Dossier zur Nutzenbewertung gemäß § 35a SGB V

Epcoritamab (Tepkinly®)

AbbVie Deutschland GmbH & Co. KG

Separater Anhang 4-G: Ergänzende Unterlagen

Zur Behandlung von erwachsenen Patienten mit einem rezidivierenden oder refraktären follikulären Lymphom (FL) nach mindestens 2 Linien einer systemischen Therapie

Stand: 13.09.2024

Anhang 4-G: Ergänzende Unterlagen

Inhaltsverzeichnis

Concomitant Medications
GCT3013-01 Dose Optimization Part - FL 1-3A Cohort - Safety Analysis Set

Anatomical Therapeutic Chemical (ATC) Level 2 Generic Name	Arm A (N=86)	Arm B (N=6)	Overall (N=92)
Subjects with at least one concomitant medication	85 (98.8%)	6 (100%)	91 (98.9%)
Antibacterials for systemic use	76 (88.4%)	6 (100%)	82 (89.1%)
Sulfamethoxazole;trimethoprim	62 (72.1%)	6 (100%)	68 (73.9%)
Piperacillin sodium;tazobactam sodium	14 (16.3%)	2 (33.3%)	16 (17.4%)
Levofloxacin	11 (12.8%)	2 (33.3%)	13 (14.1%)
Azithromycin	9 (10.5%)	1 (16.7%)	10 (10.9%)
Amoxicillin;clavulanic acid	5 (5.8%)	2 (33.3%)	7 (7.6%)
Amoxicillin	6 (7.0%)	0	6 (6.5%)
Amoxicillin trihydrate;clavulanate potassium	6 (7.0%)	0	6 (6.5%)
Ceftriaxone	6 (7.0%)	0	6 (6.5%)
Vancomycin	6 (7.0%)	0	6 (6.5%)
Cefepime	5 (5.8%)	0	5 (5.4%)
Cefuroxime	4 (4.7%)	1 (16.7%)	5 (5.4%)
Ciprofloxacin	4 (4.7%)	1 (16.7%)	5 (5.4%)

Arm A: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 3mg
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GCT3013-01 Dose Optimization Part - FL 1-3A Cohort - Safety Analysis Set

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Piperacillin;tazobactam	5 (5.8%)	0	5 (5.4%)
Cefixime	3 (3.5%)	0	3 (3.3%)
Linezolid	2 (2.3%)	1 (16.7%)	3 (3.3%)
Meropenem	3 (3.5%)	0	3 (3.3%)
Sulfamethoxazole	3 (3.5%)	0	3 (3.3%)
Trimethoprim	3 (3.5%)	0	3 (3.3%)
Antibiotics	2 (2.3%)	0	2 (2.2%)
Clavulanic acid	2 (2.3%)	0	2 (2.2%)
Clindamycin	2 (2.3%)	0	2 (2.2%)
Doxycycline	2 (2.3%)	0	2 (2.2%)
Fosfomycin	2 (2.3%)	0	2 (2.2%)
Moxifloxacin hydrochloride	2 (2.3%)	0	2 (2.2%)
Nitrofurantoin	2 (2.3%)	0	2 (2.2%)
Amikacin	1 (1.2%)	0	1 (1.1%)
Avibactam;ceftazidime	1 (1.2%)	0	1 (1.1%)

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GCT3013-01 Dose Optimization Part - FL 1-3A Cohort - Safety Analysis Set

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Cefazolin	1 (1.2%)	0	1 (1.1%)
Cefepime hydrochloride	1 (1.2%)	0	1 (1.1%)
Cefotaxime	1 (1.2%)	0	1 (1.1%)
Cefotaxime sodium	0	1 (16.7%)	1 (1.1%)
Ceftaroline	0	1 (16.7%)	1 (1.1%)
Ceftazidime	1 (1.2%)	0	1 (1.1%)
Ceftriaxone sodium	1 (1.2%)	0	1 (1.1%)
Ciprofloxacin hydrochloride	1 (1.2%)	0	1 (1.1%)
Clarithromycin	1 (1.2%)	0	1 (1.1%)
Ertapenem	1 (1.2%)	0	1 (1.1%)
Fosfomycin trometamol	0	1 (16.7%)	1 (1.1%)
Imipenem	1 (1.2%)	0	1 (1.1%)
Minocycline	1 (1.2%)	0	1 (1.1%)
Moxifloxacin	1 (1.2%)	0	1 (1.1%)

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Pivampicillin	1 (1.2%)	0	1 (1.1%)
Antivirals for systemic use	70 (81.4%)	6 (100%)	76 (82.6%)
Aciclovir	39 (45.3%)	4 (66.7%)	43 (46.7%)
Valaciclovir	25 (29.1%)	2 (33.3%)	27 (29.3%)
Nirmatrelvir;ritonavir	9 (10.5%)	2 (33.3%)	11 (12.0%)
Remdesivir	7 (8.1%)	0	7 (7.6%)
Nirmatrelvir	4 (4.7%)	0	4 (4.3%)
Ritonavir	4 (4.7%)	0	4 (4.3%)
Valaciclovir hydrochloride	3 (3.5%)	0	3 (3.3%)
Entecavir	2 (2.3%)	0	2 (2.2%)
Lamivudine	2 (2.3%)	0	2 (2.2%)
Valganciclovir	2 (2.3%)	0	2 (2.2%)
Ganciclovir	1 (1.2%)	0	1 (1.1%)
Molnupiravir	1 (1.2%)	0	1 (1.1%)

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GCT3013-01 Dose Optimization Part - FL 1-3A Cohort - Safety Analysis Set

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Oseltamivir	1 (1.2%)	0	1 (1.1%)
Ribavirin	1 (1.2%)	0	1 (1.1%)
Analgesics	65 (75.6%)	5 (83.3%)	70 (76.1%)
Paracetamol	59 (68.6%)	4 (66.7%)	63 (68.5%)
Oxycodone	6 (7.0%)	1 (16.7%)	7 (7.6%)
Metamizole	5 (5.8%)	1 (16.7%)	6 (6.5%)
Pregabalin	5 (5.8%)	1 (16.7%)	6 (6.5%)
Codeine phosphate;paracetamol	4 (4.7%)	0	4 (4.3%)
Hydromorphone	3 (3.5%)	1 (16.7%)	4 (4.3%)
Morphine	4 (4.7%)	0	4 (4.3%)
Fentanyl	2 (2.3%)	1 (16.7%)	3 (3.3%)
Acetylsalicylic acid	1 (1.2%)	1 (16.7%)	2 (2.2%)
Amitriptyline	2 (2.3%)	0	2 (2.2%)
Gabapentin	2 (2.3%)	0	2 (2.2%)

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Hydrocodone;paracetamol	1 (1.2%)	1 (16.7%)	2 (2.2%)
Morphine sulfate	2 (2.3%)	0	2 (2.2%)
Naloxone hydrochloride;oxycodone hydrochloride	2 (2.3%)	0	2 (2.2%)
Oxycodone hydrochloride	2 (2.3%)	0	2 (2.2%)
Tramadol	2 (2.3%)	0	2 (2.2%)
Tramadol hydrochloride	1 (1.2%)	1 (16.7%)	2 (2.2%)
Clonidine	1 (1.2%)	0	1 (1.1%)
Codeine	1 (1.2%)	0	1 (1.1%)
Duloxetine	1 (1.2%)	0	1 (1.1%)
Hydromorphone hydrochloride	0	1 (16.7%)	1 (1.1%)
Metamizole magnesium	0	1 (16.7%)	1 (1.1%)
Morphine hydrochloride	1 (1.2%)	0	1 (1.1%)
Nefopam	1 (1.2%)	0	1 (1.1%)
Paracetamol;tramadol hydrochloride	0	1 (16.7%)	1 (1.1%)

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Drugs for acid related disorders	59 (68.6%)	6 (100%)	65 (70.7%)
Pantoprazole	25 (29.1%)	1 (16.7%)	26 (28.3%)
Omeprazole	20 (23.3%)	4 (66.7%)	24 (26.1%)
Famotidine	4 (4.7%)	1 (16.7%)	5 (5.4%)
Pantoprazole sodium sesquihydrate	4 (4.7%)	1 (16.7%)	5 (5.4%)
Esomeprazole	4 (4.7%)	0	4 (4.3%)
Calcium carbonate;sodium alginate;sodium bicarbonate	1 (1.2%)	1 (16.7%)	2 (2.2%)
Lansoprazole	2 (2.3%)	0	2 (2.2%)
Rabeprazole	2 (2.3%)	0	2 (2.2%)
Algeldrate;magnesium hydroxide	1 (1.2%)	0	1 (1.1%)
Almagate	1 (1.2%)	0	1 (1.1%)
Aluminium hydroxide;magnesium hydroxide	1 (1.2%)	0	1 (1.1%)
Calcium carbonate	1 (1.2%)	0	1 (1.1%)
Calcium carbonate;potassium bicarbonate;sodium alginate	1 (1.2%)	0	1 (1.1%)
Chondroitin sulfate;hyaluronic acid;poloxamer 407	1 (1.2%)	0	1 (1.1%)

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Esomeprazole magnesium	1 (1.2%)	0	1 (1.1%)
Magnesium hydroxide	1 (1.2%)	0	1 (1.1%)
Antigout preparations	43 (50.0%)	1 (16.7%)	44 (47.8%)
Allopurinol	41 (47.7%)	1 (16.7%)	42 (45.7%)
Febuxostat	2 (2.3%)	0	2 (2.2%)
Antithrombotic agents	37 (43.0%)	3 (50.0%)	40 (43.5%)
Enoxaparin	10 (11.6%)	0	10 (10.9%)
Acetylsalicylic acid	5 (5.8%)	1 (16.7%)	6 (6.5%)
Rivaroxaban	6 (7.0%)	0	6 (6.5%)
Apixaban	5 (5.8%)	0	5 (5.4%)
Enoxaparin sodium	4 (4.7%)	1 (16.7%)	5 (5.4%)
Bemiparin sodium	2 (2.3%)	0	2 (2.2%)
Clopidogrel	2 (2.3%)	0	2 (2.2%)

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Edoxaban	2 (2.3%)	0	2 (2.2%)
Heparin	2 (2.3%)	0	2 (2.2%)
Dabigatran	1 (1.2%)	0	1 (1.1%)
Dalteparin	1 (1.2%)	0	1 (1.1%)
Dalteparin sodium	1 (1.2%)	0	1 (1.1%)
Nadroparin	1 (1.2%)	0	1 (1.1%)
Nadroparin calcium	1 (1.2%)	0	1 (1.1%)
Ticagrelor	1 (1.2%)	0	1 (1.1%)
Tinzaparin	0	1 (16.7%)	1 (1.1%)
Tinzaparin sodium	0	1 (16.7%)	1 (1.1%)
Blood substitutes and perfusion solutions	33 (38.4%)	2 (33.3%)	35 (38.0%)
Sodium chloride	23 (26.7%)	1 (16.7%)	24 (26.1%)
Magnesium sulfate	6 (7.0%)	2 (33.3%)	8 (8.7%)
Solutions affecting the electrolyte balance	5 (5.8%)	0	5 (5.4%)

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GCT3013-01 Dose Optimization Part - FL 1-3A Cohort - Safety Analysis Set

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Potassium chloride;sodium chloride	3 (3.5%)	0	3 (3.3%)
Calcium chloride;potassium chloride;sodium chloride;sodium lactate	2 (2.3%)	0	2 (2.2%)
Potassium chloride	2 (2.3%)	0	2 (2.2%)
Albumin human	1 (1.2%)	0	1 (1.1%)
Calcium chloride;magnesium chloride hexahydrate;potassium chloride;sodium acetate trihydrate;sodium chloride	1 (1.2%)	0	1 (1.1%)
Calcium chloride;potassium chloride;sodium chloride;sodium hydroxide;sodium lactate	1 (1.2%)	0	1 (1.1%)
Calcium chloride;potassium chloride;sodium lactate	1 (1.2%)	0	1 (1.1%)
Calcium gluconate	1 (1.2%)	0	1 (1.1%)
Electrolytes nos	1 (1.2%)	0	1 (1.1%)
Magnesium sulfate;sodium chloride	1 (1.2%)	0	1 (1.1%)
Sodium phosphate	1 (1.2%)	0	1 (1.1%)
Corticosteroids for systemic use	28 (32.6%)	3 (50.0%)	31 (33.7%)
Dexamethasone	14 (16.3%)	2 (33.3%)	16 (17.4%)
Prednisone	7 (8.1%)	1 (16.7%)	8 (8.7%)

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Methylprednisolone	3 (3.5%)	2 (33.3%)	5 (5.4%)
Prednisolone	5 (5.8%)	0	5 (5.4%)
Hydrocortisone	3 (3.5%)	0	3 (3.3%)
Dexamethasone sodium phosphate	2 (2.3%)	0	2 (2.2%)
Betamethasone	1 (1.2%)	0	1 (1.1%)
Hydrocortisone sodium succinate	1 (1.2%)	0	1 (1.1%)
Antimycotics for systemic use	29 (33.7%)	1 (16.7%)	30 (32.6%)
Nystatin	13 (15.1%)	1 (16.7%)	14 (15.2%)
Fluconazole	13 (15.1%)	0	13 (14.1%)
Pentamidine	3 (3.5%)	0	3 (3.3%)
Itraconazole	2 (2.3%)	0	2 (2.2%)
Pentamidine isethionate	2 (2.3%)	0	2 (2.2%)
Voriconazole	2 (2.3%)	0	2 (2.2%)

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GCT3013-01 Dose Optimization Part - FL 1-3A Cohort - Safety Analysis Set

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Amphotericin b	1 (1.2%)	0	1 (1.1%)
Drugs for constipation	26 (30.2%)	4 (66.7%)	30 (32.6%)
Lactulose	6 (7.0%)	1 (16.7%)	7 (7.6%)
Macrogol 3350;potassium chloride;sodium bicarbonate;sodium chloride	5 (5.8%)	2 (33.3%)	7 (7.6%)
Bisacodyl	4 (4.7%)	0	4 (4.3%)
Docusate sodium	3 (3.5%)	1 (16.7%)	4 (4.3%)
Macrogol	4 (4.7%)	0	4 (4.3%)
Sennoside a+b	3 (3.5%)	0	3 (3.3%)
Docusate;senna alexandrina	2 (2.3%)	0	2 (2.2%)
Macrogol 3350	1 (1.2%)	1 (16.7%)	2 (2.2%)
Docusate sodium;sennoside a+b	1 (1.2%)	0	1 (1.1%)
Docusate;sennoside a+b	0	1 (16.7%)	1 (1.1%)
Docusate;sennosides nos	1 (1.2%)	0	1 (1.1%)
Electrolytes nos;macrogol 3350	1 (1.2%)	0	1 (1.1%)

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Macrogol 4000	0	1 (16.7%)	1 (1.1%)
Macrogol;potassium chloride;sodium bicarbonate;sodium chloride	1 (1.2%)	0	1 (1.1%)
Magnesium citrate	1 (1.2%)	0	1 (1.1%)
Plantago ovata	1 (1.2%)	0	1 (1.1%)
Sennoside b	1 (1.2%)	0	1 (1.1%)
Sterculia urens gum	1 (1.2%)	0	1 (1.1%)
Psycholeptics	26 (30.2%)	3 (50.0%)	29 (31.5%)
Melatonin	6 (7.0%)	0	6 (6.5%)
Zopiclone	5 (5.8%)	1 (16.7%)	6 (6.5%)
Lorazepam	4 (4.7%)	1 (16.7%)	5 (5.4%)
Temazepam	5 (5.8%)	0	5 (5.4%)
Midazolam	3 (3.5%)	0	3 (3.3%)
Clonazepam	1 (1.2%)	0	1 (1.1%)
Delorazepam	1 (1.2%)	0	1 (1.1%)

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Diazepam	1 (1.2%)	0	1 (1.1%)
Diphenhydramine hydrochloride	1 (1.2%)	0	1 (1.1%)
Haloperidol	1 (1.2%)	0	1 (1.1%)
Olanzapine	1 (1.2%)	0	1 (1.1%)
Oxazepam	0	1 (16.7%)	1 (1.1%)
Paroxetine	0	1 (16.7%)	1 (1.1%)
Quetiapine	1 (1.2%)	0	1 (1.1%)
Zolpidem	1 (1.2%)	0	1 (1.1%)
Zolpidem tartrate	1 (1.2%)	0	1 (1.1%)
Mineral supplements	25 (29.1%)	1 (16.7%)	26 (28.3%)
Potassium chloride	10 (11.6%)	0	10 (10.9%)
Calcium carbonate;colecalciferol	4 (4.7%)	1 (16.7%)	5 (5.4%)
Magnesium	4 (4.7%)	0	4 (4.3%)
Magnesium amino acid chelate;magnesium oxide	3 (3.5%)	0	3 (3.3%)

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Magnesium hydroxide	3 (3.5%)	0	3 (3.3%)
Ascorbic acid;potassium bicarbonate	1 (1.2%)	1 (16.7%)	2 (2.2%)
Calcium carbonate	2 (2.3%)	0	2 (2.2%)
Calcium;vitamin d nos	1 (1.2%)	0	1 (1.1%)
Magnesium chloride	1 (1.2%)	0	1 (1.1%)
Other mineral products	1 (1.2%)	0	1 (1.1%)
Potassium bicarbonate;potassium carbonate;potassium chloride	1 (1.2%)	0	1 (1.1%)
Sodium phosphate monobasic	1 (1.2%)	0	1 (1.1%)
Sodium phosphate monobasic (anhydrous)	1 (1.2%)	0	1 (1.1%)
Antihistamines for systemic use	21 (24.4%)	2 (33.3%)	23 (25.0%)
Cetirizine	8 (9.3%)	0	8 (8.7%)
Diphenhydramine	4 (4.7%)	0	4 (4.3%)
Cetirizine hydrochloride	3 (3.5%)	0	3 (3.3%)
Dexchlorpheniramine maleate	1 (1.2%)	1 (16.7%)	2 (2.2%)

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Loratadine	2 (2.3%)	0	2 (2.2%)
Alimemazine tartrate	1 (1.2%)	0	1 (1.1%)
Chlorphenamine	1 (1.2%)	0	1 (1.1%)
Desloratadine	1 (1.2%)	0	1 (1.1%)
Dexchlorpheniramine	1 (1.2%)	0	1 (1.1%)
Diphenhydramine hydrochloride	0	1 (16.7%)	1 (1.1%)
Fexofenadine	1 (1.2%)	0	1 (1.1%)
Levocetirizine dihydrochloride	1 (1.2%)	0	1 (1.1%)
Agents acting on the renin-angiotensin system	20 (23.3%)	2 (33.3%)	22 (23.9%)
Enalapril	4 (4.7%)	0	4 (4.3%)
Lisinopril	3 (3.5%)	0	3 (3.3%)
Losartan	3 (3.5%)	0	3 (3.3%)
Ramipril	2 (2.3%)	1 (16.7%)	3 (3.3%)
Olmesartan	2 (2.3%)	0	2 (2.2%)

Arm A: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 3mg
Arm B: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 6mg
Note: Percentages calculated based on number of subjects in Safety Analysis Set.
Note: Concomitant medications are the medications other than trial drug that are taken during on-treatment period.

Concomitant Medications
GCT3013-01 Dose Optimization Part - FL 1-3A Cohort - Safety Analysis Set

Anatomical Therapeutic Chemical (ATC) Level 2 Generic Name	Arm A (N=86)	Arm B (N=6)	Overall (N=92)
Telmisartan	2 (2.3%)	0	2 (2.2%)
Candesartan	0	1 (16.7%)	1 (1.1%)
Captopril	1 (1.2%)	0	1 (1.1%)
Hydrochlorothiazide;olmesartan medoxomil	1 (1.2%)	0	1 (1.1%)
Hydrochlorothiazide;valsartan	1 (1.2%)	0	1 (1.1%)
Indapamide;perindopril erbumine	1 (1.2%)	0	1 (1.1%)
Irbesartan	1 (1.2%)	0	1 (1.1%)
Olmesartan medoxomil	1 (1.2%)	0	1 (1.1%)
Antianemic preparations	17 (19.8%)	4 (66.7%)	21 (22.8%)
Folic acid	12 (14.0%)	2 (33.3%)	14 (15.2%)
Cyanocobalamin	4 (4.7%)	0	4 (4.3%)
Ferric carboxymaltose	1 (1.2%)	1 (16.7%)	2 (2.2%)
Ferrous fumarate	1 (1.2%)	0	1 (1.1%)
Ferrous glycine sulfate	1 (1.2%)	0	1 (1.1%)

Arm A: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 3mg
Arm B: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 6mg
Note: Percentages calculated based on number of subjects in Safety Analysis Set.
Note: Concomitant medications are the medications other than trial drug that are taken during on-treatment period.

Concomitant Medications
GCT3013-01 Dose Optimization Part - FL 1-3A Cohort - Safety Analysis Set

Anatomical Therapeutic Chemical (ATC) Level 2 Generic Name	Arm A (N=86)	Arm B (N=6)	Overall (N=92)
Ferrous sulfate	1 (1.2%)	0	1 (1.1%)
Folinic acid	0	1 (16.7%)	1 (1.1%)
Lipid modifying agents	19 (22.1%)	2 (33.3%)	21 (22.8%)
Rosuvastatin	6 (7.0%)	1 (16.7%)	7 (7.6%)
Atorvastatin	6 (7.0%)	0	6 (6.5%)
Simvastatin	3 (3.5%)	1 (16.7%)	4 (4.3%)
Fenofibrate	2 (2.3%)	0	2 (2.2%)
Ezetimibe	1 (1.2%)	0	1 (1.1%)
Ezetimibe;rosuvastatin	1 (1.2%)	0	1 (1.1%)
Pravastatin	1 (1.2%)	0	1 (1.1%)
Rosuvastatin calcium	1 (1.2%)	0	1 (1.1%)
Antiemetics and antinauseants	18 (20.9%)	1 (16.7%)	19 (20.7%)
Ondansetron	11 (12.8%)	0	11 (12.0%)

Arm A: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 3mg
Arm B: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 6mg
Note: Percentages calculated based on number of subjects in Safety Analysis Set.
Note: Concomitant medications are the medications other than trial drug that are taken during on-treatment period.

Concomitant Medications
GCT3013-01 Dose Optimization Part - FL 1-3A Cohort - Safety Analysis Set

Anatomical Therapeutic Chemical (ATC) Level 2 Generic Name	Arm A (N=86)	Arm B (N=6)	Overall (N=92)
Metoclopramide	4 (4.7%)	0	4 (4.3%)
Prochlorperazine	4 (4.7%)	0	4 (4.3%)
Prochlorperazine maleate	1 (1.2%)	1 (16.7%)	2 (2.2%)
Hyoscine	1 (1.2%)	0	1 (1.1%)
Levosulpiride	1 (1.2%)	0	1 (1.1%)
Metoclopramide hydrochloride	1 (1.2%)	0	1 (1.1%)
Immunostimulants	18 (20.9%)	1 (16.7%)	19 (20.7%)
Filgrastim	16 (18.6%)	1 (16.7%)	17 (18.5%)
Granulocyte colony stimulating factor	2 (2.3%)	0	2 (2.2%)
Bcg vaccine	1 (1.2%)	0	1 (1.1%)
Immune sera and immunoglobulins	17 (19.8%)	1 (16.7%)	18 (19.6%)
Immunoglobulin human normal	11 (12.8%)	0	11 (12.0%)
Immunoglobulins nos	6 (7.0%)	0	6 (6.5%)

Arm A: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 3mg
Arm B: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 6mg
Note: Percentages calculated based on number of subjects in Safety Analysis Set.
Note: Concomitant medications are the medications other than trial drug that are taken during on-treatment period.

Concomitant Medications
GCT3013-01 Dose Optimization Part - FL 1-3A Cohort - Safety Analysis Set

Anatomical Therapeutic Chemical (ATC) Level 2 Generic Name	Arm A (N=86)	Arm B (N=6)	Overall (N=92)
Immunoglobulins	2 (2.3%)	1 (16.7%)	3 (3.3%)
Cilgavimab;tixagevimab	2 (2.3%)	0	2 (2.2%)
Cilgavimab	1 (1.2%)	0	1 (1.1%)
Immunoglobulin g human	1 (1.2%)	0	1 (1.1%)
Tixagevimab	1 (1.2%)	0	1 (1.1%)
Beta blocking agents	15 (17.4%)	2 (33.3%)	17 (18.5%)
Bisoprolol	4 (4.7%)	0	4 (4.3%)
Metoprolol	4 (4.7%)	0	4 (4.3%)
Atenolol	3 (3.5%)	0	3 (3.3%)
Bisoprolol fumarate	1 (1.2%)	1 (16.7%)	2 (2.2%)
Metoprolol succinate	2 (2.3%)	0	2 (2.2%)
Carvedilol	1 (1.2%)	0	1 (1.1%)
Metoprolol tartrate	1 (1.2%)	0	1 (1.1%)

Arm A: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 3mg
Arm B: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 6mg
Note: Percentages calculated based on number of subjects in Safety Analysis Set.
Note: Concomitant medications are the medications other than trial drug that are taken during on-treatment period.

Concomitant Medications
GCT3013-01 Dose Optimization Part - FL 1-3A Cohort - Safety Analysis Set

Anatomical Therapeutic Chemical (ATC) Level 2 Generic Name	Arm A (N=86)	Arm B (N=6)	Overall (N=92)
Propranolol hydrochloride	0	1 (16.7%)	1 (1.1%)
Antiinflammatory and antirheumatic products	14 (16.3%)	2 (33.3%)	16 (17.4%)
Ibuprofen	7 (8.1%)	1 (16.7%)	8 (8.7%)
Celecoxib	2 (2.3%)	0	2 (2.2%)
Ketoprofen	2 (2.3%)	0	2 (2.2%)
Meloxicam	2 (2.3%)	0	2 (2.2%)
Dexketoprofen	1 (1.2%)	0	1 (1.1%)
Dexketoprofen trometamol	1 (1.2%)	0	1 (1.1%)
Diclofenac	1 (1.2%)	0	1 (1.1%)
Ketorolac	0	1 (16.7%)	1 (1.1%)
Naproxen sodium	1 (1.2%)	0	1 (1.1%)
Corticosteroids, dermatological preparations	14 (16.3%)	2 (33.3%)	16 (17.4%)
Hydrocortisone	4 (4.7%)	0	4 (4.3%)

Arm A: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 3mg
Arm B: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 6mg
Note: Percentages calculated based on number of subjects in Safety Analysis Set.
Note: Concomitant medications are the medications other than trial drug that are taken during on-treatment period.

Concomitant Medications
GCT3013-01 Dose Optimization Part - FL 1-3A Cohort - Safety Analysis Set

Anatomical Therapeutic Chemical (ATC) Level 2 Generic Name	Arm A (N=86)	Arm B (N=6)	Overall (N=92)
Triamcinolone	3 (3.5%)	0	3 (3.3%)
Hydrocortisone butyrate	2 (2.3%)	0	2 (2.2%)
Triamcinolone acetonide	1 (1.2%)	1 (16.7%)	2 (2.2%)
Betamethasone	1 (1.2%)	0	1 (1.1%)
Betamethasone dipropionate	1 (1.2%)	0	1 (1.1%)
Betamethasone valerate	1 (1.2%)	0	1 (1.1%)
Clobetasol propionate	0	1 (16.7%)	1 (1.1%)
Corticosteroid nos	1 (1.2%)	0	1 (1.1%)
Corticosteroids, topical	0	1 (16.7%)	1 (1.1%)
Methylprednisolone aceponate	1 (1.2%)	0	1 (1.1%)
Mometasone furoate	1 (1.2%)	0	1 (1.1%)
All other therapeutic products	14 (16.3%)	1 (16.7%)	15 (16.3%)
Calcium folinate	9 (10.5%)	0	9 (9.8%)
Oxygen	4 (4.7%)	1 (16.7%)	5 (5.4%)

Arm A: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 3mg
Arm B: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 6mg
Note: Percentages calculated based on number of subjects in Safety Analysis Set.
Note: Concomitant medications are the medications other than trial drug that are taken during on-treatment period.

Concomitant Medications
GCT3013-01 Dose Optimization Part - FL 1-3A Cohort - Safety Analysis Set

Anatomical Therapeutic Chemical (ATC) Level 2 Generic Name	Arm A (N=86)	Arm B (N=6)	Overall (N=92)
Rasburicase	2 (2.3%)	0	2 (2.2%)
All other therapeutic products	1 (1.2%)	0	1 (1.1%)
Calcium polystyrene sulfonate	1 (1.2%)	0	1 (1.1%)
Sodium polystyrene sulfonate	1 (1.2%)	0	1 (1.1%)
Vitamins	14 (16.3%)	1 (16.7%)	15 (16.3%)
Colecalciferol	8 (9.3%)	1 (16.7%)	9 (9.8%)
Ascorbic acid	4 (4.7%)	0	4 (4.3%)
Vitamin d nos	2 (2.3%)	0	2 (2.2%)
Vitamins nos	2 (2.3%)	0	2 (2.2%)
Calcifediol	1 (1.2%)	0	1 (1.1%)
Minerals nos;vitamins nos	1 (1.2%)	0	1 (1.1%)
Pyridoxine hydrochloride	1 (1.2%)	0	1 (1.1%)
Thiamine	1 (1.2%)	0	1 (1.1%)

Arm A: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 3mg
Arm B: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 6mg
Note: Percentages calculated based on number of subjects in Safety Analysis Set.
Note: Concomitant medications are the medications other than trial drug that are taken during on-treatment period.

Concomitant Medications
GCT3013-01 Dose Optimization Part - FL 1-3A Cohort - Safety Analysis Set

Anatomical Therapeutic Chemical (ATC) Level 2 Generic Name	Arm A (N=86)	Arm B (N=6)	Overall (N=92)
Diuretics	13 (15.1%)	1 (16.7%)	14 (15.2%)
Furosemide	9 (10.5%)	1 (16.7%)	10 (10.9%)
Spironolactone	2 (2.3%)	1 (16.7%)	3 (3.3%)
Hydrochlorothiazide	2 (2.3%)	0	2 (2.2%)
Bendroflumethiazide;potassium chloride	1 (1.2%)	0	1 (1.1%)
Theobromine	1 (1.2%)	0	1 (1.1%)
Drugs for obstructive airway diseases	12 (14.0%)	2 (33.3%)	14 (15.2%)
Salbutamol	4 (4.7%)	1 (16.7%)	5 (5.4%)
Ipratropium bromide	2 (2.3%)	1 (16.7%)	3 (3.3%)
Beclometasone dipropionate;formoterol fumarate	1 (1.2%)	1 (16.7%)	2 (2.2%)
Beclometasone;formoterol	2 (2.3%)	0	2 (2.2%)
Budesonide	2 (2.3%)	0	2 (2.2%)
Beclometasone	1 (1.2%)	0	1 (1.1%)
Budesonide;formoterol fumarate	1 (1.2%)	0	1 (1.1%)

Arm A: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 3mg
Arm B: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 6mg
Note: Percentages calculated based on number of subjects in Safety Analysis Set.
Note: Concomitant medications are the medications other than trial drug that are taken during on-treatment period.

Concomitant Medications
GCT3013-01 Dose Optimization Part - FL 1-3A Cohort - Safety Analysis Set

Anatomical Therapeutic Chemical (ATC) Level 2 Generic Name	Arm A (N=86)	Arm B (N=6)	Overall (N=92)
Dupilumab	1 (1.2%)	0	1 (1.1%)
Fenoterol hydrobromide;ipratropium bromide	1 (1.2%)	0	1 (1.1%)
Ipratropium bromide monohydrate;salbutamol sulfate	1 (1.2%)	0	1 (1.1%)
Ipratropium bromide;salbutamol	1 (1.2%)	0	1 (1.1%)
Ipratropium bromide;salbutamol sulfate	1 (1.2%)	0	1 (1.1%)
Ipratropium;salbutamol	1 (1.2%)	0	1 (1.1%)
Montelukast	1 (1.2%)	0	1 (1.1%)
Olodaterol hydrochloride;tiotropium bromide monohydrate	1 (1.2%)	0	1 (1.1%)
Terbutaline sulfate	1 (1.2%)	0	1 (1.1%)
Psychoanaleptics	13 (15.1%)	0	13 (14.1%)
Citalopram	2 (2.3%)	0	2 (2.2%)
Duloxetine	2 (2.3%)	0	2 (2.2%)
Escitalopram	2 (2.3%)	0	2 (2.2%)
Sertraline	2 (2.3%)	0	2 (2.2%)

Arm A: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 3mg
Arm B: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 6mg
Note: Percentages calculated based on number of subjects in Safety Analysis Set.
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Concomitant Medications
GCT3013-01 Dose Optimization Part - FL 1-3A Cohort - Safety Analysis Set

Anatomical Therapeutic Chemical (ATC) Level 2 Generic Name	Arm A (N=86)	Arm B (N=6)	Overall (N=92)
Amitriptyline	1 (1.2%)	0	1 (1.1%)
Escitalopram oxalate	1 (1.2%)	0	1 (1.1%)
Fluoxetine	1 (1.2%)	0	1 (1.1%)
Mirtazapine	1 (1.2%)	0	1 (1.1%)
Paroxetine	1 (1.2%)	0	1 (1.1%)
Trazodone	1 (1.2%)	0	1 (1.1%)
Immunosuppressants	11 (12.8%)	0	11 (12.0%)
Tocilizumab	11 (12.8%)	0	11 (12.0%)
Urologicals	11 (12.8%)	0	11 (12.0%)
Tamsulosin	3 (3.5%)	0	3 (3.3%)
Alfuzosin	2 (2.3%)	0	2 (2.2%)
Finasteride	2 (2.3%)	0	2 (2.2%)
Tadalafil	2 (2.3%)	0	2 (2.2%)

Arm A: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 3mg
Arm B: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 6mg
Note: Percentages calculated based on number of subjects in Safety Analysis Set.
Note: Concomitant medications are the medications other than trial drug that are taken during on-treatment period.

Concomitant Medications
GCT3013-01 Dose Optimization Part - FL 1-3A Cohort - Safety Analysis Set

Anatomical Therapeutic Chemical (ATC) Level 2 Generic Name	Arm A (N=86)	Arm B (N=6)	Overall (N=92)
Alfuzosin hydrochloride	1 (1.2%)	0	1 (1.1%)
Dutasteride	1 (1.2%)	0	1 (1.1%)
Dutasteride;tamsulosin hydrochloride	1 (1.2%)	0	1 (1.1%)
Herbal drugs used in benign prostatic hypertrophy	1 (1.2%)	0	1 (1.1%)
Tamsulosin hydrochloride	1 (1.2%)	0	1 (1.1%)
Antidiarrheals, intestinal antiinflammatory/antiinfective agents	8 (9.3%)	2 (33.3%)	10 (10.9%)
Diosmectite	2 (2.3%)	1 (16.7%)	3 (3.3%)
Racecadotril	2 (2.3%)	1 (16.7%)	3 (3.3%)
Lactobacillus acidophilus	2 (2.3%)	0	2 (2.2%)
Loperamide	2 (2.3%)	0	2 (2.2%)
Bifidobacterium lactis;colostrum;fructooligosaccharides;lactobacillus acidophilus	1 (1.2%)	0	1 (1.1%)
Lactobacillus fermentum	1 (1.2%)	0	1 (1.1%)
Loperamide hydrochloride	0	1 (16.7%)	1 (1.1%)

Arm A: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 3mg
Arm B: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 6mg
Note: Percentages calculated based on number of subjects in Safety Analysis Set.
Note: Concomitant medications are the medications other than trial drug that are taken during on-treatment period.

Concomitant Medications
GCT3013-01 Dose Optimization Part - FL 1-3A Cohort - Safety Analysis Set

Anatomical Therapeutic Chemical (ATC) Level 2 Generic Name	Arm A (N=86)	Arm B (N=6)	Overall (N=92)
Rifaximin	1 (1.2%)	0	1 (1.1%)
Cough and cold preparations	9 (10.5%)	1 (16.7%)	10 (10.9%)
Dextromethorphan hydrobromide;guaifenesin	2 (2.3%)	1 (16.7%)	3 (3.3%)
Acetylcysteine	1 (1.2%)	0	1 (1.1%)
Ambroxol hydrochloride	1 (1.2%)	0	1 (1.1%)
Benzonatate	0	1 (16.7%)	1 (1.1%)
Carbocisteine	1 (1.2%)	0	1 (1.1%)
Codeine	1 (1.2%)	0	1 (1.1%)
Codeine phosphate	1 (1.2%)	0	1 (1.1%)
Dextromethorphan;guaifenesin	0	1 (16.7%)	1 (1.1%)
Dihydrocodeine bitartrate	1 (1.2%)	0	1 (1.1%)
Dihydrocodeine bitartrate;drosera rotundifolia extract;guaifenesin;nicotinamide;thymus vulgaris extract	1 (1.2%)	0	1 (1.1%)
Ocimum tenuiflorum	1 (1.2%)	0	1 (1.1%)

Arm A: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 3mg
Arm B: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 6mg
Note: Percentages calculated based on number of subjects in Safety Analysis Set.
Note: Concomitant medications are the medications other than trial drug that are taken during on-treatment period.

Concomitant Medications
GCT3013-01 Dose Optimization Part - FL 1-3A Cohort - Safety Analysis Set

Anatomical Therapeutic Chemical (ATC) Level 2 Generic Name	Arm A (N=86)	Arm B (N=6)	Overall (N=92)
Drugs for functional gastrointestinal disorders	9 (10.5%)	0	9 (9.8%)
Hyoscine butylbromide	3 (3.5%)	0	3 (3.3%)
Metoclopramide hydrochloride	3 (3.5%)	0	3 (3.3%)
Itopride hydrochloride	1 (1.2%)	0	1 (1.1%)
Mebeverine hydrochloride	1 (1.2%)	0	1 (1.1%)
Phloroglucinol	1 (1.2%)	0	1 (1.1%)
Simeticone	1 (1.2%)	0	1 (1.1%)
Drugs used in diabetes	8 (9.3%)	1 (16.7%)	9 (9.8%)
Metformin	6 (7.0%)	0	6 (6.5%)
Gliclazide	5 (5.8%)	0	5 (5.4%)
Insulin aspart	2 (2.3%)	0	2 (2.2%)
Dapagliflozin propanediol monohydrate	1 (1.2%)	0	1 (1.1%)
Empagliflozin;metformin	1 (1.2%)	0	1 (1.1%)
Insulin	1 (1.2%)	0	1 (1.1%)

Arm A: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 3mg
Arm B: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 6mg
Note: Percentages calculated based on number of subjects in Safety Analysis Set.
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Concomitant Medications
GCT3013-01 Dose Optimization Part - FL 1-3A Cohort - Safety Analysis Set

Anatomical Therapeutic Chemical (ATC) Level 2 Generic Name	Arm A (N=86)	Arm B (N=6)	Overall (N=92)
Insulin detemir	0	1 (16.7%)	1 (1.1%)
Insulin glargine	1 (1.2%)	0	1 (1.1%)
Insulin human injection, isophane	1 (1.2%)	0	1 (1.1%)
Sitagliptin	1 (1.2%)	0	1 (1.1%)
Stomatological preparations	7 (8.1%)	2 (33.3%)	9 (9.8%)
Nystatin	2 (2.3%)	0	2 (2.2%)
Sodium fluoride	1 (1.2%)	1 (16.7%)	2 (2.2%)
Aloe vera;glycyrrhizic acid;hyaluronic acid	1 (1.2%)	0	1 (1.1%)
Benzydamine hydrochloride	1 (1.2%)	0	1 (1.1%)
Chlorhexidine	1 (1.2%)	0	1 (1.1%)
Hyaluronate sodium;povidone;syringa vulgaris	1 (1.2%)	0	1 (1.1%)
Other agents for local oral treatment	1 (1.2%)	0	1 (1.1%)
Phenol	0	1 (16.7%)	1 (1.1%)

Arm A: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 3mg
Arm B: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 6mg
Note: Percentages calculated based on number of subjects in Safety Analysis Set.
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Concomitant Medications
GCT3013-01 Dose Optimization Part - FL 1-3A Cohort - Safety Analysis Set

Anatomical Therapeutic Chemical (ATC) Level 2 Generic Name	Arm A (N=86)	Arm B (N=6)	Overall (N=92)
Sodium bicarbonate	1 (1.2%)	0	1 (1.1%)
Vaccines	8 (9.3%)	1 (16.7%)	9 (9.8%)
Tozinameran	4 (4.7%)	0	4 (4.3%)
Influenza vaccine inact split 4v	3 (3.5%)	0	3 (3.3%)
Covid-19 vaccine	1 (1.2%)	0	1 (1.1%)
Elasomeran	1 (1.2%)	0	1 (1.1%)
Influenza vaccine	1 (1.2%)	0	1 (1.1%)
Pneumococcal vaccine conj 13v (crm197)	1 (1.2%)	0	1 (1.1%)
Pneumococcal vaccine polysacch 23v	1 (1.2%)	0	1 (1.1%)
Rsv vaccine	1 (1.2%)	0	1 (1.1%)
Varicella zoster vaccine rge (cho)	0	1 (16.7%)	1 (1.1%)
Anesthetics	7 (8.1%)	1 (16.7%)	8 (8.7%)
Lidocaine	4 (4.7%)	1 (16.7%)	5 (5.4%)

Arm A: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 3mg
Arm B: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 6mg
Note: Percentages calculated based on number of subjects in Safety Analysis Set.
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Concomitant Medications
GCT3013-01 Dose Optimization Part - FL 1-3A Cohort - Safety Analysis Set

Anatomical Therapeutic Chemical (ATC) Level 2 Generic Name	Arm A (N=86)	Arm B (N=6)	Overall (N=92)
Fentanyl	3 (3.5%)	0	3 (3.3%)
Anesthetics	1 (1.2%)	0	1 (1.1%)
Fentanyl citrate	1 (1.2%)	0	1 (1.1%)
Lidocaine hydrochloride	1 (1.2%)	0	1 (1.1%)
Lidocaine;prilocaine	1 (1.2%)	0	1 (1.1%)
Thyroid therapy	6 (7.0%)	2 (33.3%)	8 (8.7%)
Levothyroxine sodium	2 (2.3%)	2 (33.3%)	4 (4.3%)
Levothyroxine	3 (3.5%)	0	3 (3.3%)
Carbimazole	1 (1.2%)	0	1 (1.1%)
Calcium channel blockers	7 (8.1%)	0	7 (7.6%)
Amlodipine	5 (5.8%)	0	5 (5.4%)
Verapamil	2 (2.3%)	0	2 (2.2%)

Arm A: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 3mg
Arm B: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 6mg
Note: Percentages calculated based on number of subjects in Safety Analysis Set.
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Concomitant Medications
GCT3013-01 Dose Optimization Part - FL 1-3A Cohort - Safety Analysis Set

Anatomical Therapeutic Chemical (ATC) Level 2 Generic Name	Arm A (N=86)	Arm B (N=6)	Overall (N=92)
Amlodipine besilate	1 (1.2%)	0	1 (1.1%)
Cardiac therapy	6 (7.0%)	1 (16.7%)	7 (7.6%)
Amiodarone	2 (2.3%)	0	2 (2.2%)
Flecainide	2 (2.3%)	0	2 (2.2%)
Digoxin	1 (1.2%)	0	1 (1.1%)
Epinephrine	0	1 (16.7%)	1 (1.1%)
Glyceryl trinitrate	1 (1.2%)	0	1 (1.1%)
Norepinephrine	0	1 (16.7%)	1 (1.1%)
Procainamide	0	1 (16.7%)	1 (1.1%)
Ophthalmologicals	7 (8.1%)	0	7 (7.6%)
Dexamethasone;tobramycin	1 (1.2%)	0	1 (1.1%)
Dextran 70;hypromellose	1 (1.2%)	0	1 (1.1%)
Hyaluronate sodium	1 (1.2%)	0	1 (1.1%)

Arm A: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 3mg
Arm B: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 6mg
Note: Percentages calculated based on number of subjects in Safety Analysis Set.
Note: Concomitant medications are the medications other than trial drug that are taken during on-treatment period.

Concomitant Medications
GCT3013-01 Dose Optimization Part - FL 1-3A Cohort - Safety Analysis Set

Anatomical Therapeutic Chemical (ATC) Level 2 Generic Name	Arm A (N=86)	Arm B (N=6)	Overall (N=92)
Hypromellose	1 (1.2%)	0	1 (1.1%)
Latanoprost;timolol maleate	1 (1.2%)	0	1 (1.1%)
Macrogol 400;propylene glycol	1 (1.2%)	0	1 (1.1%)
Neomycin	1 (1.2%)	0	1 (1.1%)
Timolol maleate	1 (1.2%)	0	1 (1.1%)
Other alimentary tract and metabolism products	6 (7.0%)	1 (16.7%)	7 (7.6%)
Potassium phosphate dibasic;sodium phosphate	3 (3.5%)	0	3 (3.3%)
Sodium bicarbonate	1 (1.2%)	1 (16.7%)	2 (2.2%)
Acetylcysteine	1 (1.2%)	0	1 (1.1%)
Lysine	1 (1.2%)	0	1 (1.1%)
Sex hormones and modulators of the genital system	5 (5.8%)	0	5 (5.4%)
Estradiol	2 (2.3%)	0	2 (2.2%)
Dydrogesterone;estradiol	1 (1.2%)	0	1 (1.1%)

Arm A: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 3mg
Arm B: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 6mg
Note: Percentages calculated based on number of subjects in Safety Analysis Set.
Note: Concomitant medications are the medications other than trial drug that are taken during on-treatment period.

Concomitant Medications
GCT3013-01 Dose Optimization Part - FL 1-3A Cohort - Safety Analysis Set

Anatomical Therapeutic Chemical (ATC) Level 2 Generic Name	Arm A (N=86)	Arm B (N=6)	Overall (N=92)
Testosterone cipionate	1 (1.2%)	0	1 (1.1%)
Tibolone	1 (1.2%)	0	1 (1.1%)
Emollients and protectives	3 (3.5%)	0	3 (3.3%)
Cetomacrogol	1 (1.2%)	0	1 (1.1%)
Other emollients and protectives	1 (1.2%)	0	1 (1.1%)
Propylene glycol	1 (1.2%)	0	1 (1.1%)
Other dermatological preparations	3 (3.5%)	0	3 (3.3%)
Ibuprofen	1 (1.2%)	0	1 (1.1%)
Salicylic acid	1 (1.2%)	0	1 (1.1%)
Tacrolimus	1 (1.2%)	0	1 (1.1%)
Anti-acne preparations	2 (2.3%)	0	2 (2.2%)

Arm A: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 3mg
Arm B: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 6mg
Note: Percentages calculated based on number of subjects in Safety Analysis Set.
Note: Concomitant medications are the medications other than trial drug that are taken during on-treatment period.

Concomitant Medications
GCT3013-01 Dose Optimization Part - FL 1-3A Cohort - Safety Analysis Set

Anatomical Therapeutic Chemical (ATC) Level 2 Generic Name	Arm A (N=86)	Arm B (N=6)	Overall (N=92)
Clindamycin	2 (2.3%)	0	2 (2.2%)
Anti-parkinson drugs	2 (2.3%)	0	2 (2.2%)
Benserazide hydrochloride;levodopa	1 (1.2%)	0	1 (1.1%)
Benzatropine	1 (1.2%)	0	1 (1.1%)
Antibiotics and chemotherapeutics for dermatological use	2 (2.3%)	0	2 (2.2%)
Antibiotics	1 (1.2%)	0	1 (1.1%)
Mupirocin	1 (1.2%)	0	1 (1.1%)
Antipruritics, incl. antihistamines, anesthetics, etc.	2 (2.3%)	0	2 (2.2%)
Diphenhydramine hydrochloride	1 (1.2%)	0	1 (1.1%)
Lidocaine hydrochloride	1 (1.2%)	0	1 (1.1%)

Arm A: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 3mg
Arm B: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 6mg
Note: Percentages calculated based on number of subjects in Safety Analysis Set.
Note: Concomitant medications are the medications other than trial drug that are taken during on-treatment period.

Concomitant Medications
GCT3013-01 Dose Optimization Part - FL 1-3A Cohort - Safety Analysis Set

Anatomical Therapeutic Chemical (ATC) Level 2 Generic Name	Arm A (N=86)	Arm B (N=6)	Overall (N=92)
Bile and liver therapy	2 (2.3%)	0	2 (2.2%)
Ursodeoxycholic acid	2 (2.3%)	0	2 (2.2%)
Silybum marianum	1 (1.2%)	0	1 (1.1%)
Contrast media	2 (2.3%)	0	2 (2.2%)
Barium sulfate	1 (1.2%)	0	1 (1.1%)
Gadobutrol	1 (1.2%)	0	1 (1.1%)
Iohexol	1 (1.2%)	0	1 (1.1%)
Iopamidol	1 (1.2%)	0	1 (1.1%)
Drugs for treatment of bone diseases	2 (2.3%)	0	2 (2.2%)
Denosumab	1 (1.2%)	0	1 (1.1%)
Risedronate sodium	1 (1.2%)	0	1 (1.1%)

Arm A: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 3mg
Arm B: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 6mg
Note: Percentages calculated based on number of subjects in Safety Analysis Set.
Note: Concomitant medications are the medications other than trial drug that are taken during on-treatment period.

Concomitant Medications
GCT3013-01 Dose Optimization Part - FL 1-3A Cohort - Safety Analysis Set

Anatomical Therapeutic Chemical (ATC) Level 2 Generic Name	Arm A (N=86)	Arm B (N=6)	Overall (N=92)
Muscle relaxants	2 (2.3%)	0	2 (2.2%)
Baclofen	1 (1.2%)	0	1 (1.1%)
Cyclobenzaprine	1 (1.2%)	0	1 (1.1%)
Nasal preparations	1 (1.2%)	1 (16.7%)	2 (2.2%)
Cetirizine hydrochloride;pseudoephedrine hydrochloride	1 (1.2%)	0	1 (1.1%)
Fluticasone propionate	0	1 (16.7%)	1 (1.1%)
Unspecified herbal and traditional medicine	2 (2.3%)	0	2 (2.2%)
Plantago major	1 (1.2%)	0	1 (1.1%)
Plantago spp. seed husk	1 (1.2%)	0	1 (1.1%)
Vasoprotectives	1 (1.2%)	1 (16.7%)	2 (2.2%)
Chondrus crispus;lidocaine;titanium dioxide;zinc oxide	0	1 (16.7%)	1 (1.1%)
Diosmin;hesperidin	0	1 (16.7%)	1 (1.1%)

Arm A: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 3mg
Arm B: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 6mg
Note: Percentages calculated based on number of subjects in Safety Analysis Set.
Note: Concomitant medications are the medications other than trial drug that are taken during on-treatment period.

Concomitant Medications
GCT3013-01 Dose Optimization Part - FL 1-3A Cohort - Safety Analysis Set

Anatomical Therapeutic Chemical (ATC) Level 2 Generic Name	Arm A (N=86)	Arm B (N=6)	Overall (N=92)
Other agents for treatment of hemorrhoids and anal fissures for topical use	1 (1.2%)	0	1 (1.1%)
Antifungals for dermatological use	1 (1.2%)	0	1 (1.1%)
Miconazole	1 (1.2%)	0	1 (1.1%)
Antihemorrhagics	1 (1.2%)	0	1 (1.1%)
Phytomenadione	1 (1.2%)	0	1 (1.1%)
Antimycobacterials	1 (1.2%)	0	1 (1.1%)
Clofazimine	1 (1.2%)	0	1 (1.1%)
Antipsoriatics	0	1 (16.7%)	1 (1.1%)
Betamethasone dipropionate;calcipotriol	0	1 (16.7%)	1 (1.1%)

Arm A: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 3mg
Arm B: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 6mg
Note: Percentages calculated based on number of subjects in Safety Analysis Set.
Note: Concomitant medications are the medications other than trial drug that are taken during on-treatment period.

Concomitant Medications
GCT3013-01 Dose Optimization Part - FL 1-3A Cohort - Safety Analysis Set

Anatomical Therapeutic Chemical (ATC) Level 2 Generic Name	Arm A (N=86)	Arm B (N=6)	Overall (N=92)
Appetite stimulants	1 (1.2%)	0	1 (1.1%)
Megestrol	1 (1.2%)	0	1 (1.1%)
Diagnostic radiopharmaceuticals	1 (1.2%)	0	1 (1.1%)
Fludeoxyglucose (18f)	1 (1.2%)	0	1 (1.1%)
General nutrients	1 (1.2%)	0	1 (1.1%)
Ascorbic acid;biotin;carbohydrates nos;chloride;choline;chromium;copper;folic acid;iodine;iron;manganese;molybdenum;nicotinic acid;pantothenic acid;phosphorus;proteins nos;pyridoxine hydrochloride;retinol;riboflavin;selenium;sodium;vitamin b1 nos;vitamin b12 nos;vitamin d nos;vitamin e nos;vitamin k nos;zinc	1 (1.2%)	0	1 (1.1%)
Otologicals	1 (1.2%)	0	1 (1.1%)
Ciprofloxacin;hydrocortisone	1 (1.2%)	0	1 (1.1%)
Pituitary and hypothalamic hormones and analogues	1 (1.2%)	0	1 (1.1%)
Desmopressin	1 (1.2%)	0	1 (1.1%)

Arm A: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 3mg
Arm B: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 6mg
Note: Percentages calculated based on number of subjects in Safety Analysis Set.
Note: Concomitant medications are the medications other than trial drug that are taken during on-treatment period.

Concomitant Medications
GCT3013-01 Dose Optimization Part - FL 1-3A Cohort - Safety Analysis Set

Anatomical Therapeutic Chemical (ATC) Level 2 Generic Name	Arm A (N=86)	Arm B (N=6)	Overall (N=92)
Preparations for treatment of wounds and ulcers	1 (1.2%)	0	1 (1.1%)
Copper gluconate;hyaluronate sodium;madecassoside;manganese gluconate;zinc gluconate	1 (1.2%)	0	1 (1.1%)
Topical products for joint and muscular pain	1 (1.2%)	0	1 (1.1%)
Diclofenac	1 (1.2%)	0	1 (1.1%)
Uncoded	3 (3.5%)	0	3 (3.3%)
Uncoded (augmentin)	2 (2.3%)	0	2 (2.2%)
Uncoded (midazolam)	1 (1.2%)	0	1 (1.1%)
Uncoded (prednisone)	1 (1.2%)	0	1 (1.1%)

Arm A: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 3mg
Arm B: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 6mg
Note: Percentages calculated based on number of subjects in Safety Analysis Set.
Note: Concomitant medications are the medications other than trial drug that are taken during on-treatment period.

Demografische Charakterisierung der Studienpopulationen (Dosis-Expansionskohorte) – weitere Untersuchungen

Merkmal	**GCT3013-01 FL (N = 128)**
Alter (Jahre)	
MW (STD)	63,2 (11,20)
Median (min., max.)	65,0 (39; 84)
Alter, n (%)	
< 65 Jahre	61 (47,7)
65 – < 75 Jahre	50 (39,1)
≥ 75 Jahre	17 (13,3)
Geschlecht, n (%)	
Männlich	79 (61,7)
Weiblich	49 (38,3)
Abstammung, n (%)	
Kaukasisch	77 (60,2)
Asiatisch	7 (5,5)
Andere	2 (1,6)
Nicht dokumentiert	42 (32,8)
ECOG-PS, n (%)	
0	70 (54,7)
1	51 (39,8)
2	7 (5,5)
Nierenfunktion (in CrCl), n (%)	
Normal (≥ 90)	52 (40,6)
Geringfügig beeinträchtigt (60 – < 90)	54 (42,2)
Mäßig beeinträchtigt (30 – < 60)	22 (17,2)
Leberfunktion gemäß NCI-Kriterien, n (%)	
Normal	107 (83,6)
Leichte Dysfunktion	21 (16,4)
Moderate Dysfunktion	0 (0,0)

Dargestellt ist der Datenschnitt vom 21. April 2023.

CrCl: Kreatinin-Clearance; ECOG-PS: Eastern Cooperative Oncology Group Performance Status; FL: Follikuläres Lymphom; MW: Mittelwert; N: Patienten in der Studie; n: Patienten mit Ereignis; NCI: National Cancer Institute; STD: Standardabweichung

Krankheitsspezifische Charakteristika der Studienpopulationen (Dosis-Expansionskohorte) – weitere Untersuchungen

Merkmal	**GCT3013-01 FL (N = 128)**
Krankheitstyp zu Studieneintritt, n (%)	
FL Grad 1-3A	127 (99,2)
DLBCL[a]	1 (0,8)
Histologischer Krankheitsgrad, n (%)	
1	16 (12,5)
2	70 (54,7)
3A	41 (32,0)
Nicht anwendbar	1 (0,8)
Jahre seit der Erstdiagnose	
MW (STD)	8,1 (6,73)
Median (min., max.)	5,8 (0,6; 35,0)
Stadien nach Ann Arbor, n (%)	
I	4 (3,1)
IE	1 (0,8)
II	14 (10,9)
IIE	0 (0,0)
III	30 (23,4)
IIIE	1 (0,8)
IIIS	1 (0,8)
IIIE, S	0 (0,0)
IV	77 (60,2)
FLIPI, n (%)	
0 – 1	17 (13,3)
2	31 (24,2)
≥ 3	78 (60,9)
Unbekannt	1 (0,8)
Nicht anwendbar	1 (0,8)
B-Symptomatik, n (%)	
B-Symptome	16 (12,5)
Nachtschweiß	13 (10,2)
Gewichtsverlust[b]	6 (4,7)
Fieber	0 (0,0)
Extreme Erschöpfung	3 (2,3)
Bulky Disease nach IRC, n (%)	
≤ 7 cm	113 (88,3)
> 7 cm	15 (11,7)

Merkmal	**GCT3013-01 FL (N = 128)**
≤ 6 cm	95 (74,2)
> 6 cm	33 (25,8)
POD24-Status, n (%)	
Progress innerhalb 24 Monate nach Initiierung der Erstlinien Immunchemotherapie	
Ja	54 (42,2)
Nein	74 (57,8)
Progress innerhalb 24 Monate nach beliebiger Erstlinientherapie	
Ja	67 (52,3)
Nein	61 (47,7)
Progress innerhalb 24 Monate nach der ersten Anwendung einer Immunchemotherapie, unabhängig von der Therapielinie	
Ja	66 (51,6)
Nein	62 (48,4)
Doppelt refraktär-Status, n (%)	
Doppelt refraktär auf anti-CD20 und Alkylierungsmittel enthaltende Wirkstoffe, unabhängig davon, ob beide Vorbehandlungen in derselben oder unterschiedlichen Therapielinien liegen	
Ja	90 (70,3)
Nein	38 (29,7)
Doppelt refraktär auf anti-CD20 und Alkylierungsmittel enthaltende Wirkstoffe, mit beiden Vorbehandlungen in unterschiedlichen Therapielinien	
Ja	13 (10,2)
Nein	115 (89,8)
Patienten mit primärer refraktärer Erkrankung, n (%)	69 (53,9)
Patienten, die refraktär gegenüber ≥ 2 aufeinanderfolgenden Antilymphomtherapien sind n (%)	70 (54,7)
Letzte systemische antineoplastische Therapie, n (%)	
Refraktär[c]	88 (68,8)
Kein Ansprechen	48 (37,5)
Rezidiv innerhalb von 6 Monaten nach Therapieabschluss	40 (31,3)
Rezidiv[d]	40 (31,3)

Merkmal	GCT3013-01 FL (N = 128)
Dargestellt ist der Datenschnitt vom 21. April 2023. a: Patient wurde zu Zyklus 1 Tag 1 behandelt ohne Ergebnis der Screening-Biopsie abzuwarten. b: > 10 % über die letzten sechs Monate c: Patienten gelten als refraktär, wenn innerhalb von sechs Monaten nach Abschluss der Therapie ein Fortschreiten der Erkrankungen auftritt oder eine stabile Erkrankung als bestes Ansprechen bestimmt wurde. d: Ein Rückfall liegt vor, wenn nach mehr als sechs Monaten nach Abschluss der Therapie ein Fortschreiten der Erkrankung auftritt. CD: Cluster of Differentiation; DLBCL: Diffuses großzelliges B-Zell-Lymphom; E: Extranodal; FL: Follikuläres Lymphom; FLIPI: Follicular Lymphoma International Prognostic Index; IRC: Unabhängiges Review Komitee; MW: Mittelwert; N: Patienten in der Studie; n: Patienten mit Ereignis; POD24: Progression of Disease within 2 years; S: Milz; STD: Standardabweichung	

Behandlungsspezifische Charakteristika der Studienpopulationen (Dosis-Expansionskohorte) – weitere Untersuchungen

Merkmal	**GCT3013-01 FL (N = 128)**
Patienten mit vorheriger systemischer Antilymphomtherapie, n (%)	128 (100)
Patienten mit vorheriger Strahlentherapie, n (%)	33 (25,8)
Patienten mit vorheriger Operation[a], n (%)	13 (10,2)
Patienten mit vorheriger SZT, n (%)	24 (18,8)
autoSZT	24 (18,8)
Rezidiv (≤ 12 Monate nach autoSZT)	10 (7,8)
alloSZT	0 (0,0)
Vorherige systematische Therapien, n (%)	
Anti-CD20	128 (100)
Anti-CD19	2 (1,6)
Alkylierungsmittel enthaltende Wirkstoffe	128 (100)
Anthrazykline	99 (77,3)
Nukleotide	62 (48,4)
Topo-Inhibitoren	46 (35,9)
PI3K-Inhibitoren	29 (22,7)
BCL2-Inhibitoren	1 (0,8)
Polatuzumab-Vedotin	3 (2,3)
CAR-T-Zelltherapie	6 (4,7)
Andere	121 (94,5)
Anzahl vorheriger Antilymphomtherapien	
MW (STD)	3,3 (1,59)
Median (min., max.)	3,0 (2; 9)
1, n (%)	0 (0,0)
2, n (%)	47 (36,7)
3, n (%)	41 (32,0)
≥ 4, n (%)	40 (31,3)
Monate seit der letzten Antilymphomtherapie	
MW (STD)	12,1 (16,81)
Median (min., max.)	5,2 (1; 105)

Dargestellt ist der Datenschnitt vom 21. April 2023.

a: Chirurgische Eingriffe im Zusammenhang mit FL

allo: Allogen; auto: Autolog; BCL2: B-Zell-Lymphom 2; CAR: Chimärer Antigenrezeptor; CD: Cluster of Differentiation; FL: Follikuläres Lymphom; MW: Mittelwert; N: Patienten in der Studie; n: Patienten mit Ereignis; PI3K: Phosphoinosid-3-Kinase; STD: Standardabweichung; SZT: Stammzelltransplantation; Topo: Topoisomerase

Disposition der Studienpopulationen (Dosis-Expansionskohorte) – weitere Untersuchungen

	GCT3013-01 FL (N = 128) n (%)
Begonnene Epcoritamab-Zyklen	
MW (STD)	10,4 (7,72)
Median (min., max)	8 (1; 33)
Behandlungsdauer (Monate)	
MW (STD)	9,7 (7,3)
Median (min., max.)	8,312 (0,03; 29,96)
Noch in Behandlung	47 (36,7)
Therapie abgebrochen	81 (63,3)
Primärer Grund für den Therapieabbruch	
Krankheitsprogression[a]	44 (34,4)
Klinische Progression	2 (1,6)
Krankheitsprogression gemäß Ansprechkriterien	42 (32,8)
UE	24 (18,8)
Tod	0 (0,0)
Abbruch auf Wunsch des Patienten	3 (2,3)
Entscheidung für eine Transplantation	4 (3,1)
Andere	6 (4,7)
Noch in der Studie	89 (69,5)
Studie abgebrochen	39 (30,5)
Primärer Grund für den Studienabbruch	
Tod	34 (26,6)
Lost-to-follow-up	1 (0,8)
Rücknahme der Einwilligung zur Studienteilnahme durch den Patienten	4 (3,1)

Dargestellt ist der Datenschnitt vom 21. April 2023.

a: Die Krankheitsprogression beinhaltet sowohl die klinische Progression als auch Progression dokumentiert durch Röntgenaufnahmen.

FL: Follikuläres Lymphom; N: Patienten in der Studie; n: Patienten mit Ereignis; MW: Mittelwert; STD: Standardabweichung; UE: Unerwünschtes Ereignis

Folgetherapien der Studienpopulationen (Dosis-Expansionskohorte) – weitere Untersuchungen

	GCT3013-01 FL (N = 128) n (%)
Folgetherapien, n (%)	
Patienten mit Folgetherapien	38 (29,7)
Patienten mit nachfolgender Strahlentherapie	2 (1,6)
Patienten mit nachfolgender SZT	6 (4,7)
alloSZT	0 (0,0)
autoSZT	5 (3,9)
Patienten mit nachfolgender CAR-T-Zelltherapie	8 (6,3)
Patienten mit nachfolgender systemischer Arzneimitteltherapie	30 (23,4)

Dargestellt ist der Datenschnitt vom 21. April 2023.

allo: Allogen; auto: Autolog; CAR: Chimärer Antigenrezeptor; FL: Follikuläres Lymphom; N: Patienten in der Studie; n: Patienten mit Ereignis; SZT: Stammzelltransplantation

Ergebnisse für unerwünschte Ereignisse nach SOC und PT, die zum Therapieabbruch führten, aus weiteren Untersuchungen mit dem zu bewertenden Arzneimittel (SAF)

Ereignis	**GCT3013-01 FL (N = 86) n (%)**
Gesamt	3 (3,5)
Erkrankungen der Atemwege, des Brustraums und Mediastinums	2 (2,3)
Pneumonitis	2 (2,3)
Infektionen und parasitäre Erkrankungen	1 (1,2)
Bronchopulmonale Aspergillose	1 (1,2)

Dargestellt ist der Datenschnitt vom 08. Januar 2024.
FL: Follikuläres Lymphom; N: Patienten in der Studie; n: Patienten mit Ereignis; PT: Preferred Term; SAF: Safety Analysis Set; SOC: System Organ Class; UE: Unerwünschtes Ereignis

Overview of Treatment-Emergent Adverse Events (TEAEs) by Analysis Period
GCT3013-01 Dose Optimization Part - FL 1-3A Cohort - Safety Analysis Set

Arm A (N=86)

	Analysis period				
	Week ≤ 8 (N=86)	> Week 8 to ≤12 (N=72)	> Week 12 to ≤24 (N=60)	> Week 24 to ≤36 (N=32)	> Week 36 (N=11)
Number of Subjects with at least one					
TEAE	84 (97.7%)	37 (51.4%)	48 (80.0%)	20 (62.5%)	7 (63.6%)
Related TEAE	74 (86.0%)	22 (30.6%)	27 (45.0%)	8 (25.0%)	2 (18.2%)
Grade 3 and higher TEAE	33 (38.4%)	7 (9.7%)	10 (16.7%)	3 (9.4%)	1 (9.1%)
Grade 3 and higher related TEAE	19 (22.1%)	4 (5.6%)	6 (10.0%)	3 (9.4%)	0
TEAE by worst toxicity grade					
1	18 (20.9%)	20 (27.8%)	24 (40.0%)	7 (21.9%)	5 (45.5%)
2	33 (38.4%)	10 (13.9%)	14 (23.3%)	10 (31.3%)	1 (9.1%)
3	25 (29.1%)	4 (5.6%)	7 (11.7%)	2 (6.3%)	1 (9.1%)
4	8 (9.3%)	3 (4.2%)	3 (5.0%)	1 (3.1%)	0
5	0	0	0	0	0
Serious TEAE	32 (37.2%)	2 (2.8%)	3 (5.0%)	3 (9.4%)	1 (9.1%)
Serious Related TEAE	29 (33.7%)	0	0	2 (6.3%)	0

Arm A: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 3mg
Arm B: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 6mg
Note: Percentages calculated based on number of subjects treated or having TEAE reported in the analysis period.
Note: Adverse events are classified using MedDRA v26.1 and CTCAE v5.0, and are counted only once per category. ICANS is graded according to Lee et al 2019, CRS as per Lee et al 2019, and CTLS according to Cairo-Bishop (Coiffier et al 2008).
CRS = Cytokine Release Syndrome; ICANS = Immune Effector Cell-Associated Neurotoxicity Syndrome; CTLS = Clinical Tumor Lysis Syndrome

Overview of Treatment-Emergent Adverse Events (TEAEs) by Analysis Period
GCT3013-01 Dose Optimization Part - FL 1-3A Cohort - Safety Analysis Set

Arm A (N=86)

	Analysis period				
	Week ≤ 8 (N=86)	> Week 8 to ≤12 (N=72)	> Week 12 to ≤24 (N=60)	> Week 24 to ≤36 (N=32)	> Week 36 (N=11)
TEAE leading to treatment discontinuation	2 (2.3%)	1 (1.4%)	0	0	0
TEAE leading to dose delay	36 (41.9%)	7 (9.7%)	14 (23.3%)	8 (25.0%)	3 (27.3%)
Fatal TEAE	0	0	0	0	0
Fatal related TEAE	0	0	0	0	0
AESI					
CRS	42 (48.8%)	0	0	0	0
ICANS	0	0	0	0	0
CTLS	0	0	0	0	0

Arm A: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 3mg
Arm B: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 6mg
Note: Percentages calculated based on number of subjects treated or having TEAE reported in the analysis period.
Note: Adverse events are classified using MedDRA v26.1 and CTCAE v5.0, and are counted only once per category. ICANS is graded according to Lee et al 2019, CRS as per Lee et al 2019, and CTLS according to Cairo-Bishop (Coiffier et al 2008).
CRS = Cytokine Release Syndrome; ICANS = Immune Effector Cell-Associated Neurotoxicity Syndrome; CTLS = Clinical Tumor Lysis Syndrome

Overview of Treatment-Emergent Adverse Events (TEAEs) by Analysis Period
GCT3013-01 Dose Optimization Part - FL 1-3A Cohort - Safety Analysis Set

Arm B (N=6)

	Analysis period				
	Week ≤ 8 (N=6)	> Week 8 to ≤12 (N=6)	> Week 12 to ≤24 (N=6)	> Week 12 to ≤36 (N=5)	> Week 36 (N=5)
Number of Subjects with at least one					
TEAE	6 (100%)	2 (33.3%)	5 (83.3%)	4 (80.0%)	2 (40.0%)
Related TEAE	5 (83.3%)	1 (16.7%)	3 (50.0%)	1 (20.0%)	1 (20.0%)
Grade 3 and higher TEAE	1 (16.7%)	0	2 (33.3%)	1 (20.0%)	1 (20.0%)
Grade 3 and higher related TEAE	1 (16.7%)	0	1 (16.7%)	1 (20.0%)	1 (20.0%)
TEAE by worst toxicity grade					
1	3 (50.0%)	1 (16.7%)	1 (16.7%)	0	0
2	2 (33.3%)	1 (16.7%)	2 (33.3%)	3 (60.0%)	1 (20.0%)
3	1 (16.7%)	0	1 (16.7%)	1 (20.0%)	1 (20.0%)
4	0	0	1 (16.7%)	0	0
5	0	0	0	0	0
Serious TEAE	2 (33.3%)	0	1 (16.7%)	0	1 (20.0%)
Serious Related TEAE	2 (33.3%)	0	0	0	1 (20.0%)

Arm A: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 3mg
Arm B: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 6mg
Note: Percentages calculated based on number of subjects treated or having TEAE reported in the analysis period.
Note: Adverse events are classified using MedDRA v26.1 and CTCAE v5.0, and are counted only once per category. ICANS is graded according to Lee et al 2019, CRS as per Lee et al 2019, and CTLS according to Cairo-Bishop (Coiffier et al 2008).
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Overview of Treatment-Emergent Adverse Events (TEAEs) by Analysis Period
GCT3013-01 Dose Optimization Part - FL 1-3A Cohort - Safety Analysis Set

Arm B (N=6)

	Analysis period				
	Week ≤ 8 (N=6)	> Week 8 to ≤12 (N=6)	> Week 12 to ≤24 (N=6)	> Week 12 to ≤36 (N=5)	> Week 36 (N=5)
TEAE leading to treatment discontinuation	0	0	0	0	0
TEAE leading to dose delay	3 (50.0%)	0	1 (16.7%)	2 (40.0%)	0
Fatal TEAE	0	0	0	0	0
Fatal related TEAE	0	0	0	0	0
AESI					
CRS	3 (50.0%)	0	0	0	0
ICANS	0	0	0	0	0
CTLS	0	0	0	0	0

Arm A: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 3mg
Arm B: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 6mg
Note: Percentages calculated based on number of subjects treated or having TEAE reported in the analysis period.
Note: Adverse events are classified using MedDRA v26.1 and CTCAE v5.0, and are counted only once per category. ICANS is graded according to Lee et al 2019, CRS as per Lee et al 2019, and CTLS according to Cairo-Bishop (Coiffier et al 2008).
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Overview of Treatment-Emergent Adverse Events (TEAEs) by Analysis Period
GCT3013-01 Dose Optimization Part - FL 1-3A Cohort - Safety Analysis Set

Overall (N=92)

	Analysis period				
	Week ≤ 8 (N=92)	> Week 8 to ≤12 (N=78)	> Week 12 to ≤24 (N=66)	> Week 24 to ≤36 (N=37)	> Week 36 (N=16)
Number of Subjects with at least one					
TEAE	90 (97.8%)	39 (50.0%)	53 (80.3%)	24 (64.9%)	9 (56.3%)
Related TEAE	79 (85.9%)	23 (29.5%)	30 (45.5%)	9 (24.3%)	3 (18.8%)
Grade 3 and higher TEAE	34 (37.0%)	7 (9.0%)	12 (18.2%)	4 (10.8%)	2 (12.5%)
Grade 3 and higher related TEAE	20 (21.7%)	4 (5.1%)	7 (10.6%)	4 (10.8%)	1 (6.3%)
TEAE by worst toxicity grade					
1	21 (22.8%)	21 (26.9%)	25 (37.9%)	7 (18.9%)	5 (31.3%)
2	35 (38.0%)	11 (14.1%)	16 (24.2%)	13 (35.1%)	2 (12.5%)
3	26 (28.3%)	4 (5.1%)	8 (12.1%)	3 (8.1%)	2 (12.5%)
4	8 (8.7%)	3 (3.8%)	4 (6.1%)	1 (2.7%)	0
5	0	0	0	0	0
Serious TEAE	34 (37.0%)	2 (2.6%)	4 (6.1%)	3 (8.1%)	2 (12.5%)
Serious Related TEAE	31 (33.7%)	0	0	2 (5.4%)	1 (6.3%)

Arm A: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 3mg
Arm B: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 6mg
Note: Percentages calculated based on number of subjects treated or having TEAE reported in the analysis period.
Note: Adverse events are classified using MedDRA v26.1 and CTCAE v5.0, and are counted only once per category. ICANS is graded according to Lee et al 2019, CRS as per Lee et al 2019, and CTLS according to Cairo-Bishop (Coiffier et al 2008).
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Overview of Treatment-Emergent Adverse Events (TEAEs) by Analysis Period
GCT3013-01 Dose Optimization Part - FL 1-3A Cohort - Safety Analysis Set

Overall (N=92)

	Analysis period				
	Week ≤ 8 (N=92)	> Week 8 to ≤12 (N=78)	> Week 12 to ≤24 (N=66)	> Week 24 to ≤36 (N=37)	> Week 36 (N=16)
TEAE leading to treatment discontinuation	2 (2.2%)	1 (1.3%)	0	0	0
TEAE leading to dose delay	39 (42.4%)	7 (9.0%)	15 (22.7%)	10 (27.0%)	3 (18.8%)
Fatal TEAE	0	0	0	0	0
Fatal related TEAE	0	0	0	0	0
AESI					
CRS	45 (48.9%)	0	0	0	0
ICANS	0	0	0	0	0
CTLS	0	0	0	0	0

Arm A: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 3mg
Arm B: Priming 0.16mg, Intermediate 0.8mg, Second Intermediate 6mg
Note: Percentages calculated based on number of subjects treated or having TEAE reported in the analysis period.
Note: Adverse events are classified using MedDRA v26.1 and CTCAE v5.0, and are counted only once per category. ICANS is graded according to Lee et al 2019, CRS as per Lee et al 2019, and CTLS according to Cairo-Bishop (Coiffier et al 2008).
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