -5.0, -1.0 | -20, 8 |
Least Square Means estimates of change from baseline		
Treatment arm estimate (SE), (95% CI)	-10.62 (0.59) (-11.79,-9.44)	-4.87 (0.58) (-6.02,-3.72)
Treatment arm difference (SE), (95% CI), p-value		-5.75 (0.83) (-7.39,-4.10) p<.0001
Hedge G analysis of change from baseline		
Treatment arm difference estimate (95% CI)		-0.56 (-0.85, -0.27)

Full Analysis Set Population
Least Square Means estimates of change from baseline are calculated from a MMRM analysis, using the change from baseline as outcome, study visit as repeated variable, subject as subject effect, and baseline value, baseline disease severity stratum, treatment, study visit and the interaction effect of study visit by treatment as fixed effects.
MMRM: Mixed model for repeated measures; SD: Standard Deviation; SE: Standard Deviation.

MMRM models: POEM01-Total Score, Total population - Full Analysis Set Population
JADE TEEN (PF-04965842) - 2023 datacut

Variable / analysis	PF-04965842 200mg QD N=94	Placebo N=96
Week 8		
Return Rate (% subjects with missing data)		
Results at Week 8	4 (4.3%)	6 (6.3%)
Descriptive Results of Actual Values		
N with data	90	90
Mean (SD)	8.77 (6.76)	14.51 (7.21)
p25, median, p75 | Min,Max |	4.0, 7.0, 13.0 | 0, 28 |	9.0, 14.0, 20.0 | 0, 28 |
Descriptive Results of Change from baseline		
N with data	90	90
Mean (SD)	-10.64 (7.51)	-5.51 (7.06)
p25, median, p75 | Min,Max |	-17.0, -9.5, -5.0 | -26, 5 |	-10.0, -6.0, 0.0 | -28, 9 |
Least Square Means estimates of change from baseline		
Treatment arm estimate (SE), (95% CI)	-10.60 (0.68) (-11.94,-9.26)	-5.40 (0.67) (-6.73,-4.07)
Treatment arm difference (SE), (95% CI), p-value		-5.20 (0.96) (-7.10,-3.31) p<.0001
Hedge G analysis of change from baseline		
Treatment arm difference estimate (95% CI)		-0.57 (-0.87, -0.27)

Full Analysis Set Population
Least Square Means estimates of change from baseline are calculated from a MMRM analysis, using the change from baseline as outcome, study visit as repeated variable, subject as subject effect, and baseline value, baseline disease severity stratum, treatment, study visit and the interaction effect of study visit by treatment as fixed effects.
MMRM: Mixed model for repeated measures; SD: Standard Deviation; SE: Standard Deviation.

MMRM models: POEM01-Total Score, Total population - Full Analysis Set Population
JADE TEEN (PF-04965842) - 2023 datacut

Variable / analysis	PF-04965842 200mg QD N=94	Placebo N=96
Week 12		
Return Rate (% subjects with missing data)		
Results at Week 12	4 (4.3%)	7 (7.3%)
Descriptive Results of Actual Values		
N with data	90	89
Mean (SD)	8.53 (6.77)	12.93 (7.34)
p25, median, p75 | Min,Max |	3.0, 7.5, 12.0 | 0, 28 |	7.0, 12.0, 18.0 | 0, 28 |
Descriptive Results of Change from baseline		
N with data	90	89
Mean (SD)	-10.86 (7.14)	-7.10 (8.22)
p25, median, p75 | Min,Max |	-17.0, -10.0, -6.0 | -27, 7 |	-12.0, -6.0, -1.0 | -28, 8 |
Least Square Means estimates of change from baseline		
Treatment arm estimate (SE), (95% CI)	-10.85 (0.71) (-12.25,-9.44)	-6.99 (0.71) (-8.39,-5.59)
Treatment arm difference (SE), (95% CI), p-value		-3.86 (1.01) (-5.84,-1.87) p=0.0002
Hedge G analysis of change from baseline		
Treatment arm difference estimate (95% CI)		-0.57 (-0.87, -0.27)

Full Analysis Set Population
Least Square Means estimates of change from baseline are calculated from a MMRM analysis, using the change from baseline as outcome, study visit as repeated variable, subject as subject effect, and baseline value, baseline disease severity stratum, treatment, study visit and the interaction effect of study visit by treatment as fixed effects.
MMRM: Mixed model for repeated measures; SD: Standard Deviation; SE: Standard Deviation.

MMRM models: POEM01-Total Score, Total population - Full Analysis Set Population
JADE TEEN (PF-04965842) - 2023 datacut

Variable / analysis	PF-04965842 200mg QD N=94	Placebo N=96
Overall post-baseline		
Least Square Means estimates of change from baseline		
Treatment arm average post-baseline estimate (SE), (95% CI)	-10.07 (0.56) (-11.17,-8.97)	-5.17 (0.55) (-6.26,-4.08)
Treatment arm difference (SE), (95% CI), p-value		-4.90 (0.78) (-6.44,-3.35) p<.0001
Hedge G analysis of average post-baseline change		
Treatment arm difference estimate (95% CI)		-0.91 (-1.21, -0.61)

Full Analysis Set Population
Least Square Means estimates of change from baseline are calculated from a MMRM analysis, using the change from baseline as outcome, study visit as repeated variable, subject as subject effect, and baseline value, baseline disease severity stratum, treatment, study visit and the interaction effect of study visit by treatment as fixed effects.
MMRM: Mixed model for repeated measures; SD: Standard Deviation; SE: Standard Deviation.

MMRM models: NRS01-Worst Itching-Atopic Dermatitis-Analysis, Total population - Full Analysis Set Population
JADE TEEN (PF-04965842) - 2023 datacut

Variable / analysis	PF-04965842 200mg QD N=94	Placebo N=96
Baseline		
Return Rate (% subjects with missing data)		
Results at Baseline	0 (0.0%)	0 (0.0%)
Descriptive Results of Actual Values		
N with data	94	96
Mean (SD)	6.81 (1.97)	7.16 (1.69)
p25, median, p75 | Min,Max |	6.0, 7.0, 8.0 | 1, 10 |	6.0, 7.0, 8.0 | 4, 10 |

Full Analysis Set Population
Least Square Means estimates of change from baseline are calculated from a MMRM analysis, using the change from baseline as outcome, study visit as repeated variable, subject as subject effect, and baseline value, baseline disease severity stratum, treatment, study visit and the interaction effect of study visit by treatment as fixed effects.
MMRM: Mixed model for repeated measures; SD: Standard Deviation; SE: Standard Deviation.

MMRM models: NRS01-Worst Itching-Atopic Dermatitis-Analysis, Total population - Full Analysis Set Population
JADE TEEN (PF-04965842) - 2023 datacut

Variable / analysis	PF-04965842 200mg QD N=94	Placebo N=96
Week 2		
Return Rate (% subjects with missing data)		
Results at Week 2	3 (3.2%)	1 (1.0%)
Descriptive Results of Actual Values		
N with data	91	95
Mean (SD)	4.16 (2.17)	5.96 (2.22)
p25, median, p75 | Min,Max |	3.0, 4.0, 5.0 | 0, 10 |	5.0, 6.0, 8.0 | 0, 10 |
Descriptive Results of Change from baseline		
N with data	91	95
Mean (SD)	-2.69 (2.59)	-1.20 (1.99)
p25, median, p75 | Min,Max |	-4.0, -2.0, -1.0 | -10, 3 |	-2.0, -1.0, 0.0 | -9, 3 |
Least Square Means estimates of change from baseline		
Treatment arm estimate (SE), (95% CI)	-2.74 (0.21) (-3.16,-2.31)	-1.10 (0.21) (-1.52,-0.69)
Treatment arm difference (SE), (95% CI), p-value		-1.64 (0.30) (-2.23,-1.04) p<.0001
Hedge G analysis of change from baseline		
Treatment arm difference estimate (95% CI)		-0.55 (-0.85, -0.26)

Full Analysis Set Population
Least Square Means estimates of change from baseline are calculated from a MMRM analysis, using the change from baseline as outcome, study visit as repeated variable, subject as subject effect, and baseline value, baseline disease severity stratum, treatment, study visit and the interaction effect of study visit by treatment as fixed effects.
MMRM: Mixed model for repeated measures; SD: Standard Deviation; SE: Standard Deviation.

MMRM models: NRS01-Worst Itching-Atopic Dermatitis-Analysis, Total population - Full Analysis Set Population
JADE TEEN (PF-04965842) - 2023 datacut

Variable / analysis	PF-04965842 200mg QD N=94	Placebo N=96
Week 4		
Return Rate (% subjects with missing data)		
Results at Week 4	9 (9.6%)	5 (5.2%)
Descriptive Results of Actual Values		
N with data	85	91
Mean (SD)	3.34 (2.12)	5.25 (2.26)
p25, median, p75 | Min,Max |	2.0, 3.0, 5.0 | 0, 9 |	4.0, 5.0, 7.0 | 0, 10 |
Descriptive Results of Change from baseline		
N with data	85	91
Mean (SD)	-3.55 (2.61)	-1.96 (2.16)
p25, median, p75 | Min,Max |	-5.0, -3.0, -2.0 | -10, 3 |	-3.0, -2.0, 0.0 | -9, 1 |
Least Square Means estimates of change from baseline		
Treatment arm estimate (SE), (95% CI)	-3.54 (0.22) (-3.98,-3.10)	-1.86 (0.22) (-2.29,-1.43)
Treatment arm difference (SE), (95% CI), p-value		-1.69 (0.31) (-2.30,-1.07) p<.0001
Hedge G analysis of change from baseline		
Treatment arm difference estimate (95% CI)		-0.57 (-0.87, -0.26)

Full Analysis Set Population
Least Square Means estimates of change from baseline are calculated from a MMRM analysis, using the change from baseline as outcome, study visit as repeated variable, subject as subject effect, and baseline value, baseline disease severity stratum, treatment, study visit and the interaction effect of study visit by treatment as fixed effects.
MMRM: Mixed model for repeated measures; SD: Standard Deviation; SE: Standard Deviation.

MMRM models: NRS01-Worst Itching-Atopic Dermatitis-Analysis, Total population - Full Analysis Set Population
JADE TEEN (PF-04965842) - 2023 datacut

Variable / analysis	PF-04965842 200mg QD N=94	Placebo N=96
Week 8		
Return Rate (% subjects with missing data)		
Results at Week 8	8 (8.5%)	7 (7.3%)
Descriptive Results of Actual Values		
N with data	86	89
Mean (SD)	3.03 (2.18)	4.87 (2.60)
p25, median, p75 | Min,Max |	1.0, 3.0, 5.0 | 0, 10 |	3.0, 5.0, 7.0 | 0, 10 |
Descriptive Results of Change from baseline		
N with data	86	89
Mean (SD)	-3.81 (2.62)	-2.31 (2.44)
p25, median, p75 | Min,Max |	-6.0, -4.0, -2.0 | -9, 3 |	-4.0, -2.0, 0.0 | -10, 2 |
Least Square Means estimates of change from baseline		
Treatment arm estimate (SE), (95% CI)	-3.94 (0.24)	-2.29 (0.24)
	(-4.42,-3.46)	(-2.77,-1.82)
Treatment arm difference (SE), (95% CI), p-value		-1.65 (0.34)
		(-2.32,-0.97) p<.0001
Hedge G analysis of change from baseline		
Treatment arm difference estimate (95% CI)		-0.57 (-0.87, -0.27)

Full Analysis Set Population
Least Square Means estimates of change from baseline are calculated from a MMRM analysis, using the change from baseline as outcome, study visit as repeated variable, subject as subject effect, and baseline value, baseline disease severity stratum, treatment, study visit and the interaction effect of study visit by treatment as fixed effects.
MMRM: Mixed model for repeated measures; SD: Standard Deviation; SE: Standard Deviation.

MMRM models: NRS01-Worst Itching-Atopic Dermatitis-Analysis, Total population - Full Analysis Set Population
JADE TEEN (PF-04965842) - 2023 datacut

Variable / analysis	PF-04965842 200mg QD N=94	Placebo N=96
Week 12		
Return Rate (% subjects with missing data)		
Results at Week 12	21 (22.3%)	16 (16.7%)
Descriptive Results of Actual Values		
N with data	73	80
Mean (SD)	3.00 (2.20)	4.40 (2.49)
p25, median, p75 | Min,Max |	2.0, 3.0, 4.0 | 0, 10 |	2.5, 4.0, 6.0 | 0, 10 |
Descriptive Results of Change from baseline		
N with data	73	80
Mean (SD)	-3.97 (2.55)	-2.64 (2.68)
p25, median, p75 | Min,Max |	-6.0, -4.0, -2.0 | -10, 1 |	-4.0, -2.0, 0.0 | -10, 2 |
Least Square Means estimates of change from baseline		
Treatment arm estimate (SE), (95% CI)	-3.93 (0.25) (-4.42,-3.43)	-2.60 (0.24) (-3.08,-2.12)
Treatment arm difference (SE), (95% CI), p-value		-1.32 (0.35) (-2.02,-0.63) p=0.0002
Hedge G analysis of change from baseline		
Treatment arm difference estimate (95% CI)		-0.61 (-0.93, -0.28)

Full Analysis Set Population
Least Square Means estimates of change from baseline are calculated from a MMRM analysis, using the change from baseline as outcome, study visit as repeated variable, subject as subject effect, and baseline value, baseline disease severity stratum, treatment, study visit and the interaction effect of study visit by treatment as fixed effects.
MMRM: Mixed model for repeated measures; SD: Standard Deviation; SE: Standard Deviation.

MMRM models: NRS01-Worst Itching-Atopic Dermatitis-Analysis, Total population - Full Analysis Set Population
JADE TEEN (PF-04965842) - 2023 datacut

Variable / analysis	PF-04965842 200mg QD N=94	Placebo N=96
Overall post-baseline		
Least Square Means estimates of change from baseline		
Treatment arm average post-baseline estimate (SE), (95% CI)	-3.54 (0.19)	-1.96 (0.19)
	(-3.92,-3.15)	(-2.34,-1.59)
Treatment arm difference (SE), (95% CI), p-value		-1.57 (0.27)
		(-2.11,-1.04) p<.0001
Hedge G analysis of average post-baseline change		
Treatment arm difference estimate (95% CI)		-0.84 (-1.14, -0.54)

Full Analysis Set Population
Least Square Means estimates of change from baseline are calculated from a MMRM analysis, using the change from baseline as outcome, study visit as repeated variable, subject as subject effect, and baseline value, baseline disease severity stratum, treatment, study visit and the interaction effect of study visit by treatment as fixed effects.
MMRM: Mixed model for repeated measures; SD: Standard Deviation; SE: Standard Deviation.

MMRM models: CDLQ1-Total Score, Total population - Full Analysis Set Population
JADE TEEN (PF-04965842) - 2023 datacut

Variable / analysis	PF-04965842 200mg QD N=94	Placebo N=96
Baseline		
Return Rate (% subjects with missing data)		
Results at Baseline	0 (0.0%)	0 (0.0%)
Descriptive Results of Actual Values		
N with data	94	96
Mean (SD)	13.62 (7.02)	14.04 (6.69)
p25, median, p75 | Min,Max |	8.0, 13.0, 19.0 | 3, 30 |	9.0, 14.0, 19.0 | 2, 30 |

Full Analysis Set Population
Least Square Means estimates of change from baseline are calculated from a MMRM analysis, using the change from baseline as outcome, study visit as repeated variable, subject as subject effect, and baseline value, baseline disease severity stratum, treatment, study visit and the interaction effect of study visit by treatment as fixed effects.
MMRM: Mixed model for repeated measures; SD: Standard Deviation; SE: Standard Deviation.

MMRM models: CDLQ1-Total Score, Total population - Full Analysis Set Population
JADE TEEN (PF-04965842) - 2023 datacut

Variable / analysis	PF-04965842 200mg QD N=94	Placebo N=96
Week 2		
Return Rate (% subjects with missing data)		
Results at Week 2	2 (2.1%)	4 (4.2%)
Descriptive Results of Actual Values		
N with data	92	92
Mean (SD)	7.57 (5.78)	9.84 (6.29)
p25, median, p75 | Min,Max |	3.0, 6.0, 11.0 | 0, 26 |	5.0, 9.0, 14.0 | 1, 25 |
Descriptive Results of Change from baseline		
N with data	92	92
Mean (SD)	-6.16 (6.51)	-4.24 (4.28)
p25, median, p75 | Min,Max |	-9.0, -5.0, -2.0 | -26, 11 |	-7.0, -4.0, -1.0 | -17, 8 |
Least Square Means estimates of change from baseline		
Treatment arm estimate (SE), (95% CI)	-6.20 (0.49)	-4.15 (0.49)
	(-7.17,-5.23)	(-5.11,-3.19)
Treatment arm difference (SE), (95% CI), p-value		-2.05 (0.69)
		(-3.42,-0.69) p=0.0034
Hedge G analysis of change from baseline		
Treatment arm difference estimate (95% CI)		-0.48 (-0.77, -0.18)

Full Analysis Set Population
Least Square Means estimates of change from baseline are calculated from a MMRM analysis, using the change from baseline as outcome, study visit as repeated variable, subject as subject effect, and baseline value, baseline disease severity stratum, treatment, study visit and the interaction effect of study visit by treatment as fixed effects.
MMRM: Mixed model for repeated measures; SD: Standard Deviation; SE: Standard Deviation.

MMRM models: CDLQ1-Total Score, Total population - Full Analysis Set Population
JADE TEEN (PF-04965842) - 2023 datacut

Variable / analysis	PF-04965842 200mg QD N=94	Placebo N=96
Week 4		
Return Rate (% subjects with missing data)		
Results at Week 4	3 (3.2%)	0 (0.0%)
Descriptive Results of Actual Values		
N with data	91	96
Mean (SD)	6.13 (5.05)	8.58 (5.89)
p25, median, p75 | Min,Max |	2.0, 5.0, 9.0 | 0, 21 |	4.0, 8.0, 12.0 | 0, 27 |
Descriptive Results of Change from baseline		
N with data	91	96
Mean (SD)	-7.53 (6.23)	-5.46 (5.42)
p25, median, p75 | Min,Max |	-11.0, -7.0, -3.0 | -27, 3 |	-8.0, -5.0, -2.0 | -23, 7 |
Least Square Means estimates of change from baseline		
Treatment arm estimate (SE), (95% CI)	-7.57 (0.47) (-8.50,-6.63)	-5.37 (0.46) (-6.28,-4.46)
Treatment arm difference (SE), (95% CI), p-value		-2.20 (0.66) (-3.50,-0.90) p=0.0010
Hedge G analysis of change from baseline		
Treatment arm difference estimate (95% CI)		-0.47 (-0.76, -0.18)

Full Analysis Set Population
Least Square Means estimates of change from baseline are calculated from a MMRM analysis, using the change from baseline as outcome, study visit as repeated variable, subject as subject effect, and baseline value, baseline disease severity stratum, treatment, study visit and the interaction effect of study visit by treatment as fixed effects.
MMRM: Mixed model for repeated measures; SD: Standard Deviation; SE: Standard Deviation.

MMRM models: CDLQ1-Total Score, Total population - Full Analysis Set Population
JADE TEEN (PF-04965842) - 2023 datacut

Variable / analysis	PF-04965842 200mg QD N=94	Placebo N=96
Week 8		
Return Rate (% subjects with missing data)		
Results at Week 8	4 (4.3%)	5 (5.2%)
Descriptive Results of Actual Values		
N with data	90	91
Mean (SD)	5.61 (5.33)	7.96 (6.38)
p25, median, p75 | Min,Max |	2.0, 4.0, 7.0 | 0, 26 |	3.0, 7.0, 11.0 | 0, 28 |
Descriptive Results of Change from baseline		
N with data	90	91
Mean (SD)	-8.16 (6.96)	-6.10 (5.53)
p25, median, p75 | Min,Max |	-12.0, -8.0, -3.0 | -27, 12 |	-10.0, -6.0, -2.0 | -20, 11 |
Least Square Means estimates of change from baseline		
Treatment arm estimate (SE), (95% CI)	-8.11 (0.52) (-9.14,-7.07)	-5.99 (0.52) (-7.01,-4.97)
Treatment arm difference (SE), (95% CI), p-value		-2.11 (0.74) (-3.57,-0.66) p=0.0046
Hedge G analysis of change from baseline		
Treatment arm difference estimate (95% CI)		-0.48 (-0.78, -0.18)

Full Analysis Set Population
Least Square Means estimates of change from baseline are calculated from a MMRM analysis, using the change from baseline as outcome, study visit as repeated variable, subject as subject effect, and baseline value, baseline disease severity stratum, treatment, study visit and the interaction effect of study visit by treatment as fixed effects.
MMRM: Mixed model for repeated measures; SD: Standard Deviation; SE: Standard Deviation.

MMRM models: CDLQ1-Total Score, Total population - Full Analysis Set Population
JADE TEEN (PF-04965842) - 2023 datacut

Variable / analysis	PF-04965842 200mg QD N=94	Placebo N=96
Week 12		
Return Rate (% subjects with missing data)		
Results at Week 12	4 (4.3%)	6 (6.3%)
Descriptive Results of Actual Values		
N with data	90	90
Mean (SD)	5.14 (4.74)	7.82 (6.24)
p25, median, p75 | Min,Max |	2.0, 4.0, 8.0 | 0, 29 |	3.0, 6.5, 12.0 | 0, 28 |
Descriptive Results of Change from baseline		
N with data	90	90
Mean (SD)	-8.57 (6.57)	-6.44 (6.37)
p25, median, p75 | Min,Max |	-13.0, -8.0, -4.0 | -23, 9 |	-10.0, -6.0, -2.0 | -22, 9 |
Least Square Means estimates of change from baseline		
Treatment arm estimate (SE), (95% CI)	-8.58 (0.51) (-9.59,-7.58)	-6.26 (0.50) (-7.26,-5.27)
Treatment arm difference (SE), (95% CI), p-value		-2.32 (0.72) (-3.74,-0.91) p=0.0014
Hedge G analysis of change from baseline		
Treatment arm difference estimate (95% CI)		-0.48 (-0.78, -0.18)

Full Analysis Set Population
Least Square Means estimates of change from baseline are calculated from a MMRM analysis, using the change from baseline as outcome, study visit as repeated variable, subject as subject effect, and baseline value, baseline disease severity stratum, treatment, study visit and the interaction effect of study visit by treatment as fixed effects.
MMRM: Mixed model for repeated measures; SD: Standard Deviation; SE: Standard Deviation.

MMRM models: CDLQ1-Total Score, Total population - Full Analysis Set Population
JADE TEEN (PF-04965842) - 2023 datacut

Variable / analysis	PF-04965842 200mg QD N=94	Placebo N=96
Overall post-baseline		
Least Square Means estimates of change from baseline		
Treatment arm average post-baseline estimate (SE), (95% CI)	-7.61 (0.42)	-5.44 (0.41)
	(-8.44,-6.78)	(-6.26,-4.63)
Treatment arm difference (SE), (95% CI), p-value		-2.17 (0.59)
		(-3.34,-1.01) p=0.0003
Hedge G analysis of average post-baseline change		
Treatment arm difference estimate (95% CI)		-0.54 (-0.83, -0.24)

Full Analysis Set Population
Least Square Means estimates of change from baseline are calculated from a MMRM analysis, using the change from baseline as outcome, study visit as repeated variable, subject as subject effect, and baseline value, baseline disease severity stratum, treatment, study visit and the interaction effect of study visit by treatment as fixed effects.
MMRM: Mixed model for repeated measures; SD: Standard Deviation; SE: Standard Deviation.

MMRM models: EQ5D03-EQ VAS Score, Total population - Full Analysis Set Population
JADE TEEN (PF-04965842) - 2023 datacut

Variable / analysis	PF-04965842 200mg QD N=94	Placebo N=96
Baseline		
Return Rate (% subjects with missing data)		
Results at Baseline	0 (0.0%)	0 (0.0%)
Descriptive Results of Actual Values		
N with data	94	96
Mean (SD)	64.94 (21.61)	63.51 (24.83)
p25, median, p75 | Min,Max |	50.0, 65.0, 82.0 | 9, 100 |	48.0, 65.5, 85.0 | 5, 100 |

Full Analysis Set Population
Least Square Means estimates of change from baseline are calculated from a MMRM analysis, using the change from baseline as outcome, study visit as repeated variable, subject as subject effect, and baseline value, baseline disease severity stratum, treatment, study visit and the interaction effect of study visit by treatment as fixed effects.
MMRM: Mixed model for repeated measures; SD: Standard Deviation; SE: Standard Deviation.

MMRM models: EQ5D03-EQ VAS Score, Total population - Full Analysis Set Population
JADE TEEN (PF-04965842) - 2023 datacut

Variable / analysis	PF-04965842 200mg QD N=94	Placebo N=96
Week 2		
Return Rate (% subjects with missing data)		
Results at Week 2	2 (2.1%)	4 (4.2%)
Descriptive Results of Actual Values		
N with data	92	92
Mean (SD)	76.36 (17.10)	70.70 (21.78)
p25, median, p75 | Min,Max |	64.0, 80.0, 90.0 | 22, 100 |	60.0, 75.0, 88.5 | 0, 100 |
Descriptive Results of Change from baseline		
N with data	92	92
Mean (SD)	11.80 (21.67)	7.50 (21.65)
p25, median, p75 | Min,Max |	-0.5, 9.5, 25.0 | -45, 75 |	-4.0, 3.0, 19.5 | -45, 78 |
Least Square Means estimates of change from baseline		
Treatment arm estimate (SE), (95% CI)	11.92 (1.76) (8.45,15.39)	7.00 (1.75) (3.55,10.44)
Treatment arm difference (SE), (95% CI), p-value		4.93 (2.48) (0.03,9.82) p=0.0484
Hedge G analysis of change from baseline		
Treatment arm difference estimate (95% CI)		0.33 (0.04, 0.62)

Full Analysis Set Population
Least Square Means estimates of change from baseline are calculated from a MMRM analysis, using the change from baseline as outcome, study visit as repeated variable, subject as subject effect, and baseline value, baseline disease severity stratum, treatment, study visit and the interaction effect of study visit by treatment as fixed effects.
MMRM: Mixed model for repeated measures; SD: Standard Deviation; SE: Standard Deviation.

MMRM models: EQ5D03-EQ VAS Score, Total population - Full Analysis Set Population
JADE TEEN (PF-04965842) - 2023 datacut

Variable / analysis	PF-04965842 200mg QD N=94	Placebo N=96
Week 4		
Return Rate (% subjects with missing data)		
Results at Week 4	3 (3.2%)	0 (0.0%)
Descriptive Results of Actual Values		
N with data	91	96
Mean (SD)	79.03 (15.91)	72.46 (20.58)
p25, median, p75 | Min,Max |	73.0, 80.0, 90.0 | 20, 100 |	62.5, 75.0, 89.5 | 12, 100 |
Descriptive Results of Change from baseline		
N with data	91	96
Mean (SD)	14.47 (19.45)	8.95 (22.06)
p25, median, p75 | Min,Max |	0.0, 11.0, 26.0 | -27, 77 |	-4.5, 5.0, 21.0 | -40, 76 |
Least Square Means estimates of change from baseline		
Treatment arm estimate (SE), (95% CI)	14.47 (1.64) (11.23,17.71)	8.64 (1.60) (5.48,11.80)
Treatment arm difference (SE), (95% CI), p-value		5.83 (2.30) (1.30,10.36) p=0.0119
Hedge G analysis of change from baseline		
Treatment arm difference estimate (95% CI)		0.32 (0.04, 0.61)

Full Analysis Set Population
Least Square Means estimates of change from baseline are calculated from a MMRM analysis, using the change from baseline as outcome, study visit as repeated variable, subject as subject effect, and baseline value, baseline disease severity stratum, treatment, study visit and the interaction effect of study visit by treatment as fixed effects.
MMRM: Mixed model for repeated measures; SD: Standard Deviation; SE: Standard Deviation.

MMRM models: EQ5D03-EQ VAS Score, Total population - Full Analysis Set Population
JADE TEEN (PF-04965842) - 2023 datacut

Variable / analysis	PF-04965842 200mg QD N=94	Placebo N=96
Week 8		
Return Rate (% subjects with missing data)		
Results at Week 8	4 (4.3%)	5 (5.2%)
Descriptive Results of Actual Values		
N with data	90	91
Mean (SD)	78.97 (19.73)	71.92 (20.54)
p25, median, p75 | Min,Max |	74.0, 85.0, 93.0 | 18, 100 |	60.0, 74.0, 90.0 | 17, 100 |
Descriptive Results of Change from baseline		
N with data	90	91
Mean (SD)	14.48 (22.87)	8.82 (21.50)
p25, median, p75 | Min,Max |	-3.0, 11.5, 31.0 | -51, 74 |	-2.0, 5.0, 21.0 | -42, 76 |
Least Square Means estimates of change from baseline		
Treatment arm estimate (SE), (95% CI)	14.45 (1.84) (10.82,18.08)	8.28 (1.82) (4.70,11.86)
Treatment arm difference (SE), (95% CI), p-value		6.16 (2.59) (1.06,11.26) p=0.0181
Hedge G analysis of change from baseline		
Treatment arm difference estimate (95% CI)		0.33 (0.04, 0.62)

Full Analysis Set Population
Least Square Means estimates of change from baseline are calculated from a MMRM analysis, using the change from baseline as outcome, study visit as repeated variable, subject as subject effect, and baseline value, baseline disease severity stratum, treatment, study visit and the interaction effect of study visit by treatment as fixed effects.
MMRM: Mixed model for repeated measures; SD: Standard Deviation; SE: Standard Deviation.

MMRM models: EQ5D03-EQ VAS Score, Total population - Full Analysis Set Population
JADE TEEN (PF-04965842) - 2023 datacut

Variable / analysis	PF-04965842 200mg QD N=94	Placebo N=96
Week 12		
Return Rate (% subjects with missing data)		
Results at Week 12	4 (4.3%)	6 (6.3%)
Descriptive Results of Actual Values		
N with data	90	90
Mean (SD)	80.12 (17.68)	72.94 (21.97)
p25, median, p75 | Min,Max |	71.0, 85.0, 92.0 | 0, 100 |	62.0, 75.0, 91.0 | 0, 100 |
Descriptive Results of Change from baseline		
N with data	90	90
Mean (SD)	15.71 (21.19)	10.32 (23.92)
p25, median, p75 | Min,Max |	1.0, 13.5, 30.0 | -39, 61 |	-3.0, 6.5, 24.0 | -41, 90 |
Least Square Means estimates of change from baseline		
Treatment arm estimate (SE), (95% CI)	15.54 (1.83) (11.93,19.15)	9.79 (1.82) (6.21,13.38)
Treatment arm difference (SE), (95% CI), p-value		5.75 (2.58) (0.66,10.84) p=0.0270
Hedge G analysis of change from baseline		
Treatment arm difference estimate (95% CI)		0.33 (0.04, 0.63)

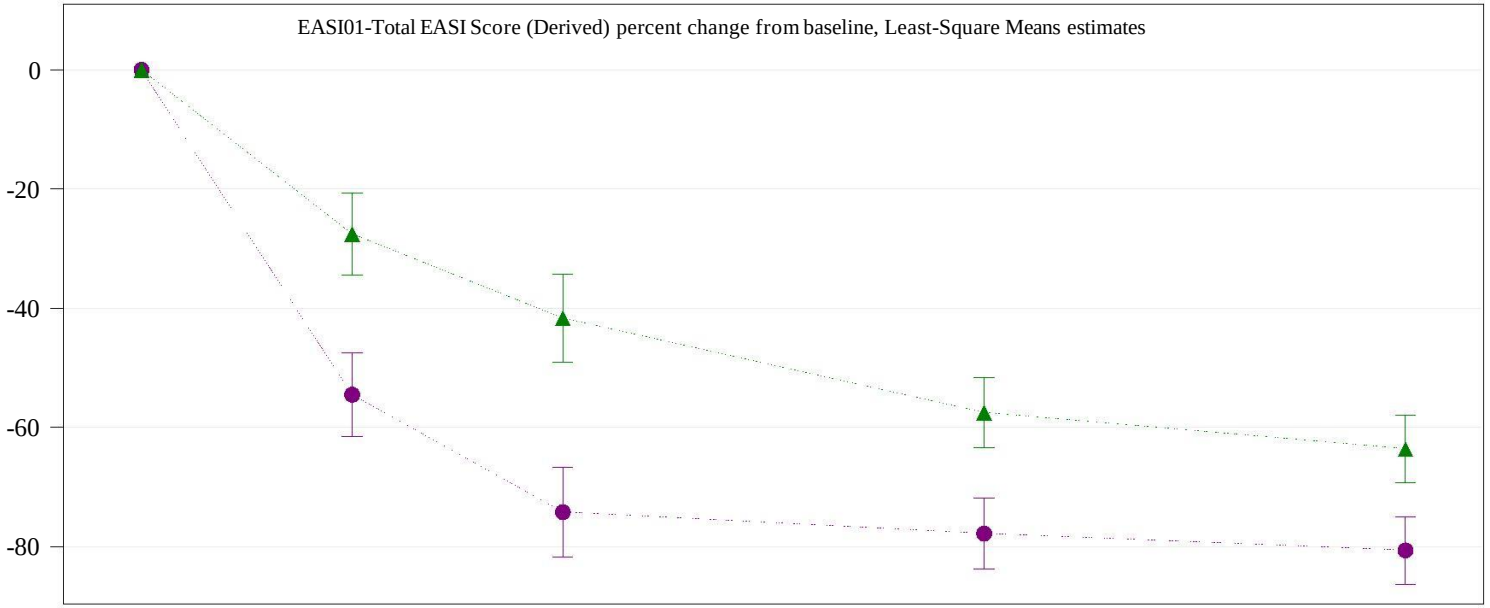
Full Analysis Set Population
Least Square Means estimates of change from baseline are calculated from a MMRM analysis, using the change from baseline as outcome, study visit as repeated variable, subject as subject effect, and baseline value, baseline disease severity stratum, treatment, study visit and the interaction effect of study visit by treatment as fixed effects.
MMRM: Mixed model for repeated measures; SD: Standard Deviation; SE: Standard Deviation.

MMRM models: EQ5D03-EQ VAS Score, Total population - Full Analysis Set Population
JADE TEEN (PF-04965842) - 2023 datacut

Variable / analysis	PF-04965842 200mg QD N=94	Placebo N=96
Overall post-baseline		
Least Square Means estimates of change from baseline		
Treatment arm average post-baseline estimate (SE), (95% CI)	14.10 (1.42) (11.30,16.89)	8.43 (1.39) (5.68,11.17)
Treatment arm difference (SE), (95% CI), p-value		5.67 (1.99) (1.75,9.59) p=0.0048
Hedge G analysis of average post-baseline change		
Treatment arm difference estimate (95% CI)		0.41 (0.13, 0.70)

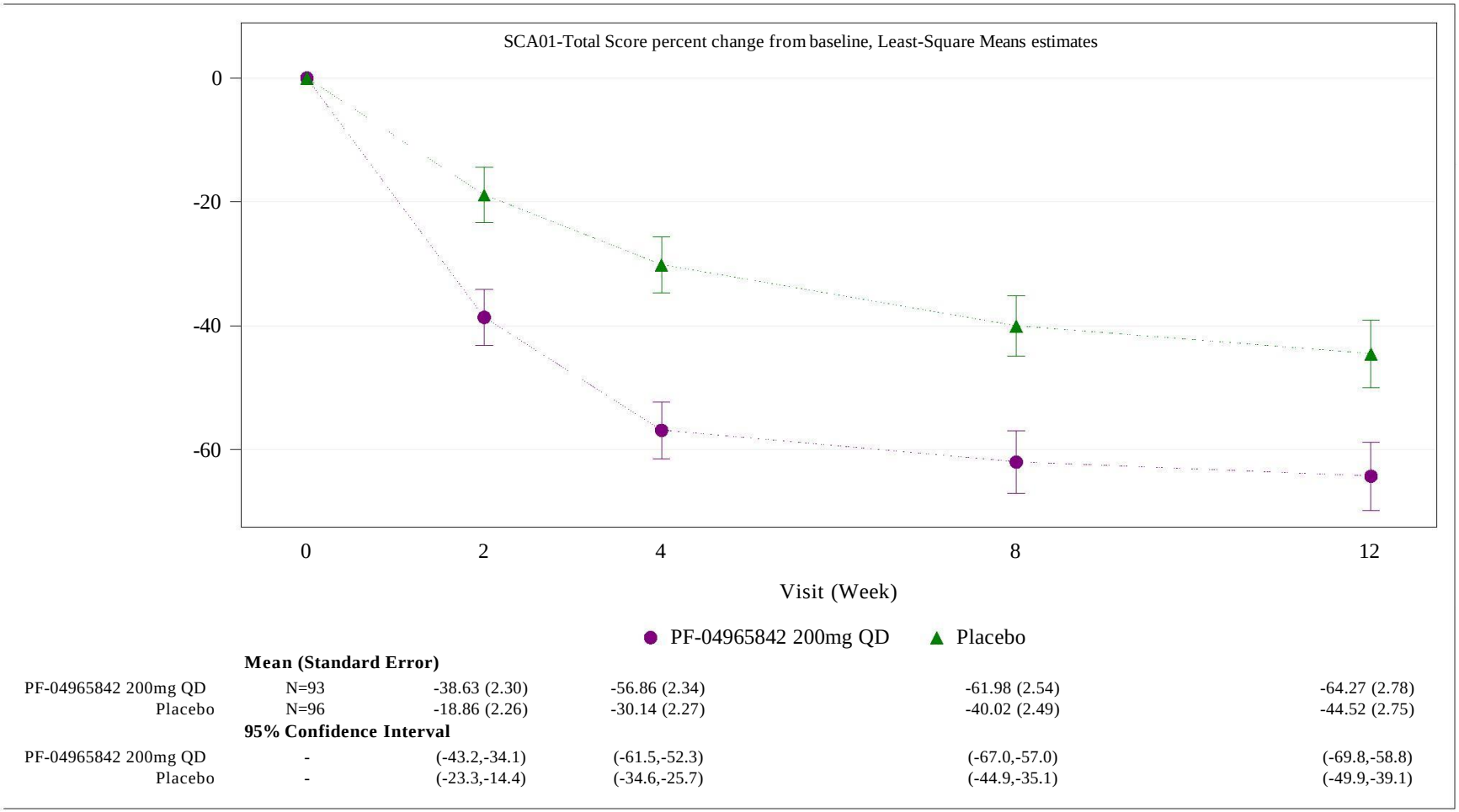
Full Analysis Set Population
Least Square Means estimates of change from baseline are calculated from a MMRM analysis, using the change from baseline as outcome, study visit as repeated variable, subject as subject effect, and baseline value, baseline disease severity stratum, treatment, study visit and the interaction effect of study visit by treatment as fixed effects.
MMRM: Mixed model for repeated measures; SD: Standard Deviation; SE: Standard Deviation.

EASI01-Total EASI Score (Derived) percent change from baseline, Least-Square Means estimates



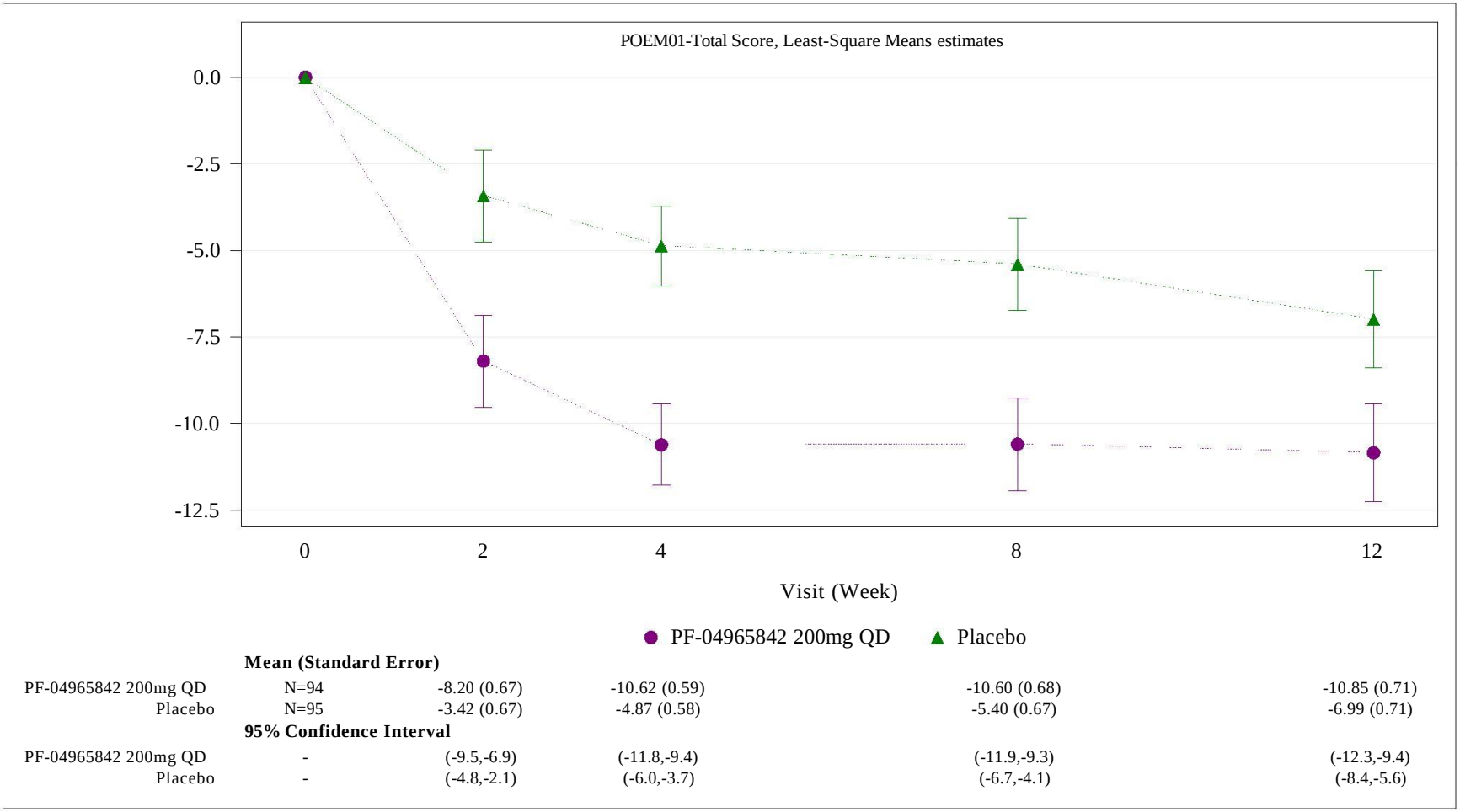
	Mean (Standard Error)				
PF-04965842 200mg QD	N=94	-54.55 (3.55)	-74.26 (3.82)	-77.87 (3.03)	-80.68 (2.86)
Placebo	N=96	-27.56 (3.51)	-41.71 (3.74)	-57.56 (2.99)	-63.65 (2.84)
	95% Confidence Interval				
PF-04965842 200mg QD	-	(-61.6,-47.5)	(-81.8,-66.7)	(-83.9,-71.9)	(-86.3,-75.0)
Placebo	-	(-34.5,-20.6)	(-49.1,-34.3)	(-63.5,-51.7)	(-69.3,-58.1)

SCA01-Total Score percent change from baseline, Least-Square Means estimates



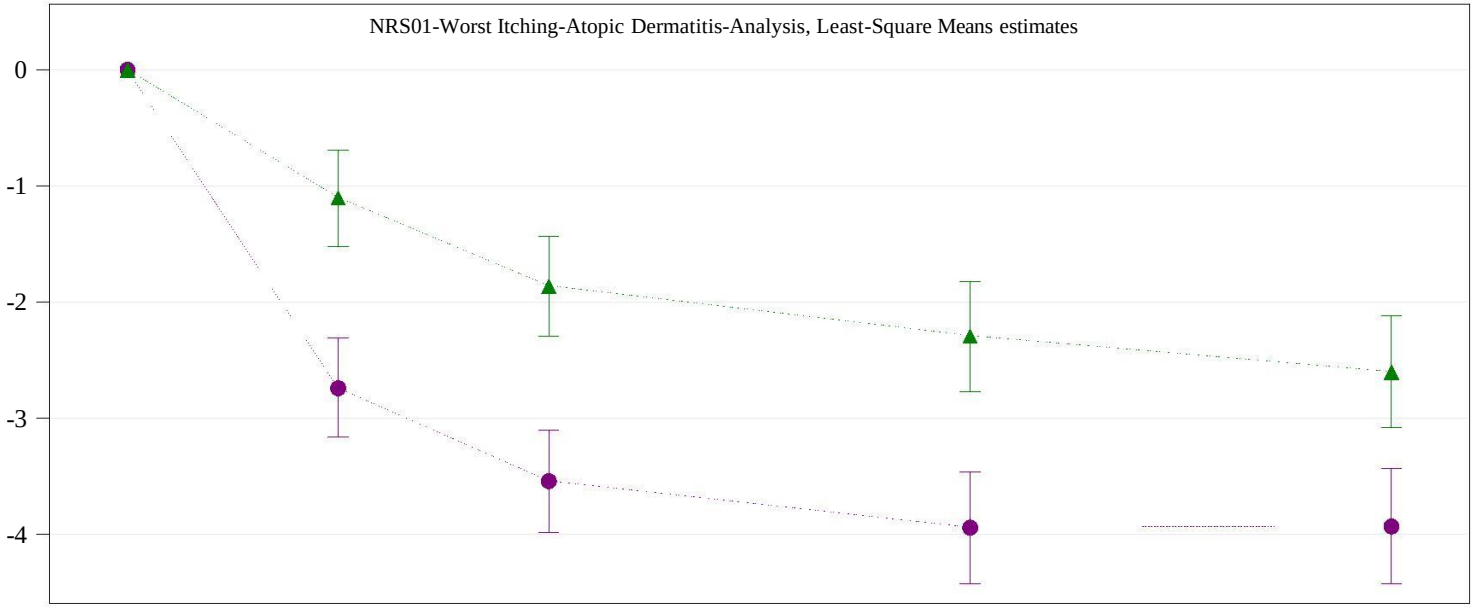
	Mean (Standard Error)				
PF-04965842 200mg QD	N=93	-38.63 (2.30)	-56.86 (2.34)	-61.98 (2.54)	-64.27 (2.78)
Placebo	N=96	-18.86 (2.26)	-30.14 (2.27)	-40.02 (2.49)	-44.52 (2.75)
	95% Confidence Interval				
PF-04965842 200mg QD	-	(-43.2,-34.1)	(-61.5,-52.3)	(-67.0,-57.0)	(-69.8,-58.8)
Placebo	-	(-23.3,-14.4)	(-34.6,-25.7)	(-44.9,-35.1)	(-49.9,-39.1)

POEM01-Total Score, Least-Square Means estimates



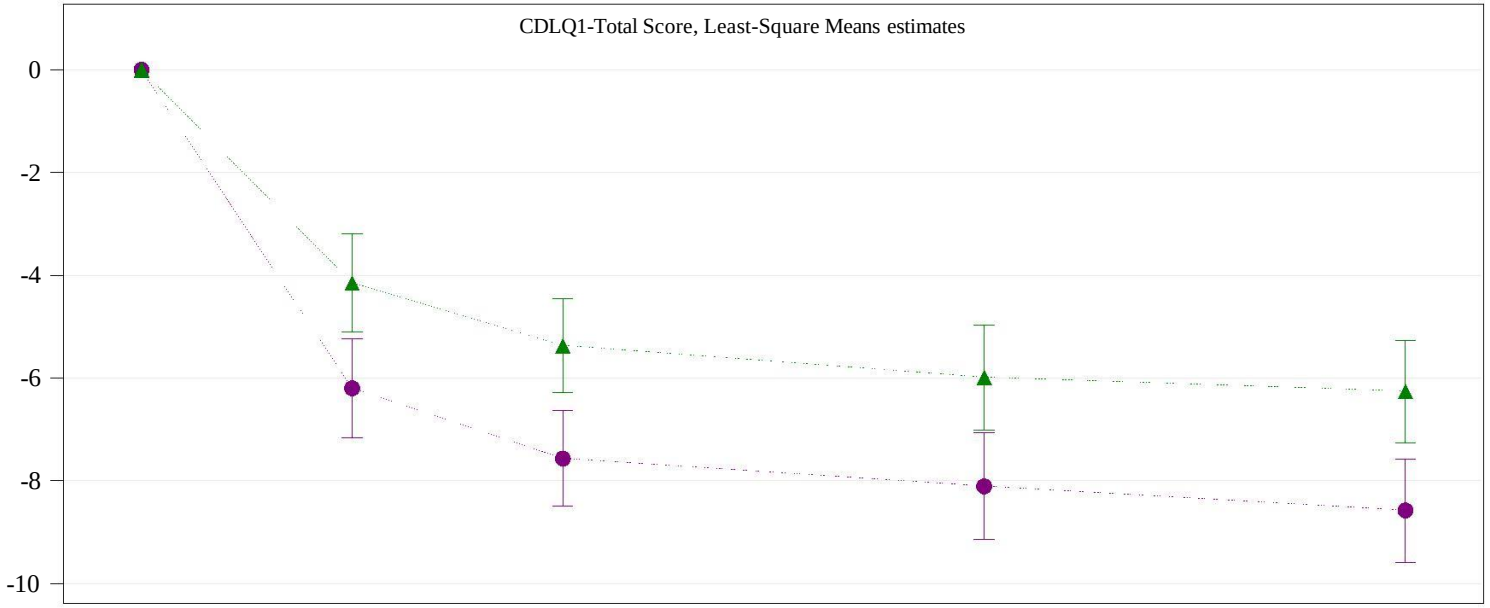
	Mean (Standard Error)				
PF-04965842 200mg QD	N=94	-8.20 (0.67)	-10.62 (0.59)	-10.60 (0.68)	-10.85 (0.71)
Placebo	N=95	-3.42 (0.67)	-4.87 (0.58)	-5.40 (0.67)	-6.99 (0.71)
	95% Confidence Interval				
PF-04965842 200mg QD	-	(-9.5,-6.9)	(-11.8,-9.4)	(-11.9,-9.3)	(-12.3,-9.4)
Placebo	-	(-4.8,-2.1)	(-6.0,-3.7)	(-6.7,-4.1)	(-8.4,-5.6)

NRS01-Worst Itching-Atopic Dermatitis-Analysis, Least-Square Means estimates



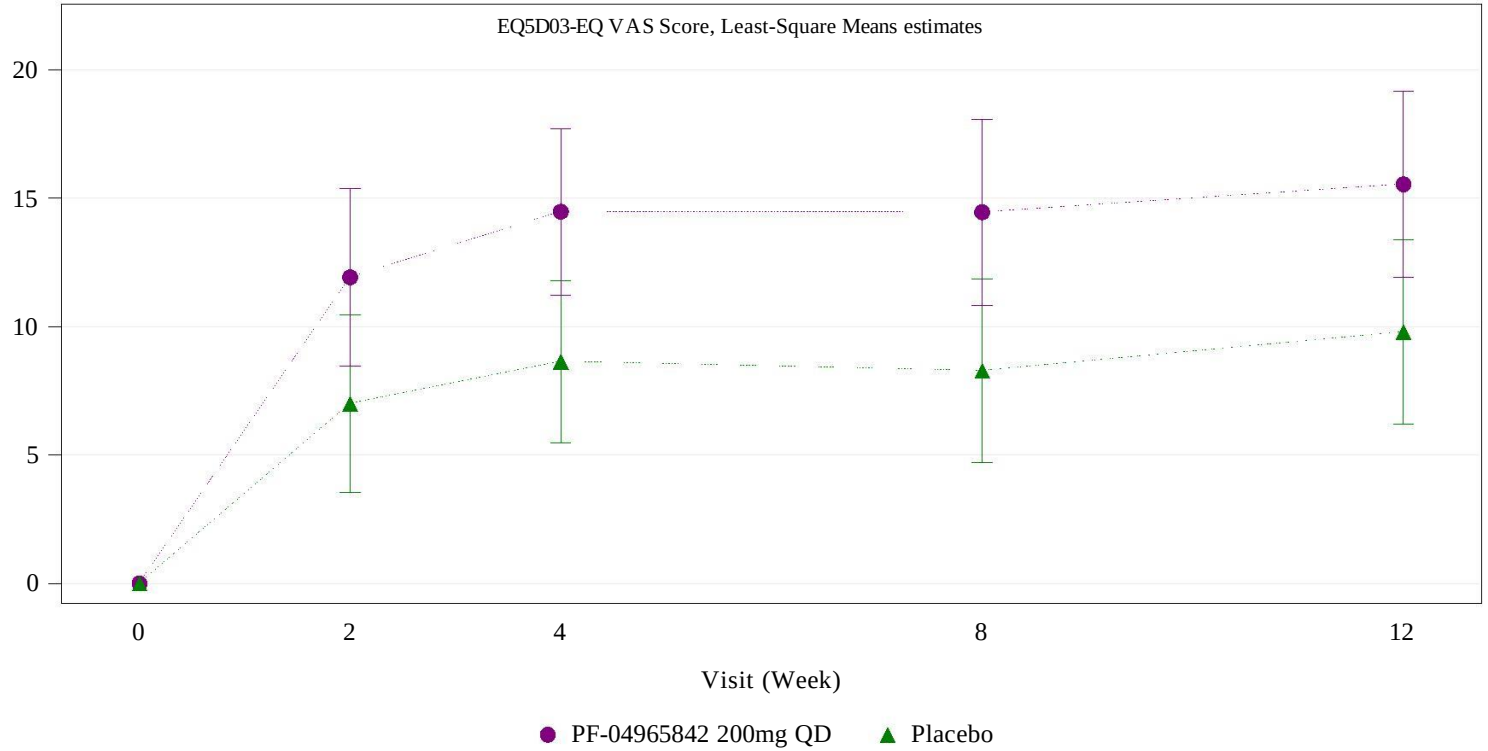
	Mean (Standard Error)				
PF-04965842 200mg QD	N=94	-2.74 (0.21)	-3.54 (0.22)	-3.94 (0.24)	-3.93 (0.25)
Placebo	N=96	-1.10 (0.21)	-1.86 (0.22)	-2.29 (0.24)	-2.60 (0.24)
	95% Confidence Interval				
PF-04965842 200mg QD	-	(-3.2,-2.3)	(-4.0,-3.1)	(-4.4,-3.5)	(-4.4,-3.4)
Placebo	-	(-1.5,-0.7)	(-2.3,-1.4)	(-2.8,-1.8)	(-3.1,-2.1)

CDLQ1-Total Score, Least-Square Means estimates



	Mean (Standard Error)				
PF-04965842 200mg QD	N=94	-6.20 (0.49)	-7.57 (0.47)	-8.11 (0.52)	-8.58 (0.51)
Placebo	N=96	-4.15 (0.49)	-5.37 (0.46)	-5.99 (0.52)	-6.26 (0.50)
	95% Confidence Interval				
PF-04965842 200mg QD	-	(-7.2,-5.2)	(-8.5,-6.6)	(-9.1,-7.1)	(-9.6,-7.6)
Placebo	-	(-5.1,-3.2)	(-6.3,-4.5)	(-7.0,-5.0)	(-7.3,-5.3)

EQ5D03-EQ VAS Score, Least-Square Means estimates



	Mean (Standard Error)				
PF-04965842 200mg QD	N=94	11.92 (1.76)	14.47 (1.64)	14.45 (1.84)	15.54 (1.83)
Placebo	N=96	7.00 (1.75)	8.64 (1.60)	8.28 (1.82)	9.79 (1.82)
	95% Confidence Interval				
PF-04965842 200mg QD	-	(8.5,15.4)	(11.2,17.7)	(10.8,18.1)	(11.9,19.2)
Placebo	-	(3.6,10.4)	(5.5,11.8)	(4.7,11.9)	(6.2,13.4)

Zusatzanalysen JADE DARE und JADE TEEN (Woche 2 bis Woche 26)

Binary Outcome Analysis: SCORAD-90 response - Full Analysis Set Safety Population
JADE TEEN and DARE (PF-04965842) - 2023 datacuts

	Abrocitinib 200mg QD [DARE]		Dupilumab 300mg Q2W [DARE]		Abrocitinib 200mg QD [TEEN]	
	n	Events (%) (95% CI)	n	Events (%) (95% CI)	n	Events (%) (95% CI)
Overall						
- Visit Week 2	362	7 (1.9%) (0.8%, 3.9%)	365	2 (0.5%) (0.1%, 2.0%)	93	1 (1.1%) (0.0%, 5.8%)
- Visit Week 4	362	28 (7.7%) (5.2%, 11.0%)	365	7 (1.9%) (0.8%, 3.9%)	93	6 (6.5%) (2.4%, 13.5%)
- Visit Week 8	362	48 (13.3%) (9.9%, 17.2%)	365	15 (4.1%) (2.3%, 6.7%)	93	9 (9.7%) (4.5%, 17.6%)
- Visit Week 12	362	60 (16.6%) (12.9%, 20.8%)	365	24 (6.6%) (4.3%, 9.6%)	93	11 (11.8%) (6.1%, 20.2%)
- Visit Week 16	362	71 (19.6%) (15.6%, 24.1%)	365	31 (8.5%) (5.8%, 11.8%)	0	0
- Visit Week 20	362	79 (21.8%) (17.7%, 26.4%)	365	44 (12.1%) (8.9%, 15.8%)	0	0
- Visit Week 26	362	80 (22.1%) (17.9%, 26.7%)	365	52 (14.2%) (10.8%, 18.3%)	0	0

Notes:
Number of subjects: Full Analysis Set Safety Population
Analysis on overall population is calculated based on stratified CMH (Cochran-Mantel-Haenszel) models, for OR, RR, and RD, stratified by by disease activity (moderate, severe) at enrollment.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.

Binary Outcome Analysis: SCORAD-100 response - Full Analysis Set Safety Population
JADE TEEN and DARE (PF-04965842) - 2023 datacuts

	Abrocitinib 200mg QD [DARE]		Dupilumab 300mg Q2W [DARE]		Abrocitinib 200mg QD [TEEN]	
	n	Events (%) (95% CI)	n	Events (%) (95% CI)	n	Events (%) (95% CI)
Overall						
- Visit Week 2	362	0 (0.0%)	365	1 (0.3%) (0.0%, 1.5%)	93	0 (0.0%)
- Visit Week 4	362	11 (3.0%) (1.5%, 5.4%)	365	3 (0.8%) (0.2%, 2.4%)	93	1 (1.1%) (0.0%, 5.8%)
- Visit Week 8	362	15 (4.1%) (2.3%, 6.7%)	365	4 (1.1%) (0.3%, 2.8%)	93	3 (3.2%) (0.7%, 9.1%)
- Visit Week 12	362	21 (5.8%) (3.6%, 8.7%)	365	6 (1.6%) (0.6%, 3.5%)	93	3 (3.2%) (0.7%, 9.1%)
- Visit Week 16	362	29 (8.0%) (5.4%, 11.3%)	365	9 (2.5%) (1.1%, 4.6%)	0	0
- Visit Week 20	362	36 (9.9%) (7.1%, 13.5%)	365	21 (5.8%) (3.6%, 8.7%)	0	0
- Visit Week 26	362	37 (10.2%) (7.3%, 13.8%)	365	22 (6.0%) (3.8%, 9.0%)	0	0

Notes:
Number of subjects: Full Analysis Set Safety Population
Analysis on overall population is calculated based on stratified CMH (Cochran-Mantel-Haenszel) models, for OR, RR, and RD, stratified by by disease activity (moderate, severe) at enrollment.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.

Binary Outcome Analysis: EASI-100 response - Full Analysis Set Safety Population
JADE TEEN and DARE (PF-04965842) - 2023 datacuts

	Abrocitinib 200mg QD [DARE]		Dupilumab 300mg Q2W [DARE]		Abrocitinib 200mg QD [TEEN]	
	n	Events (%) (95% CI)	n	Events (%) (95% CI)	n	Events (%) (95% CI)
Overall						
- Visit Week 2	362	7 (1.9%) (0.8%, 3.9%)	365	3 (0.8%) (0.2%, 2.4%)	94	0 (0.0%)
- Visit Week 4	362	27 (7.5%) (5.0%, 10.7%)	365	9 (2.5%) (1.1%, 4.6%)	94	5 (5.3%) (1.7%, 12.0%)
- Visit Week 8	362	45 (12.4%) (9.2%, 16.3%)	365	13 (3.6%) (1.9%, 6.0%)	94	9 (9.6%) (4.5%, 17.4%)
- Visit Week 12	362	56 (15.5%) (11.9%, 19.6%)	365	20 (5.5%) (3.4%, 8.3%)	94	8 (8.5%) (3.7%, 16.1%)
- Visit Week 16	362	70 (19.3%) (15.4%, 23.8%)	365	33 (9.0%) (6.3%, 12.5%)	0	0
- Visit Week 20	362	74 (20.4%) (16.4%, 25.0%)	365	45 (12.3%) (9.1%, 16.1%)	0	0
- Visit Week 26	362	79 (21.8%) (17.7%, 26.4%)	365	50 (13.7%) (10.3%, 17.7%)	0	0

Notes:
Number of subjects: Full Analysis Set Safety Population
Analysis on overall population is calculated based on stratified CMH (Cochran-Mantel-Haenszel) models, for OR, RR, and RD, stratified by by disease activity (moderate, severe) at enrollment.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.

Binary Outcome Analysis: Achieving 0-2 in POEM total score - Full Analysis Set Safety Population
JADE TEEN and DARE (PF-04965842) - 2023 datacuts

	Abrocitinib 200mg QD [DARE]		Dupilumab 300mg Q2W [DARE]		Abrocitinib 200mg QD [TEEN]	
	n	Events (%) (95% CI)	n	Events (%) (95% CI)	n	Events (%) (95% CI)
Overall						
- Visit Week 2	358	0 (0.0%)	363	0 (0.0%)	94	7 (7.4%) (3.0%, 14.7%)
- Visit Week 4	358	1 (0.3%) (0.0%, 1.5%)	363	0 (0.0%)	94	14 (14.9%) (8.4%, 23.7%)
- Visit Week 8	358	0 (0.0%)	363	0 (0.0%)	94	15 (16.0%) (9.2%, 25.0%)
- Visit Week 12	358	108 (30.2%) (25.5%, 35.2%)	363	61 (16.8%) (13.1%, 21.1%)	94	18 (19.1%) (11.8%, 28.6%)
- Visit Week 16	358	104 (29.1%) (24.4%, 34.1%)	363	55 (15.2%) (11.6%, 19.3%)	0	0
- Visit Week 20	358	0 (0.0%)	363	2 (0.6%) (0.1%, 2.0%)	0	0
- Visit Week 26	358	106 (29.6%) (24.9%, 34.6%)	363	69 (19.0%) (15.1%, 23.4%)	0	0

Notes:
Number of subjects: Full Analysis Set Safety Population
Number of subjects: Full Analysis Set Safety Population, excluding subjects with baseline POEM 0-2.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.

Binary Outcome Analysis: Achieving 0 in POEM total score - Full Analysis Set Safety Population
JADE TEEN and DARE (PF-04965842) - 2023 datacuts

Abrocitinib 200mg QD [DARE]		Dupilumab 300mg Q2W [DARE]		Abrocitinib 200mg QD [TEEN]	
n	Events (%) (95% CI)	n	Events (%) (95% CI)	n	Events (%) (95% CI)
Overall					
- Visit Week 2					
359	0 (0.0%)	365	0 (0.0%)	94	4 (4.3%) (1.2%, 10.5%)
- Visit Week 4					
359	1 (0.3%) (0.0%, 1.5%)	365	0 (0.0%)	94	5 (5.3%) (1.7%, 12.0%)
- Visit Week 8					
359	0 (0.0%)	365	0 (0.0%)	94	3 (3.2%) (0.7%, 9.0%)
- Visit Week 12					
359	49 (13.6%) (10.3%, 17.6%)	365	11 (3.0%) (1.5%, 5.3%)	94	6 (6.4%) (2.4%, 13.4%)
- Visit Week 16					
359	45 (12.5%) (9.3%, 16.4%)	365	16 (4.4%) (2.5%, 7.0%)	0	0
- Visit Week 20					
359	0 (0.0%)	365	0 (0.0%)	0	0
- Visit Week 26					
359	49 (13.6%) (10.3%, 17.6%)	365	26 (7.1%) (4.7%, 10.3%)	0	0

Notes:
Number of subjects: Full Analysis Set Safety Population
Number of subjects: Full Analysis Set Safety Population, excluding subjects with baseline POEM 0.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.

Binary Outcome Analysis: Achieving 0-1 in DLQI total score - Full Analysis Set Safety Population
JADE TEEN and DARE (PF-04965842) - 2023 datacuts

	Abrocitinib 200mg QD [DARE]		Dupilumab 300mg Q2W [DARE]		Abrocitinib 200mg QD [TEEN]	
	n	Events (%) (95% CI)	n	Events (%) (95% CI)	n	Events (%) (95% CI)
Overall						
- Visit Week 2	358	81 (22.6%) (18.4%, 27.3%)	361	23 (6.4%) (4.1%, 9.4%)	94	8 (8.5%) (3.7%, 16.1%)
- Visit Week 4	358	3 (0.8%) (0.2%, 2.4%)	361	1 (0.3%) (0.0%, 1.5%)	94	17 (18.1%) (10.9%, 27.4%)
- Visit Week 8	358	0 (0.0%)	361	0 (0.0%)	94	15 (16.0%) (9.2%, 25.0%)
- Visit Week 12	358	126 (35.2%) (30.2%, 40.4%)	361	110 (30.5%) (25.8%, 35.5%)	94	21 (22.3%) (14.4%, 32.1%)
- Visit Week 16	358	147 (41.1%) (35.9%, 46.4%)	361	107 (29.6%) (25.0%, 34.6%)	0	0
- Visit Week 20	358	154 (43.0%) (37.8%, 48.3%)	361	119 (33.0%) (28.1%, 38.1%)	0	0
- Visit Week 26	358	137 (38.3%) (33.2%, 43.5%)	361	114 (31.6%) (26.8%, 36.6%)	0	0

Notes:
Number of subjects: Full Analysis Set Safety Population
Number of subjects: Full Analysis Set Safety Population, excluding subjects with baseline DLQI 0-1.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.

Binary Outcome Analysis: Achieving 0-1 in PP-NRS total score - Full Analysis Set Safety Population
JADE TEEN and DARE (PF-04965842) - 2023 datacuts

	Abrocitinib 200mg QD [DARE]		Dupilumab 300mg Q2W [DARE]		Abrocitinib 200mg QD [TEEN]	
	n	Events (%) (95% CI)	n	Events (%) (95% CI)	n	Events (%) (95% CI)
Overall						
- Visit Week 2	362	62 (17.1%) (13.4%, 21.4%)	365	17 (4.7%) (2.7%, 7.4%)	94	10 (10.6%) (5.2%, 18.7%)
- Visit Week 4	362	101 (27.9%) (23.3%, 32.8%)	365	41 (11.2%) (8.2%, 14.9%)	94	16 (17.0%) (10.1%, 26.2%)
- Visit Week 8	362	125 (34.5%) (29.6%, 39.7%)	365	76 (20.8%) (16.8%, 25.4%)	94	25 (26.6%) (18.0%, 36.7%)
- Visit Week 12	362	135 (37.3%) (32.3%, 42.5%)	365	91 (24.9%) (20.6%, 29.7%)	94	18 (19.1%) (11.8%, 28.6%)
- Visit Week 16	362	130 (35.9%) (31.0%, 41.1%)	365	99 (27.1%) (22.6%, 32.0%)	0	0
- Visit Week 20	362	139 (38.4%) (33.4%, 43.6%)	365	98 (26.8%) (22.4%, 31.7%)	0	0
- Visit Week 26	362	139 (38.4%) (33.4%, 43.6%)	365	114 (31.2%) (26.5%, 36.3%)	0	0

Notes:
Number of subjects: Full Analysis Set Safety Population
Analysis on overall population is calculated based on stratified CMH (Cochran-Mantel-Haenszel) models, for OR, RR, and RD, stratified by by disease activity (moderate, severe) at enrollment.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.

Zusatzanalysen JADE DARE (Woche 2 bis Woche 26)

Binary Outcome Analysis: SCORAD-90 response - Full Analysis Set Safety Population
JADE DARE (PF-04965842) - 2023 datacut

Abrocitinib 200mg QD [DARE]		Dupilumab 300mg Q2W [DARE]		Abrocitinib 200mg QD [DARE] vs. Dupilumab 300mg Q2W [DARE]			
n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH p-value [+]
Overall							
- Visit Week 2							
362	7 (1.9%) (0.8%, 3.9%)	365	2 (0.5%) (0.1%, 2.0%)	3.58 (0.74, 17.35)	3.53 (0.74, 16.87)	1.4% (-0.2%, 3.0%)	0.0913+
- Visit Week 4							
362	28 (7.7%) (5.2%, 11.0%)	365	7 (1.9%) (0.8%, 3.9%)	4.29 (1.85, 9.95)	4.03 (1.78, 9.12)	5.8% (2.7%, 8.9%)	0.0003+*
- Visit Week 8							
362	48 (13.3%) (9.9%, 17.2%)	365	15 (4.1%) (2.3%, 6.7%)	3.57 (1.96, 6.50)	3.23 (1.84, 5.66)	9.2% (5.1%, 13.2%)	<0.0001+*
- Visit Week 12							
362	60 (16.6%) (12.9%, 20.8%)	365	24 (6.6%) (4.3%, 9.6%)	2.82 (1.72, 4.65)	2.52 (1.61, 3.96)	10.0% (5.4%, 14.6%)	<0.0001+*
- Visit Week 16							
362	71 (19.6%) (15.6%, 24.1%)	365	31 (8.5%) (5.8%, 11.8%)	2.63 (1.68, 4.12)	2.31 (1.55, 3.43)	11.1% (6.1%, 16.1%)	<0.0001+*
- Visit Week 20							
362	79 (21.8%) (17.7%, 26.4%)	365	44 (12.1%) (8.9%, 15.8%)	2.04 (1.36, 3.04)	1.81 (1.29, 2.54)	9.8% (4.4%, 15.2%)	0.0004+*
- Visit Week 26							
362	80 (22.1%) (17.9%, 26.7%)	365	52 (14.2%) (10.8%, 18.3%)	1.71 (1.16, 2.51)	1.55 (1.13, 2.13)	7.9% (2.3%, 13.4%)	0.0061+*

Notes:
Number of subjects: Full Analysis Set Safety Population
Analysis on overall population is calculated based on stratified CMH (Cochran-Mantel-Haenszel) models, for OR, RR, and RD, stratified by by disease activity (moderate, severe) at enrollment.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.

Binary Outcome Analysis: SCORAD-100 response - Full Analysis Set Safety Population
JADE DARE (PF-04965842) - 2023 datacut

Abrocitinib 200mg QD [DARE]		Dupilumab 300mg Q2W [DARE]		Abrocitinib 200mg QD [DARE] vs. Dupilumab 300mg Q2W [DARE]			
n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH p-value [+]
Overall							
- Visit Week 2							
362	0 (0.0%)	365	1 (0.3%) (0.0%, 1.5%)	<0.01 (NE, NE)	NE (NE, NE)	-0.3% (-0.8%, 0.3%)	0.3193+
- Visit Week 4							
362	11 (3.0%) (1.5%, 5.4%)	365	3 (0.8%) (0.2%, 2.4%)	3.78 (1.05, 13.67)	3.70 (1.04, 13.14)	2.2% (0.2%, 4.2%)	0.0298+*
- Visit Week 8							
362	15 (4.1%) (2.3%, 6.7%)	365	4 (1.1%) (0.3%, 2.8%)	3.90 (1.28, 11.87)	3.78 (1.27, 11.28)	3.0% (0.7%, 5.4%)	0.0101+*
- Visit Week 12							
362	21 (5.8%) (3.6%, 8.7%)	365	6 (1.6%) (0.6%, 3.5%)	3.68 (1.47, 9.24)	3.53 (1.44, 8.64)	4.2% (1.4%, 6.9%)	0.0031+*
- Visit Week 16							
362	29 (8.0%) (5.4%, 11.3%)	365	9 (2.5%) (1.1%, 4.6%)	3.44 (1.61, 7.39)	3.25 (1.56, 6.77)	5.5% (2.3%, 8.8%)	0.0008+*
- Visit Week 20							
362	36 (9.9%) (7.1%, 13.5%)	365	21 (5.8%) (3.6%, 8.7%)	1.81 (1.03, 3.16)	1.73 (1.03, 2.90)	4.2% (0.3%, 8.1%)	0.0357+*
- Visit Week 26							
362	37 (10.2%) (7.3%, 13.8%)	365	22 (6.0%) (3.8%, 9.0%)	1.77 (1.03, 3.07)	1.70 (1.02, 2.82)	4.2% (0.2%, 8.2%)	0.0386+*

Notes:
Number of subjects: Full Analysis Set Safety Population
Analysis on overall population is calculated based on stratified CMH (Cochran-Mantel-Haenszel) models, for OR, RR, and RD, stratified by by disease activity (moderate, severe) at enrollment.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.

Binary Outcome Analysis: EASI-100 response - Full Analysis Set Safety Population
JADE DARE (PF-04965842) - 2023 datacut

Abrocitinib 200mg QD [DARE]		Dupilumab 300mg Q2W [DARE]		Abrocitinib 200mg QD [DARE] vs. Dupilumab 300mg Q2W [DARE]			
n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH p-value [+]
Overall							
- Visit Week 2							
362	7 (1.9%) (0.8%, 3.9%)	365	3 (0.8%) (0.2%, 2.4%)	2.38 (0.61, 9.27)	2.35 (0.61, 9.03)	1.1% (-0.6%, 2.8%)	0.1985+
- Visit Week 4							
362	27 (7.5%) (5.0%, 10.7%)	365	9 (2.5%) (1.1%, 4.6%)	3.19 (1.48, 6.88)	3.02 (1.44, 6.34)	5.0% (1.9%, 8.1%)	0.0019+*
- Visit Week 8							
362	45 (12.4%) (9.2%, 16.3%)	365	13 (3.6%) (1.9%, 6.0%)	3.84 (2.04, 7.26)	3.49 (1.92, 6.36)	8.9% (5.0%, 12.8%)	<0.0001+*
- Visit Week 12							
362	56 (15.5%) (11.9%, 19.6%)	365	20 (5.5%) (3.4%, 8.3%)	3.16 (1.85, 5.38)	2.82 (1.73, 4.61)	10.0% (5.6%, 14.4%)	<0.0001+*
- Visit Week 16							
362	70 (19.3%) (15.4%, 23.8%)	365	33 (9.0%) (6.3%, 12.5%)	2.41 (1.55, 3.76)	2.14 (1.45, 3.15)	10.3% (5.3%, 15.3%)	<0.0001+*
- Visit Week 20							
362	74 (20.4%) (16.4%, 25.0%)	365	45 (12.3%) (9.1%, 16.1%)	1.83 (1.22, 2.73)	1.66 (1.18, 2.33)	8.1% (2.8%, 13.5%)	0.0031+*
- Visit Week 26							
362	79 (21.8%) (17.7%, 26.4%)	365	50 (13.7%) (10.3%, 17.7%)	1.76 (1.19, 2.59)	1.59 (1.15, 2.20)	8.1% (2.6%, 13.7%)	0.0042+*

Notes:
Number of subjects: Full Analysis Set Safety Population
Analysis on overall population is calculated based on stratified CMH (Cochran-Mantel-Haenszel) models, for OR, RR, and RD, stratified by by disease activity (moderate, severe) at enrollment.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.

Binary Outcome Analysis: Achieving 0-2 in POEM total score - Full Analysis Set Safety Population
JADE DARE (PF-04965842) - 2023 datacut

Abrocitinib 200mg QD [DARE]		Dupilumab 300mg Q2W [DARE]		Abrocitinib 200mg QD [DARE] vs. Dupilumab 300mg Q2W [DARE]			
n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH p-value [+]
Overall							
- Visit Week 2							
358	0 (0.0%)	363	0 (0.0%)	1.01 (0.02, 51.24)	1.01 (0.02, 50.96)	0.0% (-0.5%, 0.5%)	NE
- Visit Week 4							
358	1 (0.3%) (0.0%, 1.5%)	363	0 (0.0%)	NE (NE, NE)	NE (NE, NE)	0.3% (-0.3%, 0.8%)	0.3140+
- Visit Week 8							
358	0 (0.0%)	363	0 (0.0%)	1.01 (0.02, 51.24)	1.01 (0.02, 50.96)	0.0% (-0.5%, 0.5%)	NE
- Visit Week 12							
358	108 (30.2%) (25.5%, 35.2%)	363	61 (16.8%) (13.1%, 21.1%)	2.14 (1.50, 3.05)	1.80 (1.36, 2.37)	13.4% (7.2%, 19.5%)	<0.0001+*
- Visit Week 16							
358	104 (29.1%) (24.4%, 34.1%)	363	55 (15.2%) (11.6%, 19.3%)	2.29 (1.59, 3.31)	1.92 (1.43, 2.57)	13.9% (7.9%, 19.9%)	<0.0001+*
- Visit Week 20							
358	0 (0.0%)	363	2 (0.6%) (0.1%, 2.0%)	<0.01 (NE, NE)	NE (NE, NE)	-0.6% (-1.3%, 0.2%)	0.1599+
- Visit Week 26							
358	106 (29.6%) (24.9%, 34.6%)	363	69 (19.0%) (15.1%, 23.4%)	1.79 (1.27, 2.54)	1.56 (1.19, 2.03)	10.6% (4.4%, 16.8%)	0.0009+*

Notes:
Number of subjects: Full Analysis Set Safety Population
Number of subjects: Full Analysis Set Safety Population, excluding subjects with baseline POEM 0-2.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.

Binary Outcome Analysis: Achieving 0 in POEM total score - Full Analysis Set Safety Population
JADE DARE (PF-04965842) - 2023 datacut

Abrocitinib 200mg QD [DARE]		Dupilumab 300mg Q2W [DARE]		Abrocitinib 200mg QD [DARE] vs. Dupilumab 300mg Q2W [DARE]			
n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH p-value [+]
Overall							
- Visit Week 2							
359	0 (0.0%)	365	0 (0.0%)	1.02 (0.02, 51.38)	1.02 (0.02, 51.10)	0.0% (-0.5%, 0.5%)	NE
- Visit Week 4							
359	1 (0.3%) (0.0%, 1.5%)	365	0 (0.0%)	NE (NE, NE)	NE (NE, NE)	0.3% (-0.3%, 0.8%)	0.3133+
- Visit Week 8							
359	0 (0.0%)	365	0 (0.0%)	1.02 (0.02, 51.38)	1.02 (0.02, 51.10)	0.0% (-0.5%, 0.5%)	NE
- Visit Week 12							
359	49 (13.6%) (10.3%, 17.6%)	365	11 (3.0%) (1.5%, 5.3%)	5.09 (2.60, 9.96)	4.53 (2.39, 8.57)	10.6% (6.7%, 14.6%)	<0.0001+*
- Visit Week 16							
359	45 (12.5%) (9.3%, 16.4%)	365	16 (4.4%) (2.5%, 7.0%)	3.13 (1.73, 5.64)	2.86 (1.65, 4.96)	8.2% (4.1%, 12.2%)	<0.0001+*
- Visit Week 20							
359	0 (0.0%)	365	0 (0.0%)	1.02 (0.02, 51.38)	1.02 (0.02, 51.10)	0.0% (-0.5%, 0.5%)	NE
- Visit Week 26							
359	49 (13.6%) (10.3%, 17.6%)	365	26 (7.1%) (4.7%, 10.3%)	2.06 (1.25, 3.40)	1.92 (1.22, 3.01)	6.5% (2.1%, 11.0%)	0.0040+*

Notes:
Number of subjects: Full Analysis Set Safety Population
Number of subjects: Full Analysis Set Safety Population, excluding subjects with baseline POEM 0.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.

Binary Outcome Analysis: Achieving 0-1 in DLQI total score - Full Analysis Set Safety Population
JADE DARE (PF-04965842) - 2023 datacut

Abrocitinib 200mg QD [DARE]		Dupilumab 300mg Q2W [DARE]		Abrocitinib 200mg QD [DARE] vs. Dupilumab 300mg Q2W [DARE]			
n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH p-value [+]
Overall							
- Visit Week 2							
358	81 (22.6%) (18.4%, 27.3%)	361	23 (6.4%) (4.1%, 9.4%)	4.30 (2.63, 7.01)	3.55 (2.29, 5.51)	16.3% (11.2%, 21.3%)	<0.0001+*
- Visit Week 4							
358	3 (0.8%) (0.2%, 2.4%)	361	1 (0.3%) (0.0%, 1.5%)	3.04 (0.31, 29.39)	3.03 (0.32, 28.95)	0.6% (-0.5%, 1.6%)	0.3123+
- Visit Week 8							
358	0 (0.0%)	361	0 (0.0%)	1.01 (0.02, 50.96)	1.01 (0.02, 50.68)	0.0% (-0.5%, 0.5%)	NE
- Visit Week 12							
358	126 (35.2%) (30.2%, 40.4%)	361	110 (30.5%) (25.8%, 35.5%)	1.24 (0.91, 1.69)	1.16 (0.94, 1.42)	4.7% (-2.1%, 11.6%)	0.1777+
- Visit Week 16							
358	147 (41.1%) (35.9%, 46.4%)	361	107 (29.6%) (25.0%, 34.6%)	1.65 (1.21, 2.25)	1.39 (1.13, 1.69)	11.4% (4.5%, 18.4%)	0.0014+*
- Visit Week 20							
358	154 (43.0%) (37.8%, 48.3%)	361	119 (33.0%) (28.1%, 38.1%)	1.54 (1.13, 2.08)	1.30 (1.08, 1.58)	10.1% (3.0%, 17.1%)	0.0055+*
- Visit Week 26							
358	137 (38.3%) (33.2%, 43.5%)	361	114 (31.6%) (26.8%, 36.6%)	1.34 (0.99, 1.83)	1.21 (0.99, 1.48)	6.7% (-0.3%, 13.6%)	0.0601+

Notes:
Number of subjects: Full Analysis Set Safety Population
Number of subjects: Full Analysis Set Safety Population, excluding subjects with baseline DLQI 0-1.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.

Binary Outcome Analysis: Achieving 0-1 in PP-NRS total score - Full Analysis Set Safety Population
JADE DARE (PF-04965842) - 2023 datacut

Abrocitinib 200mg QD [DARE]		Dupilumab 300mg Q2W [DARE]		Abrocitinib 200mg QD [DARE] vs. Dupilumab 300mg Q2W [DARE]			
n	Events (%) (95% CI)	n	Events (%) (95% CI)	OR (95% CI)	RR (95% CI)	RD (95% CI)	CMH p-value [+]
Overall							
- Visit Week 2							
362	62 (17.1%) (13.4%, 21.4%)	365	17 (4.7%) (2.7%, 7.4%)	4.23 (2.42, 7.39)	3.68 (2.19, 6.16)	12.5% (8.0%, 16.9%)	<0.0001+*
- Visit Week 4							
362	101 (27.9%) (23.3%, 32.8%)	365	41 (11.2%) (8.2%, 14.9%)	3.06 (2.05, 4.55)	2.48 (1.78, 3.46)	16.7% (11.0%, 22.3%)	<0.0001+*
- Visit Week 8							
362	125 (34.5%) (29.6%, 39.7%)	365	76 (20.8%) (16.8%, 25.4%)	2.01 (1.44, 2.80)	1.66 (1.30, 2.12)	13.7% (7.3%, 20.1%)	<0.0001+*
- Visit Week 12							
362	135 (37.3%) (32.3%, 42.5%)	365	91 (24.9%) (20.6%, 29.7%)	1.79 (1.30, 2.46)	1.50 (1.20, 1.87)	12.4% (5.7%, 19.0%)	0.0003+*
- Visit Week 16							
362	130 (35.9%) (31.0%, 41.1%)	365	99 (27.1%) (22.6%, 32.0%)	1.51 (1.10, 2.06)	1.32 (1.07, 1.65)	8.8% (2.1%, 15.5%)	0.0108+*
- Visit Week 20							
362	139 (38.4%) (33.4%, 43.6%)	365	98 (26.8%) (22.4%, 31.7%)	1.70 (1.24, 2.32)	1.43 (1.15, 1.77)	11.5% (4.8%, 18.3%)	0.0009+*
- Visit Week 26							
362	139 (38.4%) (33.4%, 43.6%)	365	114 (31.2%) (26.5%, 36.3%)	1.37 (1.01, 1.86)	1.23 (1.01, 1.50)	7.2% (0.3%, 14.1%)	0.0427+*

Notes:
Number of subjects: Full Analysis Set Safety Population
Analysis on overall population is calculated based on stratified CMH (Cochran-Mantel-Haenszel) models, for OR, RR, and RD, stratified by by disease activity (moderate, severe) at enrollment.
Non-responder imputation is applied: subjects without a value at the corresponding visit is considered a non-responder. If a subject withdrew from the study or used rescue therapy, then this subject was counted as non-responder after that point.
The 95% confidence intervals for the event rates are exact Clopper-Pearson intervals.