Dossier zur Nutzenbewertung gemäß § 35a SGB V

Isavuconazol (CRESEMBA)

Pfizer Pharma GmbH

Modul 4 – Anhang 4G

Stand: 18.09.2024

Inhaltsverzeichnis

1 Patientencharakteristika

1.1 Vorerkrankungen und medizinisch relevante Begleitumstände

Medical History (MedDRA v23.0)
Safety Analysis Set

System Organ Class Preferred Term [1]	Total (N=31)
Overall	31 (100.0%)
Blood and lymphatic system disorders	27 (87.1%)
Anaemia	18 (58.1%)
Thrombocytopenia	11 (35.5%)
Neutropenia	6 (19.4%)
Febrile neutropenia	5 (16.1%)
Leukocytosis	4 (12.9%)
Pancytopenia	4 (12.9%)
Iron deficiency anaemia	3 (9.7%)
Leukopenia	3 (9.7%)
Splenomegaly	3 (9.7%)
Coagulopathy	2 (6.5%)
Anaemia macrocytic	1 (3.2%)
Lymphopenia	1 (3.2%)
Thrombotic microangiopathy	1 (3.2%)
Cytopenia	1 (3.2%)
Autoimmune haemolytic anaemia	1 (3.2%)
Autoimmune anaemia	1 (3.2%)
Immune thrombocytopenia	1 (3.2%)
Cardiac disorders	20 (64.5%)
Tachycardia	16 (51.6%)
Pericardial effusion	3 (9.7%)
Bradycardia	2 (6.5%)
Ventricular extrasystoles	2 (6.5%)
Cardiomegaly	1 (3.2%)
Mitral valve incompetence	1 (3.2%)
Supraventricular extrasystoles	1 (3.2%)
Tricuspid valve incompetence	1 (3.2%)
Left ventricular hypertrophy	1 (3.2%)
Right ventricular hypertrophy	1 (3.2%)
Right atrial enlargement	1 (3.2%)

[1] Within a System Organ Class, subjects may have reported more than one Preferred Term
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects by Preferred Term. In case of ties, ascending order by Preferred Term Code is applied.

Medical History (MedDRA v23.0)
Safety Analysis Set

System Organ Class Preferred Term [1]	Total (N=31)
Mitral valve disease	1 (3.2%)
Acute left ventricular failure	1 (3.2%)
Cardiac dysfunction	1 (3.2%)
Congenital, familial and genetic disorders	5 (16.1%)
Combined immunodeficiency	1 (3.2%)
Double outlet right ventricle	1 (3.2%)
Gastroschisis	1 (3.2%)
Hypoplastic left heart syndrome	1 (3.2%)
Transposition of the great vessels	1 (3.2%)
Trisomy 21	1 (3.2%)
Asplenia	1 (3.2%)
Intestinal atresia	1 (3.2%)
Heterotaxia	1 (3.2%)
Griscelli syndrome	1 (3.2%)
Ear and labyrinth disorders	1 (3.2%)
Hypoacusis	1 (3.2%)
Endocrine disorders	4 (12.9%)
Hypothyroidism	3 (9.7%)
Adrenal insufficiency	2 (6.5%)
Cushingoid	1 (3.2%)
Eye disorders	6 (19.4%)
Dry eye	2 (6.5%)
Chorioretinal atrophy	1 (3.2%)
Eye pain	1 (3.2%)
Eyelid ptosis	1 (3.2%)
Lenticular opacities	1 (3.2%)
Periorbital oedema	1 (3.2%)
Uveitis	1 (3.2%)

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Sorting order: ascending order by System Organ Class Code and descending by the number of subjects by Preferred Term. In case of ties, ascending order by Preferred Term Code is applied.

Medical History (MedDRA v23.0)
Safety Analysis Set

System Organ Class Preferred Term [1]	Total (N=31)
Gastrointestinal disorders	26 (83.9%)
Nausea	20 (64.5%)
Vomiting	17 (54.8%)
Constipation	10 (32.3%)
Diarrhoea	8 (25.8%)
Abdominal pain	6 (19.4%)
Aphthous ulcer	5 (16.1%)
Abdominal distension	4 (12.9%)
Abdominal pain upper	3 (9.7%)
Colitis	2 (6.5%)
Gastrooesophageal reflux disease	2 (6.5%)
Lip dry	2 (6.5%)
Abdominal discomfort	1 (3.2%)
Abdominal tenderness	1 (3.2%)
Anal fissure	1 (3.2%)
Ascites	1 (3.2%)
Dyspepsia	1 (3.2%)
Enteritis	1 (3.2%)
Gastrointestinal disorder	1 (3.2%)
Gastrointestinal haemorrhage	1 (3.2%)
Gastrointestinal necrosis	1 (3.2%)
Gingival hypertrophy	1 (3.2%)
Haemorrhoids	1 (3.2%)
Intestinal dilatation	1 (3.2%)
Intestinal perforation	1 (3.2%)
Lip ulceration	1 (3.2%)
Malabsorption	1 (3.2%)
Mouth ulceration	1 (3.2%)
Proctalgia	1 (3.2%)
Rectal haemorrhage	1 (3.2%)
Stomatitis	1 (3.2%)
Tongue discolouration	1 (3.2%)
Lip disorder	1 (3.2%)

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Medical History (MedDRA v23.0)
Safety Analysis Set

System Organ Class Preferred Term [1]	Total (N=31)
Short-bowel syndrome	1 (3.2%)
Enterocutaneous fistula	1 (3.2%)
Perianal erythema	1 (3.2%)
Infrequent bowel movements	1 (3.2%)
Anorectal discomfort	1 (3.2%)
Functional gastrointestinal disorder	1 (3.2%)
Oral pigmentation	1 (3.2%)
General disorders and administration site conditions	25 (80.6%)
Pyrexia	18 (58.1%)
Fatigue	7 (22.6%)
Chills	6 (19.4%)
Malaise	6 (19.4%)
Pain	6 (19.4%)
Non-cardiac chest pain	6 (19.4%)
Mucosal inflammation	3 (9.7%)
Oedema peripheral	3 (9.7%)
Face oedema	2 (6.5%)
Oedema	2 (6.5%)
Chest pain	1 (3.2%)
Crepitations	1 (3.2%)
Drug withdrawal syndrome	1 (3.2%)
Influenza like illness	1 (3.2%)
Swelling	1 (3.2%)
Peripheral swelling	1 (3.2%)
Treatment noncompliance	1 (3.2%)
Catheter site erythema	1 (3.2%)
Catheter site inflammation	1 (3.2%)
Catheter site pain	1 (3.2%)
Foaming at mouth	1 (3.2%)
Infusion site haemorrhage	1 (3.2%)
Complication associated with device	1 (3.2%)
Multiple organ dysfunction syndrome	1 (3.2%)

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Sorting order: ascending order by System Organ Class Code and descending by the number of subjects by Preferred Term. In case of ties, ascending order by Preferred Term Code is applied.

Medical History (MedDRA v23.0)
Safety Analysis Set

System Organ Class Preferred Term [1]	Total (N=31)
Hepatobiliary disorders	10 (32.3%)
Hepatomegaly	6 (19.4%)
Hepatic steatosis	1 (3.2%)
Hepatosplenomegaly	1 (3.2%)
Jaundice	1 (3.2%)
Bile duct obstruction	1 (3.2%)
Gallbladder necrosis	1 (3.2%)
Liver injury	1 (3.2%)
Immune system disorders	10 (32.3%)
Drug hypersensitivity	3 (9.7%)
Hypogammaglobulinaemia	2 (6.5%)
Graft versus host disease in gastrointestinal tract	2 (6.5%)
Anti-neutrophil cytoplasmic antibody positive vasculitis	1 (3.2%)
Lung transplant rejection	1 (3.2%)
Intestine transplant rejection	1 (3.2%)
Immunosuppression	1 (3.2%)
Graft versus host disease in skin	1 (3.2%)
Haemophagocytic lymphohistiocytosis	1 (3.2%)
Infusion related hypersensitivity reaction	1 (3.2%)
Infections and infestations	26 (83.9%)
Sepsis	9 (29.0%)
Pneumonia	4 (12.9%)
COVID-19	3 (9.7%)
Bronchopulmonary aspergillosis	2 (6.5%)
Clostridium difficile colitis	2 (6.5%)
Rhinitis	2 (6.5%)
Septic shock	2 (6.5%)
Streptococcal sepsis	2 (6.5%)
Cytomegalovirus viraemia	2 (6.5%)
Adenovirus infection	2 (6.5%)
Pneumonia bacterial	2 (6.5%)

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Medical History (MedDRA v23.0)
Safety Analysis Set

System Organ Class Preferred Term [1]	Total (N=31)
Pneumonia fungal	2 (6.5%)
Device related sepsis	2 (6.5%)
Atypical pneumonia	1 (3.2%)
Bacteraemia	1 (3.2%)
Campylobacter gastroenteritis	1 (3.2%)
Coccidioidomycosis	1 (3.2%)
Cytomegalovirus infection	1 (3.2%)
Escherichia sepsis	1 (3.2%)
Oral candidiasis	1 (3.2%)
Peritonitis	1 (3.2%)
Upper respiratory tract infection	1 (3.2%)
Urinary tract infection	1 (3.2%)
Viral myocarditis	1 (3.2%)
Vulval abscess	1 (3.2%)
Anal abscess	1 (3.2%)
Oropharyngeal candidiasis	1 (3.2%)
Streptococcal bacteraemia	1 (3.2%)
Coronavirus infection	1 (3.2%)
Fusarium infection	1 (3.2%)
Skin bacterial infection	1 (3.2%)
Bacterial sepsis	1 (3.2%)
Enterococcal sepsis	1 (3.2%)
Escherichia bacteraemia	1 (3.2%)
Alpha haemolytic streptococcal infection	1 (3.2%)
BK virus infection	1 (3.2%)
Viral haemorrhagic cystitis	1 (3.2%)
Wound infection pseudomonas	1 (3.2%)
Corynebacterium infection	1 (3.2%)
Enterococcal infection	1 (3.2%)
Pseudomonas infection	1 (3.2%)
Respiratory syncytial virus infection	1 (3.2%)
Neisseria infection	1 (3.2%)
Acarodermatitis	1 (3.2%)

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Medical History (MedDRA v23.0)
Safety Analysis Set

System Organ Class Preferred Term [1]	Total (N=31)
Lower respiratory tract infection fungal	1 (3.2%)
Atypical mycobacterial pneumonia	1 (3.2%)
Candida infection	1 (3.2%)
Aspergillus infection	1 (3.2%)
Bacillus bacteraemia	1 (3.2%)
Bacterial abdominal infection	1 (3.2%)
Herpes simplex viraemia	1 (3.2%)
Disseminated coccidioidomycosis	1 (3.2%)
Vascular device infection	1 (3.2%)
Polyomavirus viraemia	1 (3.2%)
Asymptomatic COVID-19	1 (3.2%)
Injury, poisoning and procedural complications	6 (19.4%)
Parenteral nutrition associated liver disease	2 (6.5%)
Spinal compression fracture	1 (3.2%)
Infusion related reaction	1 (3.2%)
Vasoplegia syndrome	1 (3.2%)
Perineal injury	1 (3.2%)
Investigations	19 (61.3%)
Transaminases increased	5 (16.1%)
C-reactive protein increased	4 (12.9%)
Platelet count decreased	3 (9.7%)
Human rhinovirus test positive	3 (9.7%)
Blood fibrinogen increased	2 (6.5%)
Neutrophil count decreased	2 (6.5%)
Oxygen saturation decreased	2 (6.5%)
Enterovirus test positive	2 (6.5%)
Activated partial thromboplastin time prolonged	1 (3.2%)
Aspartate aminotransferase increased	1 (3.2%)
Blood creatinine increased	1 (3.2%)
Blood potassium decreased	1 (3.2%)
Blood pressure increased	1 (3.2%)

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Medical History (MedDRA v23.0)
Safety Analysis Set

System Organ Class Preferred Term [1]	Total (N=31)
Blood uric acid decreased	1 (3.2%)
Electrocardiogram QT prolonged	1 (3.2%)
Haemoglobin decreased	1 (3.2%)
Liver function test abnormal	1 (3.2%)
Prothrombin time prolonged	1 (3.2%)
Brain natriuretic peptide increased	1 (3.2%)
Troponin increased	1 (3.2%)
Blood alkaline phosphatase decreased	1 (3.2%)
Urine output decreased	1 (3.2%)
Human herpes virus 6 serology	1 (3.2%)
Antineutrophil cytoplasmic antibody positive	1 (3.2%)
Vitamin D decreased	1 (3.2%)
Epstein-Barr virus test positive	1 (3.2%)
Breath sounds abnormal	1 (3.2%)
Gastric occult blood positive	1 (3.2%)
Streptococcus test positive	1 (3.2%)
Human metapneumovirus test positive	1 (3.2%)
Liver function test increased	1 (3.2%)
Blood beta-D-glucan positive	1 (3.2%)
Metabolism and nutrition disorders	28 (90.3%)
Hypoalbuminaemia	13 (41.9%)
Hypokalaemia	12 (38.7%)
Hyperglycaemia	5 (16.1%)
Electrolyte imbalance	4 (12.9%)
Hypocalcaemia	4 (12.9%)
Hypomagnesaemia	4 (12.9%)
Hypophosphataemia	4 (12.9%)
Decreased appetite	4 (12.9%)
Hypochloraemia	3 (9.7%)
Hyponatraemia	3 (9.7%)
Obesity	3 (9.7%)
Vitamin D deficiency	3 (9.7%)

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Medical History (MedDRA v23.0)
Safety Analysis Set

System Organ Class Preferred Term [1]	Total (N=31)
Fluid imbalance	3 (9.7%)
Hypophagia	3 (9.7%)
Acidosis	2 (6.5%)
Hypoglycaemia	2 (6.5%)
Metabolic acidosis	2 (6.5%)
Malnutrition	2 (6.5%)
Dehydration	1 (3.2%)
Folate deficiency	1 (3.2%)
Hypercalcaemia	1 (3.2%)
Hyperphosphataemia	1 (3.2%)
Hypertriglyceridaemia	1 (3.2%)
Hyperuricaemia	1 (3.2%)
Hypervolaemia	1 (3.2%)
Hypoproteinaemia	1 (3.2%)
Metabolic alkalosis	1 (3.2%)
Overweight	1 (3.2%)
Tumour lysis syndrome	1 (3.2%)
Hyperalbuminaemia	1 (3.2%)
Vitamin B complex deficiency	1 (3.2%)
Steroid diabetes	1 (3.2%)
Musculoskeletal and connective tissue disorders	7 (22.6%)
Musculoskeletal pain	3 (9.7%)
Pain in extremity	3 (9.7%)
Back pain	2 (6.5%)
Arthralgia	1 (3.2%)
Groin pain	1 (3.2%)
Muscular weakness	1 (3.2%)
Myalgia	1 (3.2%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4 (12.9%)
Acute myeloid leukaemia	1 (3.2%)

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Medical History (MedDRA v23.0)
Safety Analysis Set

System Organ Class Preferred Term [1]	Total (N=31)
B-cell type acute leukaemia	1 (3.2%)
Hodgkin's disease	1 (3.2%)
Post transplant lymphoproliferative disorder	1 (3.2%)
Metastases to meninges	1 (3.2%)
Nervous system disorders	15 (48.4%)
Headache	4 (12.9%)
Neuropathy peripheral	2 (6.5%)
Sedation	2 (6.5%)
Posterior reversible encephalopathy syndrome	2 (6.5%)
Ataxia	1 (3.2%)
Cerebral venous thrombosis	1 (3.2%)
Depressed level of consciousness	1 (3.2%)
Epilepsy	1 (3.2%)
Migraine	1 (3.2%)
Paralysis	1 (3.2%)
Peroneal nerve palsy	1 (3.2%)
Seizure	1 (3.2%)
Tremor	1 (3.2%)
Visual field defect	1 (3.2%)
Hypoglycaemic seizure	1 (3.2%)
Restless legs syndrome	1 (3.2%)
Pregnancy, puerperium and perinatal conditions	2 (6.5%)
Premature baby	2 (6.5%)
Psychiatric disorders	14 (45.2%)
Anxiety	5 (16.1%)
Agitation	4 (12.9%)
Insomnia	4 (12.9%)
Adjustment disorder with anxiety	2 (6.5%)
Adjustment disorder	2 (6.5%)
Confusional state	1 (3.2%)

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Medical History (MedDRA v23.0)
Safety Analysis Set

System Organ Class Preferred Term [1]	Total (N=31)
Delirium	1 (3.2%)
Depressed mood	1 (3.2%)
Depression	1 (3.2%)
Post-traumatic stress disorder	1 (3.2%)
Mental status changes	1 (3.2%)
Anxiety disorder	1 (3.2%)
Renal and urinary disorders	12 (38.7%)
Acute kidney injury	6 (19.4%)
Haematuria	3 (9.7%)
Proteinuria	2 (6.5%)
Renal failure	2 (6.5%)
Atonic urinary bladder	1 (3.2%)
Glycosuria	1 (3.2%)
Oliguria	1 (3.2%)
Polyuria	1 (3.2%)
Renal tubular necrosis	1 (3.2%)
Kidney enlargement	1 (3.2%)
Chronic kidney disease	1 (3.2%)
End stage renal disease	1 (3.2%)
Reproductive system and breast disorders	2 (6.5%)
Pelvic pain	1 (3.2%)
Vaginal haemorrhage	1 (3.2%)
Respiratory, thoracic and mediastinal disorders	24 (77.4%)
Cough	15 (48.4%)
Pleural effusion	6 (19.4%)
Tachypnoea	6 (19.4%)
Hypoxia	5 (16.1%)
Rales	5 (16.1%)
Atelectasis	4 (12.9%)
Asthma	3 (9.7%)

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Medical History (MedDRA v23.0)
Safety Analysis Set

System Organ Class Preferred Term [1]	Total (N=31)
Epistaxis	3 (9.7%)
Rhinorrhoea	3 (9.7%)
Wheezing	3 (9.7%)
Pulmonary mass	3 (9.7%)
Oropharyngeal pain	3 (9.7%)
Acute respiratory distress syndrome	2 (6.5%)
Dyspnoea	2 (6.5%)
Haemoptysis	2 (6.5%)
Interstitial lung disease	2 (6.5%)
Pulmonary congestion	2 (6.5%)
Pulmonary oedema	2 (6.5%)
Oropharyngeal plaque	2 (6.5%)
Lung opacity	2 (6.5%)
Acute respiratory failure	1 (3.2%)
Dysphonia	1 (3.2%)
Hypercapnia	1 (3.2%)
Nasal congestion	1 (3.2%)
Obliterative bronchiolitis	1 (3.2%)
Productive cough	1 (3.2%)
Pulmonary haemorrhage	1 (3.2%)
Pulmonary hypertension	1 (3.2%)
Respiratory distress	1 (3.2%)
Rhonchi	1 (3.2%)
Sleep apnoea syndrome	1 (3.2%)
Nasal flaring	1 (3.2%)
Bronchomalacia	1 (3.2%)
Pharyngeal erythema	1 (3.2%)
Increased bronchial secretion	1 (3.2%)
Pulmonary arterial hypertension	1 (3.2%)
Bronchial wall thickening	1 (3.2%)
Pharyngeal disorder	1 (3.2%)
Use of accessory respiratory muscles	1 (3.2%)

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Medical History (MedDRA v23.0)
Safety Analysis Set

System Organ Class Preferred Term [1]	Total (N=31)
Skin and subcutaneous tissue disorders	17 (54.8%)
Pruritus	5 (16.1%)
Alopecia	4 (12.9%)
Petechiae	3 (9.7%)
Rash	3 (9.7%)
Urticaria	3 (9.7%)
Rash maculo-papular	2 (6.5%)
Red man syndrome	2 (6.5%)
Acne	1 (3.2%)
Decubitus ulcer	1 (3.2%)
Dermatitis atopic	1 (3.2%)
Dermatitis contact	1 (3.2%)
Dry skin	1 (3.2%)
Ecchymosis	1 (3.2%)
Papule	1 (3.2%)
Rash pruritic	1 (3.2%)
Skin hyperpigmentation	1 (3.2%)
Skin lesion	1 (3.2%)
Skin mass	1 (3.2%)
Interstitial granulomatous dermatitis	1 (3.2%)
Social circumstances	1 (3.2%)
Disease risk factor	1 (3.2%)
Surgical and medical procedures	8 (25.8%)
Central venous catheterisation	4 (12.9%)
Parenteral nutrition	3 (9.7%)
Gastrostomy	2 (6.5%)
Ileostomy closure	2 (6.5%)
Nothing by mouth order	2 (6.5%)
Adenoidectomy	1 (3.2%)
Cholecystectomy	1 (3.2%)
Colectomy total	1 (3.2%)

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Medical History (MedDRA v23.0)
Safety Analysis Set

System Organ Class Preferred Term [1]	Total (N=31)
Ileostomy	1 (3.2%)
Ventricular assist device insertion	1 (3.2%)
Duodenostomy	1 (3.2%)
Intestinal resection	1 (3.2%)
Intestinal anastomosis	1 (3.2%)
Central venous catheter removal	1 (3.2%)
Mechanical ventilation	1 (3.2%)
Allogenic stem cell transplantation	1 (3.2%)
Drain placement	1 (3.2%)
Enterorrhaphy	1 (3.2%)
Multivisceral transplantation	1 (3.2%)
Lung assist device therapy	1 (3.2%)
Ileocaecal resection	1 (3.2%)
Vascular disorders	18 (58.1%)
Hypertension	10 (32.3%)
Pallor	8 (25.8%)
Hypotension	6 (19.4%)
Venoocclusive disease	2 (6.5%)
Blood pressure fluctuation	1 (3.2%)
Flushing	1 (3.2%)
Haematoma	1 (3.2%)
Hypoperfusion	1 (3.2%)
Product issues	2 (6.5%)
Device leakage	1 (3.2%)
Device occlusion	1 (3.2%)

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2 Subgruppenauswertungen

2.1 Gesamtmortalität

Descriptive Summary of All-Cause Mortality at Day 42 by Subgroups
Full Analysis Set

Timepoint	Subgroup	Category	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Day 42	Age Category (Years)	>= 1 to < 12	0	0	0	0	0
		>= 12 to < 18	1/12 (8.3%)	0	1/16 (6.3%)	0	2/31 (6.5%)
	Gender	Male	0	0	0	0	0
		Female	1/12 (8.3%)	0	1/16 (6.3%)	0	2/31 (6.5%)
	Race	White	1/12 (8.3%)	0	1/16 (6.3%)	0	2/31 (6.5%)
		Black or African American	0	0	0	0	0
		Asian	0	0	0	0	0
		American Indian or Alaska Native	0	0	0	0	0
		Native Hawaiian or Other Pacific Islander	0	0	0	0	0
		Other	0	0	0	0	0
	Ethnicity	Hispanic or Latino	1/12 (8.3%)	0	0	0	1/31 (3.2%)
		Not Hispanic or Latino	0	0	1/16 (6.3%)	0	1/31 (3.2%)
	BMI Category (kg/m^2)	< 25	0	0	1/16 (6.3%)	0	1/31 (3.2%)
		>= 25 to < 30	1/12 (8.3%)	0	0	0	1/31 (3.2%)
		>= 30	0	0	0	0	0
	Neutropenic	Yes	0	0	1/16 (6.3%)	0	1/31 (3.2%)
		No	1/12 (8.3%)	0	0	0	1/31 (3.2%)

IFD: Invasive Fungal Disease; IA: Invasive Aspergillosis; IM: Invasive Mucormycosis; BMI: Body Mass Index.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.

Descriptive Summary of All-Cause Mortality at Day 84 and EOT by Subgroups
Full Analysis Set

Timepoint	Subgroup	Category	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Day 84	Age Category (Years)	>= 1 to < 12	0	0	0	0	0
		>= 12 to < 18	2/12 (16.7%)	0	1/16 (6.3%)	0	3/31 (9.7%)
	Gender	Male	0	0	0	0	0
		Female	2/12 (16.7%)	0	1/16 (6.3%)	0	3/31 (9.7%)
	Race	White	2/12 (16.7%)	0	1/16 (6.3%)	0	3/31 (9.7%)
		Black or African American	0	0	0	0	0
		Asian	0	0	0	0	0
		American Indian or Alaska Native	0	0	0	0	0
		Native Hawaiian or Other Pacific Islander	0	0	0	0	0
		Other	0	0	0	0	0
	Ethnicity	Hispanic or Latino	1/12 (8.3%)	0	0	0	1/31 (3.2%)
		Not Hispanic or Latino	1/12 (8.3%)	0	1/16 (6.3%)	0	2/31 (6.5%)
	BMI Category (kg/m^2)	< 25	1/12 (8.3%)	0	1/16 (6.3%)	0	2/31 (6.5%)
		>= 25 to < 30	1/12 (8.3%)	0	0	0	1/31 (3.2%)
		>= 30	0	0	0	0	0
	Neutropenic	Yes	1/12 (8.3%)	0	1/16 (6.3%)	0	2/31 (6.5%)
		No	1/12 (8.3%)	0	0	0	1/31 (3.2%)

IFD: Invasive Fungal Disease; IA: Invasive Aspergillosis; IM: Invasive Mucormycosis; BMI: Body Mass Index; EOT: End of Treatment.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.

2.2 Klinisches, mykologisches, radiologisches und Gesamtansprechen nach Altersgruppen

Investigator-Assessed Clinical Response - Overall and by Age Group
Full Analysis Set

Timepoint	Subgroup Outcome	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Day 42	Overall	5 (41.7%)	0	11 (68.8%)	0	16 (51.6%)
	Success	5 (41.7%)	0	8 (50.0%)	0	13 (41.9%)
	Failure	0	0	3 (18.8%)	0	3 (9.7%)
	Not Evaluable	0	0	0	0	0
	Age Group					
	1 to < 12 yrs	4 (33.3%)	0	8 (50.0%)	0	12 (38.7%)
	Success	4 (33.3%)	0	5 (31.3%)	0	9 (29.0%)
	Failure	0	0	3 (18.8%)	0	3 (9.7%)
	Not Evaluable	0	0	0	0	0
	Age Group					
	12 to < 18 yrs	1 (8.3%)	0	3 (18.8%)	0	4 (12.9%)
	Success	1 (8.3%)	0	3 (18.8%)	0	4 (12.9%)
	Failure	0	0	0	0	0
	Not Evaluable	0	0	0	0	0
Day 84	Overall	4 (33.3%)	0	6 (37.5%)	0	10 (32.3%)
	Success	4 (33.3%)	0	6 (37.5%)	0	10 (32.3%)
	Failure	0	0	0	0	0
	Not Evaluable	0	0	0	0	0
	Age Group					
	1 to < 12 yrs	3 (25.0%)	0	4 (25.0%)	0	7 (22.6%)
	Success	3 (25.0%)	0	4 (25.0%)	0	7 (22.6%)
	Failure	0	0	0	0	0
	Not Evaluable	0	0	0	0	0
	Age Group					
	12 to < 18 yrs	1 (8.3%)	0	2 (12.5%)	0	3 (9.7%)
	Success	1 (8.3%)	0	2 (12.5%)	0	3 (9.7%)
	Failure	0	0	0	0	0
	Not Evaluable	0	0	0	0	0
EOT	Overall	11 (91.7%)	1 (100.0%)	15 (93.8%)	2 (100.0%)	29 (93.5%)
	Success	8 (66.7%)	0	11 (68.8%)	0	19 (61.3%)

IFD: Invasive Fungal Disease; IA: Invasive Aspergillosis; IM: Invasive Mucormycosis; EOT: End of Treatment.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.

Investigator-Assessed Clinical Response - Overall and by Age Group
Full Analysis Set

Timepoint	Subgroup Outcome	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
EOT	Failure	3 (25.0%)	1 (100.0%)	4 (25.0%)	1 (50.0%)	9 (29.0%)
	Not Evaluable	0	0	0	1 (50.0%)	1 (3.2%)
	Age Group					
	1 to < 12 yrs	7 (58.3%)	0	11 (68.8%)	1 (50.0%)	19 (61.3%)
	Success	7 (58.3%)	0	8 (50.0%)	0	15 (48.4%)
	Failure	0	0	3 (18.8%)	1 (50.0%)	4 (12.9%)
	Not Evaluable	0	0	0	0	0
	Age Group					
	12 to < 18 yrs	4 (33.3%)	1 (100.0%)	4 (25.0%)	1 (50.0%)	10 (32.3%)
	Success	1 (8.3%)	0	3 (18.8%)	0	4 (12.9%)
	Failure	3 (25.0%)	1 (100.0%)	1 (6.3%)	0	5 (16.1%)
	Not Evaluable	0	0	0	1 (50.0%)	1 (3.2%)

IFD: Invasive Fungal Disease; IA: Invasive Aspergillosis; IM: Invasive Mucormycosis; EOT: End of Treatment.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.

AC-Assessed Overall/Clinical/Mycological/Radiological Response by Age Group
Full Analysis Set

Age Group=1 to <12 Years (N=19)

Outcome	Timepoint	Response	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Overall Response	Day 42	Success	3 (25.0%)	0	2 (12.5%)	0	5 (16.1%)
		Complete	0	0	1 (6.3%)	0	1 (3.2%)
		Partial	3 (25.0%)	0	1 (6.3%)	0	4 (12.9%)
		Failure	0	0	2 (12.5%)	0	2 (6.5%)
		Stable	0	0	1 (6.3%)	0	1 (3.2%)
		Progression	0	0	1 (6.3%)	0	1 (3.2%)
		Not Evaluable	1 (8.3%)	0	5 (31.3%)	0	6 (19.4%)
		Not Evaluable	1 (8.3%)	0	5 (31.3%)	0	6 (19.4%)
	Day 84	Success	4 (33.3%)	0	1 (6.3%)	0	5 (16.1%)
		Complete	1 (8.3%)	0	0	0	1 (3.2%)
		Partial	3 (25.0%)	0	1 (6.3%)	0	4 (12.9%)
		Failure	0	0	0	0	0
		Stable	0	0	0	0	0
		Progression	0	0	0	0	0
		Not Evaluable	0	0	3 (18.8%)	0	3 (9.7%)
		Not Evaluable	0	0	3 (18.8%)	0	3 (9.7%)
	EOT	Success	6 (50.0%)	0	5 (31.3%)	0	11 (35.5%)
		Complete	2 (16.7%)	0	2 (12.5%)	0	4 (12.9%)
		Partial	4 (33.3%)	0	3 (18.8%)	0	7 (22.6%)
		Failure	0	0	1 (6.3%)	0	1 (3.2%)
		Stable	0	0	0	0	0
		Progression	0	0	1 (6.3%)	0	1 (3.2%)
		Not Evaluable	1 (8.3%)	0	5 (31.3%)	1 (50.0%)	7 (22.6%)
		Not Evaluable	1 (8.3%)	0	5 (31.3%)	1 (50.0%)	7 (22.6%)

AC: Adjudication Committee; IA: Invasive Aspergillosis; IM: Invasive Mucormycosis; IFD: Invasive Fungal Disease; EOT: End of Treatment.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
If subject did not reach Day 42 or Day 84 of therapy then the AC did not perform these assessments.
The frequency 'N' in a column heading represents the number of subjects by the Investigator assessment of IFD diagnosis.
Overall Response will be based on a composite of clinical, mycological, and radiological responses with success criteria assessed.
Overall Response is considered 'Not-evaluable' when one of the composite responses is 'Not Assessed'.

AC-Assessed Overall/Clinical/Mycological/Radiological Response by Age Group
Full Analysis Set

Age Group=1 to <12 Years (N=19)

Outcome	Timepoint	Response	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Clinical Response	Day 42	Success	0	0	0	0	0
		Complete	0	0	0	0	0
		Partial	0	0	0	0	0
		Failure	0	0	0	0	0
		Stable	0	0	0	0	0
		Progression	0	0	0	0	0
		Not Evaluable	4 (33.3%)	0	9 (56.3%)	0	13 (41.9%)
		No Clinical Signs or Symptoms at Baseline	0	0	0	0	0
		Not Assessed	4 (33.3%)	0	9 (56.3%)	0	13 (41.9%)
	Day 84	Success	0	0	0	0	0
		Complete	0	0	0	0	0
		Partial	0	0	0	0	0
		Failure	0	0	0	0	0
		Stable	0	0	0	0	0
		Progression	0	0	0	0	0
		Not Evaluable	4 (33.3%)	0	4 (25.0%)	0	8 (25.8%)
		No Clinical Signs or Symptoms at Baseline	0	0	0	0	0
		Not Assessed	4 (33.3%)	0	4 (25.0%)	0	8 (25.8%)
	EOT	Success	0	0	2 (12.5%)	0	2 (6.5%)
		Complete	0	0	2 (12.5%)	0	2 (6.5%)
		Partial	0	0	0	0	0
		Failure	0	0	0	0	0

AC: Adjudication Committee; IA: Invasive Aspergillosis; IM: Invasive Mucormycosis; IFD: Invasive Fungal Disease; EOT: End of Treatment.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
If subject did not reach Day 42 or Day 84 of therapy then the AC did not perform these assessments.
The frequency 'N' in a column heading represents the number of subjects by the Investigator assessment of IFD diagnosis.
Overall Response will be based on a composite of clinical, mycological, and radiological responses with success criteria assessed.
Overall Response is considered 'Not-evaluable' when one of the composite responses is 'Not Assessed'.

AC-Assessed Overall/Clinical/Mycological/Radiological Response by Age Group
Full Analysis Set

Age Group=1 to <12 Years (N=19)

Outcome	Timepoint	Response	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Clinical Response	EOT	Stable	0	0	0	0	0
		Progression	0	0	0	0	0
		Not Evaluable	7 (58.3%)	0	9 (56.3%)	1 (50.0%)	17 (54.8%)
		No Clinical Signs or Symptoms at Baseline	0	0	0	0	0
		Not Assessed	7 (58.3%)	0	9 (56.3%)	1 (50.0%)	17 (54.8%)
Mycological Response	Day 42	Success	4 (33.3%)	0	2 (12.5%)	0	6 (19.4%)
		Eradication	0	0	0	0	0
		Presumed Eradication	4 (33.3%)	0	2 (12.5%)	0	6 (19.4%)
		Failure	0	0	0	0	0
		Persistence	0	0	0	0	0
		Presumed Persistence	0	0	0	0	0
		Not Evaluable	0	0	7 (43.8%)	0	7 (22.6%)
		No Mycological Evidence	0	0	7 (43.8%)	0	7 (22.6%)
	Day 84	Success	4 (33.3%)	0	1 (6.3%)	0	5 (16.1%)
		Eradication	0	0	0	0	0
		Presumed Eradication	4 (33.3%)	0	1 (6.3%)	0	5 (16.1%)
		Failure	0	0	0	0	0
		Persistence	0	0	0	0	0
		Presumed Persistence	0	0	0	0	0
		Not Evaluable	0	0	3 (18.8%)	0	3 (9.7%)
		No Mycological Evidence	0	0	3 (18.8%)	0	3 (9.7%)

AC: Adjudication Committee; IA: Invasive Aspergillosis; IM: Invasive Mucormycosis; IFD: Invasive Fungal Disease; EOT: End of Treatment.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
If subject did not reach Day 42 or Day 84 of therapy then the AC did not perform these assessments.
The frequency 'N' in a column heading represents the number of subjects by the Investigator assessment of IFD diagnosis.
Overall Response will be based on a composite of clinical, mycological, and radiological responses with success criteria assessed.
Overall Response is considered 'Not-evaluable' when one of the composite responses is 'Not Assessed'.

AC-Assessed Overall/Clinical/Mycological/Radiological Response by Age Group
Full Analysis Set

Age Group=1 to <12 Years (N=19)

Outcome	Timepoint	Response	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Mycological Response	EOT	Success	6 (50.0%)	0	2 (12.5%)	0	8 (25.8%)
		Eradication	0	0	0	0	0
		Presumed Eradication	6 (50.0%)	0	2 (12.5%)	0	8 (25.8%)
		Failure	1 (8.3%)	0	0	0	1 (3.2%)
		Persistence	0	0	0	0	0
		Presumed Persistence	1 (8.3%)	0	0	0	1 (3.2%)
		Not Evaluable	0	0	9 (56.3%)	1 (50.0%)	10 (32.3%)
		No Mycological Evidence	0	0	9 (56.3%)	1 (50.0%)	10 (32.3%)
Radiological Response	Day 42	Success	3 (25.0%)	0	2 (12.5%)	0	5 (16.1%)
		Complete	0	0	1 (6.3%)	0	1 (3.2%)
		Partial	3 (25.0%)	0	1 (6.3%)	0	4 (12.9%)
		Failure	0	0	2 (12.5%)	0	2 (6.5%)
		Stable	0	0	1 (6.3%)	0	1 (3.2%)
		Progression	0	0	1 (6.3%)	0	1 (3.2%)
		Not Evaluable	1 (8.3%)	0	5 (31.3%)	0	6 (19.4%)
		No Post Baseline Radiology Available With Baseline Evidence of Radiologic Disease	1 (8.3%)	0	3 (18.8%)	0	4 (12.9%)
		Radiology Not Applicable at Baseline	0	0	2 (12.5%)	0	2 (6.5%)
	Day 84	Success	4 (33.3%)	0	1 (6.3%)	0	5 (16.1%)
		Complete	1 (8.3%)	0	0	0	1 (3.2%)
		Partial	3 (25.0%)	0	1 (6.3%)	0	4 (12.9%)

AC: Adjudication Committee; IA: Invasive Aspergillosis; IM: Invasive Mucormycosis; IFD: Invasive Fungal Disease; EOT: End of Treatment.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
If subject did not reach Day 42 or Day 84 of therapy then the AC did not perform these assessments.
The frequency 'N' in a column heading represents the number of subjects by the Investigator assessment of IFD diagnosis.
Overall Response will be based on a composite of clinical, mycological, and radiological responses with success criteria assessed.
Overall Response is considered 'Not-evaluable' when one of the composite responses is 'Not Assessed'.

AC-Assessed Overall/Clinical/Mycological/Radiological Response by Age Group
Full Analysis Set

Age Group=1 to <12 Years (N=19)

Outcome	Timepoint	Response	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Radiological Response	Day 84	Failure	0	0	0	0	0
		Stable	0	0	0	0	0
		Progression	0	0	0	0	0
		Not Evaluable	0	0	3 (18.8%)	0	3 (9.7%)
		No Post Baseline Radiology Available With Baseline Evidence of Radiologic Disease	0	0	1 (6.3%)	0	1 (3.2%)
		Radiology Not Applicable at Baseline	0	0	2 (12.5%)	0	2 (6.5%)
	EOT	Success	6 (50.0%)	0	4 (25.0%)	0	10 (32.3%)
		Complete	2 (16.7%)	0	2 (12.5%)	0	4 (12.9%)
		Partial	4 (33.3%)	0	2 (12.5%)	0	6 (19.4%)
		Failure	0	0	1 (6.3%)	1 (50.0%)	2 (6.5%)
		Stable	0	0	0	1 (50.0%)	1 (3.2%)
		Progression	0	0	1 (6.3%)	0	1 (3.2%)
		Not Evaluable	1 (8.3%)	0	6 (37.5%)	0	7 (22.6%)
		No Post Baseline Radiology Available With Baseline Evidence of Radiologic Disease	1 (8.3%)	0	4 (25.0%)	0	5 (16.1%)
		Radiology Not Applicable at Baseline	0	0	2 (12.5%)	0	2 (6.5%)

AC: Adjudication Committee; IA: Invasive Aspergillosis; IM: Invasive Mucormycosis; IFD: Invasive Fungal Disease; EOT: End of Treatment.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
If subject did not reach Day 42 or Day 84 of therapy then the AC did not perform these assessments.
The frequency 'N' in a column heading represents the number of subjects by the Investigator assessment of IFD diagnosis.
Overall Response will be based on a composite of clinical, mycological, and radiological responses with success criteria assessed.
Overall Response is considered 'Not-evaluable' when one of the composite responses is 'Not Assessed'.

AC-Assessed Overall/Clinical/Mycological/Radiological Response by Age Group
Full Analysis Set

Age Group=>=12 to <18 Years (N=12)

Outcome	Timepoint	Response	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Overall Response	Day 42	Success	1 (8.3%)	0	3 (18.8%)	0	4 (12.9%)
		Complete	0	0	0	0	0
		Partial	1 (8.3%)	0	3 (18.8%)	0	4 (12.9%)
		Failure	0	0	0	0	0
		Stable	0	0	0	0	0
		Progression	0	0	0	0	0
		Not Evaluable	0	0	1 (6.3%)	0	1 (3.2%)
		Not Evaluable	0	0	1 (6.3%)	0	1 (3.2%)
	Day 84	Success	1 (8.3%)	0	2 (12.5%)	0	3 (9.7%)
		Complete	0	0	1 (6.3%)	0	1 (3.2%)
		Partial	1 (8.3%)	0	1 (6.3%)	0	2 (6.5%)
		Failure	0	0	0	0	0
		Stable	0	0	0	0	0
		Progression	0	0	0	0	0
		Not Evaluable	0	0	0	0	0
		Not Evaluable	0	0	0	0	0
	EOT	Success	2 (16.7%)	0	4 (25.0%)	0	6 (19.4%)
		Complete	1 (8.3%)	0	1 (6.3%)	0	2 (6.5%)
		Partial	1 (8.3%)	0	3 (18.8%)	0	4 (12.9%)
		Failure	2 (16.7%)	1 (100.0%)	0	0	3 (9.7%)
		Stable	0	0	0	0	0
		Progression	2 (16.7%)	1 (100.0%)	0	0	3 (9.7%)
		Not Evaluable	1 (8.3%)	0	1 (6.3%)	1 (50.0%)	3 (9.7%)
		Not Evaluable	1 (8.3%)	0	1 (6.3%)	1 (50.0%)	3 (9.7%)

AC: Adjudication Committee; IA: Invasive Aspergillosis; IM: Invasive Mucormycosis; IFD: Invasive Fungal Disease; EOT: End of Treatment.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
If subject did not reach Day 42 or Day 84 of therapy then the AC did not perform these assessments.
The frequency 'N' in a column heading represents the number of subjects by the Investigator assessment of IFD diagnosis.
Overall Response will be based on a composite of clinical, mycological, and radiological responses with success criteria assessed.
Overall Response is considered 'Not-evaluable' when one of the composite responses is 'Not Assessed'.

AC-Assessed Overall/Clinical/Mycological/Radiological Response by Age Group
Full Analysis Set

Age Group=>=12 to <18 Years (N=12)

Outcome	Timepoint	Response	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Clinical Response	Day 42	Success	0	0	0	0	0
		Complete	0	0	0	0	0
		Partial	0	0	0	0	0
		Failure	0	0	0	0	0
		Stable	0	0	0	0	0
		Progression	0	0	0	0	0
		Not Evaluable	1 (8.3%)	0	4 (25.0%)	0	5 (16.1%)
		No Clinical Signs or Symptoms at Baseline	0	0	0	0	0
		Not Assessed	1 (8.3%)	0	4 (25.0%)	0	5 (16.1%)
	Day 84	Success	0	0	0	0	0
		Complete	0	0	0	0	0
		Partial	0	0	0	0	0
		Failure	0	0	0	0	0
		Stable	0	0	0	0	0
		Progression	0	0	0	0	0
		Not Evaluable	1 (8.3%)	0	2 (12.5%)	0	3 (9.7%)
		No Clinical Signs or Symptoms at Baseline	0	0	0	0	0
		Not Assessed	1 (8.3%)	0	2 (12.5%)	0	3 (9.7%)
	EOT	Success	0	0	0	0	0
		Complete	0	0	0	0	0
		Partial	0	0	0	0	0
		Failure	1 (8.3%)	1 (100.0%)	1 (6.3%)	0	3 (9.7%)

AC: Adjudication Committee; IA: Invasive Aspergillosis; IM: Invasive Mucormycosis; IFD: Invasive Fungal Disease; EOT: End of Treatment.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
If subject did not reach Day 42 or Day 84 of therapy then the AC did not perform these assessments.
The frequency 'N' in a column heading represents the number of subjects by the Investigator assessment of IFD diagnosis.
Overall Response will be based on a composite of clinical, mycological, and radiological responses with success criteria assessed.
Overall Response is considered 'Not-evaluable' when one of the composite responses is 'Not Assessed'.

AC-Assessed Overall/Clinical/Mycological/Radiological Response by Age Group
Full Analysis Set

Age Group=>=12 to <18 Years (N=12)

Outcome	Timepoint	Response	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Clinical Response	EOT	Stable	0	0	1 (6.3%)	0	1 (3.2%)
		Progression	1 (8.3%)	1 (100.0%)	0	0	2 (6.5%)
		Not Evaluable	4 (33.3%)	0	4 (25.0%)	1 (50.0%)	9 (29.0%)
		No Clinical Signs or Symptoms at Baseline	0	0	0	0	0
		Not Assessed	4 (33.3%)	0	4 (25.0%)	1 (50.0%)	9 (29.0%)
Mycological Response	Day 42	Success	0	0	0	0	0
		Eradication	0	0	0	0	0
		Presumed Eradication	0	0	0	0	0
		Failure	1 (8.3%)	0	0	0	1 (3.2%)
		Persistence	0	0	0	0	0
		Presumed Persistence	1 (8.3%)	0	0	0	1 (3.2%)
		Not Evaluable	0	0	4 (25.0%)	0	4 (12.9%)
		No Mycological Evidence	0	0	4 (25.0%)	0	4 (12.9%)
	Day 84	Success	1 (8.3%)	0	0	0	1 (3.2%)
		Eradication	0	0	0	0	0
		Presumed Eradication	1 (8.3%)	0	0	0	1 (3.2%)
		Failure	0	0	0	0	0
		Persistence	0	0	0	0	0
		Presumed Persistence	0	0	0	0	0
		Not Evaluable	0	0	2 (12.5%)	0	2 (6.5%)
		No Mycological Evidence	0	0	2 (12.5%)	0	2 (6.5%)

AC: Adjudication Committee; IA: Invasive Aspergillosis; IM: Invasive Mucormycosis; IFD: Invasive Fungal Disease; EOT: End of Treatment.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
If subject did not reach Day 42 or Day 84 of therapy then the AC did not perform these assessments.
The frequency 'N' in a column heading represents the number of subjects by the Investigator assessment of IFD diagnosis.
Overall Response will be based on a composite of clinical, mycological, and radiological responses with success criteria assessed.
Overall Response is considered 'Not-evaluable' when one of the composite responses is 'Not Assessed'.

AC-Assessed Overall/Clinical/Mycological/Radiological Response by Age Group
Full Analysis Set

Age Group=>=12 to <18 Years (N=12)

Outcome	Timepoint	Response	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Mycological Response	EOT	Success	3 (25.0%)	0	0	0	3 (9.7%)
		Eradication	0	0	0	0	0
		Presumed Eradication	3 (25.0%)	0	0	0	3 (9.7%)
		Failure	2 (16.7%)	1 (100.0%)	0	0	3 (9.7%)
		Persistence	1 (8.3%)	0	0	0	1 (3.2%)
		Presumed Persistence	1 (8.3%)	1 (100.0%)	0	0	2 (6.5%)
		Not Evaluable	0	0	5 (31.3%)	1 (50.0%)	6 (19.4%)
		No Mycological Evidence	0	0	5 (31.3%)	1 (50.0%)	6 (19.4%)
Radiological Response	Day 42	Success	1 (8.3%)	0	3 (18.8%)	0	4 (12.9%)
		Complete	0	0	0	0	0
		Partial	1 (8.3%)	0	3 (18.8%)	0	4 (12.9%)
		Failure	0	0	0	0	0
		Stable	0	0	0	0	0
		Progression	0	0	0	0	0
		Not Evaluable	0	0	1 (6.3%)	0	1 (3.2%)
		No Post Baseline Radiology Available With Baseline Evidence of Radiologic Disease	0	0	1 (6.3%)	0	1 (3.2%)
		Radiology Not Applicable at Baseline	0	0	0	0	0
	Day 84	Success	1 (8.3%)	0	2 (12.5%)	0	3 (9.7%)
		Complete	0	0	1 (6.3%)	0	1 (3.2%)
		Partial	1 (8.3%)	0	1 (6.3%)	0	2 (6.5%)

AC: Adjudication Committee; IA: Invasive Aspergillosis; IM: Invasive Mucormycosis; IFD: Invasive Fungal Disease; EOT: End of Treatment.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
If subject did not reach Day 42 or Day 84 of therapy then the AC did not perform these assessments.
The frequency 'N' in a column heading represents the number of subjects by the Investigator assessment of IFD diagnosis.
Overall Response will be based on a composite of clinical, mycological, and radiological responses with success criteria assessed.
Overall Response is considered 'Not-evaluable' when one of the composite responses is 'Not Assessed'.

AC-Assessed Overall/Clinical/Mycological/Radiological Response by Age Group
Full Analysis Set

Age Group=>=12 to <18 Years (N=12)

Outcome	Timepoint	Response	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Radiological Response	Day 84	Failure	0	0	0	0	0
		Stable	0	0	0	0	0
		Progression	0	0	0	0	0
		Not Evaluable	0	0	0	0	0
		No Post Baseline Radiology Available With Baseline Evidence of Radiologic Disease	0	0	0	0	0
		Radiology Not Applicable at Baseline	0	0	0	0	0
	EOT	Success	2 (16.7%)	0	4 (25.0%)	0	6 (19.4%)
		Complete	1 (8.3%)	0	1 (6.3%)	0	2 (6.5%)
		Partial	1 (8.3%)	0	3 (18.8%)	0	4 (12.9%)
		Failure	2 (16.7%)	1 (100.0%)	0	0	3 (9.7%)
		Stable	0	0	0	0	0
		Progression	2 (16.7%)	1 (100.0%)	0	0	3 (9.7%)
		Not Evaluable	1 (8.3%)	0	1 (6.3%)	1 (50.0%)	3 (9.7%)
		No Post Baseline Radiology Available With Baseline Evidence of Radiologic Disease	1 (8.3%)	0	1 (6.3%)	0	2 (6.5%)
		Radiology Not Applicable at Baseline	0	0	0	1 (50.0%)	1 (3.2%)

AC: Adjudication Committee; IA: Invasive Aspergillosis; IM: Invasive Mucormycosis; IFD: Invasive Fungal Disease; EOT: End of Treatment.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
If subject did not reach Day 42 or Day 84 of therapy then the AC did not perform these assessments.
The frequency 'N' in a column heading represents the number of subjects by the Investigator assessment of IFD diagnosis.
Overall Response will be based on a composite of clinical, mycological, and radiological responses with success criteria assessed.
Overall Response is considered 'Not-evaluable' when one of the composite responses is 'Not Assessed'.

2.3 Sicherheit

Treatment-Emergent Adverse Event (MedDRA v23.0) by Age Group
Safety Analysis Set
Subgroup Factor: Age (Year)

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Overall	1 to <12	6/ 7 (85.7%)	0	10/11 (90.9%)	1/ 1 (100.0%)	17/19 (89.5%)
	>=12 to <18	5/ 5 (100.0%)	1/ 1 (100.0%)	5/ 5 (100.0%)	1/ 1 (100.0%)	12/12 (100.0%)
Blood and lymphatic system disorders	1 to <12	3/ 7 (42.9%)	0	4/11 (36.4%)	0	7/19 (36.8%)
	>=12 to <18	3/ 5 (60.0%)	0	1/ 5 (20.0%)	1/ 1 (100.0%)	5/12 (41.7%)
Anaemia	1 to <12	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
	>=12 to <18	1/ 5 (20.0%)	0	1/ 5 (20.0%)	0	2/12 (16.7%)
Febrile neutropenia	1 to <12	2/ 7 (28.6%)	0	0	0	2/19 (10.5%)
	>=12 to <18	1/ 5 (20.0%)	0	0	0	1/12 (8.3%)
Lymphopenia	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	1/ 5 (20.0%)	0	0	1/ 1 (100.0%)	2/12 (16.7%)
Thrombocytopenia	1 to <12	0	0	2/11 (18.2%)	0	2/19 (10.5%)
	>=12 to <18	1/ 5 (20.0%)	0	0	0	1/12 (8.3%)
Neutropenia	1 to <12	0	0	0	0	0
	>=12 to <18	1/ 5 (20.0%)	0	1/ 5 (20.0%)	0	2/12 (16.7%)
Coagulopathy	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Leukocytosis	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Age Group
Safety Analysis Set
Subgroup Factor: Age (Year)

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Leukopenia	1 to <12	0	0	0	0	0
	>=12 to <18	1/ 5 (20.0%)	0	0	0	1/12 (8.3%)
Thrombocytosis	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Immune thrombocytopenia	1 to <12	0	0	0	0	0
	>=12 to <18	1/ 5 (20.0%)	0	0	0	1/12 (8.3%)
Cardiac disorders	1 to <12	0	0	3/11 (27.3%)	0	3/19 (15.8%)
	>=12 to <18	1/ 5 (20.0%)	0	2/ 5 (40.0%)	0	3/12 (25.0%)
Tachycardia	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	1/ 5 (20.0%)	0	1/ 5 (20.0%)	0	2/12 (16.7%)
Arrhythmia supraventricular	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Cardiac failure	1 to <12	0	0	0	0	0
	>=12 to <18	1/ 5 (20.0%)	0	0	0	1/12 (8.3%)
Cardio-respiratory arrest	1 to <12	0	0	0	0	0
	>=12 to <18	1/ 5 (20.0%)	0	0	0	1/12 (8.3%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Age Group
Safety Analysis Set
Subgroup Factor: Age (Year)

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Pericardial effusion	1 to <12	0	0	0	0	0
	>=12 to <18	0	0	1/ 5 (20.0%)	0	1/12 (8.3%)
Sinus arrhythmia	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Ventricular hypokinesia	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Right atrial enlargement	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Ear and labyrinth disorders	1 to <12	2/ 7 (28.6%)	0	0	0	2/19 (10.5%)
	>=12 to <18	0	0	0	0	0
Ear pain	1 to <12	2/ 7 (28.6%)	0	0	0	2/19 (10.5%)
	>=12 to <18	0	0	0	0	0
Endocrine disorders	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	1/ 1 (100.0%)	1/12 (8.3%)
Cushingoid	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Thyroid cyst	1 to <12	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Age Group
Safety Analysis Set
Subgroup Factor: Age (Year)

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Thyroid cyst	>=12 to <18	0	0	0	1/ 1 (100.0%)	1/12 (8.3%)
Eye disorders	1 to <12	2/ 7 (28.6%)	0	1/11 (9.1%)	0	3/19 (15.8%)
	>=12 to <18	0	0	1/ 5 (20.0%)	1/ 1 (100.0%)	2/12 (16.7%)
Episcleritis	1 to <12	0	0	0	0	0
	>=12 to <18	0	0	0	1/ 1 (100.0%)	1/12 (8.3%)
Eye pain	1 to <12	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Mydriasis	1 to <12	0	0	0	0	0
	>=12 to <18	0	0	1/ 5 (20.0%)	0	1/12 (8.3%)
Pupils unequal	1 to <12	0	0	0	0	0
	>=12 to <18	0	0	1/ 5 (20.0%)	0	1/12 (8.3%)
Strabismus	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Swelling of eyelid	1 to <12	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Meibomian gland dysfunction	1 to <12	0	0	0	0	0
	>=12 to <18	0	0	0	1/ 1 (100.0%)	1/12 (8.3%)
Gastrointestinal disorders	1 to <12	5/ 7 (71.4%)	0	7/11 (63.6%)	1/ 1 (100.0%)	13/19 (68.4%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Age Group
Safety Analysis Set
Subgroup Factor: Age (Year)

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Gastrointestinal disorders	>=12 to <18	3/ 5 (60.0%)	1/ 1 (100.0%)	3/ 5 (60.0%)	1/ 1 (100.0%)	8/12 (66.7%)
Diarrhoea	1 to <12	3/ 7 (42.9%)	0	2/11 (18.2%)	0	5/19 (26.3%)
	>=12 to <18	1/ 5 (20.0%)	1/ 1 (100.0%)	1/ 5 (20.0%)	0	3/12 (25.0%)
Vomiting	1 to <12	3/ 7 (42.9%)	0	1/11 (9.1%)	0	4/19 (21.1%)
	>=12 to <18	1/ 5 (20.0%)	0	2/ 5 (40.0%)	0	3/12 (25.0%)
Stomatitis	1 to <12	2/ 7 (28.6%)	0	1/11 (9.1%)	1/ 1 (100.0%)	4/19 (21.1%)
	>=12 to <18	0	0	1/ 5 (20.0%)	0	1/12 (8.3%)
Abdominal distension	1 to <12	1/ 7 (14.3%)	0	1/11 (9.1%)	0	2/19 (10.5%)
	>=12 to <18	1/ 5 (20.0%)	0	1/ 5 (20.0%)	0	2/12 (16.7%)
Aphthous ulcer	1 to <12	3/ 7 (42.9%)	0	1/11 (9.1%)	0	4/19 (21.1%)
	>=12 to <18	0	0	0	0	0
Nausea	1 to <12	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
	>=12 to <18	1/ 5 (20.0%)	0	2/ 5 (40.0%)	0	3/12 (25.0%)
Abdominal pain	1 to <12	0	0	1/11 (9.1%)	1/ 1 (100.0%)	2/19 (10.5%)
	>=12 to <18	0	0	1/ 5 (20.0%)	0	1/12 (8.3%)
Constipation	1 to <12	2/ 7 (28.6%)	0	0	1/ 1 (100.0%)	3/19 (15.8%)
	>=12 to <18	0	0	0	0	0

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Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Age Group
Safety Analysis Set
Subgroup Factor: Age (Year)

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Abdominal pain upper	1 to <12	0	0	0	0	0
	>=12 to <18	0	0	0	1/ 1 (100.0%)	1/12 (8.3%)
Dental caries	1 to <12	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Dysphagia	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Gastrointestinal haemorrhage	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Gingival bleeding	1 to <12	0	0	0	0	0
	>=12 to <18	0	0	1/ 5 (20.0%)	0	1/12 (8.3%)
Haematochezia	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Lip dry	1 to <12	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Lip ulceration	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Mouth haemorrhage	1 to <12	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Age Group
Safety Analysis Set
Subgroup Factor: Age (Year)

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Oral pain	1 to <12	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Rectal haemorrhage	1 to <12	0	0	0	0	0
	>=12 to <18	0	0	1/ 5 (20.0%)	0	1/12 (8.3%)
Anal inflammation	1 to <12	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Oral pruritus	1 to <12	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
General disorders and administration site conditions	1 to <12	6/ 7 (85.7%)	0	4/11 (36.4%)	1/ 1 (100.0%)	11/19 (57.9%)
	>=12 to <18	2/ 5 (40.0%)	1/ 1 (100.0%)	3/ 5 (60.0%)	1/ 1 (100.0%)	7/12 (58.3%)
Pyrexia	1 to <12	2/ 7 (28.6%)	0	3/11 (27.3%)	0	5/19 (26.3%)
	>=12 to <18	1/ 5 (20.0%)	0	2/ 5 (40.0%)	1/ 1 (100.0%)	4/12 (33.3%)
Non-cardiac chest pain	1 to <12	2/ 7 (28.6%)	0	1/11 (9.1%)	1/ 1 (100.0%)	4/19 (21.1%)
	>=12 to <18	0	0	1/ 5 (20.0%)	0	1/12 (8.3%)
Chills	1 to <12	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
	>=12 to <18	0	0	1/ 5 (20.0%)	0	1/12 (8.3%)
Pain	1 to <12	0	0	0	1/ 1 (100.0%)	1/19 (5.3%)
	>=12 to <18	0	1/ 1 (100.0%)	0	0	1/12 (8.3%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Age Group
Safety Analysis Set
Subgroup Factor: Age (Year)

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Infusion site pain	1 to <12	0	0	0	0	0
	>=12 to <18	2/ 5 (40.0%)	0	0	0	2/12 (16.7%)
Chest pain	1 to <12	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Influenza like illness	1 to <12	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Injection site reaction	1 to <12	0	0	0	0	0
	>=12 to <18	1/ 5 (20.0%)	0	0	0	1/12 (8.3%)
Malaise	1 to <12	0	0	0	0	0
	>=12 to <18	1/ 5 (20.0%)	0	0	0	1/12 (8.3%)
Oedema	1 to <12	0	0	0	0	0
	>=12 to <18	0	0	1/ 5 (20.0%)	0	1/12 (8.3%)
Oedema peripheral	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Catheter site haemorrhage	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Infusion site pruritus	1 to <12	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Age Group
Safety Analysis Set
Subgroup Factor: Age (Year)

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Infusion site pruritus	>=12 to <18	1/ 5 (20.0%)	0	0	0	1/12 (8.3%)
Infusion site extravasation	1 to <12	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Mucosal induration	1 to <12	0	0	0	1/ 1 (100.0%)	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Catheter site ulcer	1 to <12	0	0	0	0	0
	>=12 to <18	0	0	1/ 5 (20.0%)	0	1/12 (8.3%)
Hepatobiliary disorders	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	1/ 5 (20.0%)	0	1/12 (8.3%)
Jaundice	1 to <12	0	0	0	0	0
	>=12 to <18	0	0	1/ 5 (20.0%)	0	1/12 (8.3%)
Liver disorder	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Venoocclusive liver disease	1 to <12	0	0	0	0	0
	>=12 to <18	0	0	1/ 5 (20.0%)	0	1/12 (8.3%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Age Group
Safety Analysis Set
Subgroup Factor: Age (Year)

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Hypertransaminasaemia	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Immune system disorders	1 to <12	2/ 7 (28.6%)	0	2/11 (18.2%)	0	4/19 (21.1%)
	>=12 to <18	0	0	0	0	0
Drug hypersensitivity	1 to <12	2/ 7 (28.6%)	0	0	0	2/19 (10.5%)
	>=12 to <18	0	0	0	0	0
Graft versus host disease	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Hypogammaglobulinaemia	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Infections and infestations	1 to <12	5/ 7 (71.4%)	0	6/11 (54.5%)	0	11/19 (57.9%)
	>=12 to <18	3/ 5 (60.0%)	0	4/ 5 (80.0%)	0	7/12 (58.3%)
Rhinitis	1 to <12	1/ 7 (14.3%)	0	1/11 (9.1%)	0	2/19 (10.5%)
	>=12 to <18	0	0	1/ 5 (20.0%)	0	1/12 (8.3%)
Septic shock	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	2/ 5 (40.0%)	0	2/12 (16.7%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Age Group
Safety Analysis Set
Subgroup Factor: Age (Year)

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Folliculitis	1 to <12	2/ 7 (28.6%)	0	0	0	2/19 (10.5%)
	>=12 to <18	0	0	0	0	0
Pneumonia	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	1/ 5 (20.0%)	0	0	0	1/12 (8.3%)
Oral herpes	1 to <12	2/ 7 (28.6%)	0	0	0	2/19 (10.5%)
	>=12 to <18	0	0	0	0	0
COVID-19	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	1/ 5 (20.0%)	0	0	0	1/12 (8.3%)
Bacteraemia	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Brain abscess	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Cryptosporidiosis infection	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Epstein-Barr virus infection	1 to <12	0	0	0	0	0
	>=12 to <18	1/ 5 (20.0%)	0	0	0	1/12 (8.3%)
Escherichia sepsis	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Age Group
Safety Analysis Set
Subgroup Factor: Age (Year)

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Gingivitis	1 to <12	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Herpes simplex	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Influenza	1 to <12	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Nasopharyngitis	1 to <12	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Pneumonia pseudomonal	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Sepsis	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Sinusitis	1 to <12	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Subcutaneous abscess	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Streptococcal sepsis	1 to <12	0	0	0	0	0
	>=12 to <18	0	0	1/ 5 (20.0%)	0	1/12 (8.3%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Age Group
Safety Analysis Set
Subgroup Factor: Age (Year)

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Staphylococcal bacteraemia	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Bacterial sepsis	1 to <12	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Pneumococcal sepsis	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Urinary tract infection bacterial	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Clostridium difficile infection	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Klebsiella bacteraemia	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Enterobacter bacteraemia	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Age Group
Safety Analysis Set
Subgroup Factor: Age (Year)

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Pseudomonal bacteraemia	1 to <12	0	0	0	0	0
	>=12 to <18	1/ 5 (20.0%)	0	0	0	1/12 (8.3%)
Respiratory tract infection bacterial	1 to <12	0	0	0	0	0
	>=12 to <18	1/ 5 (20.0%)	0	0	0	1/12 (8.3%)
Herpes dermatitis	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Device related infection	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Vascular device infection	1 to <12	0	0	0	0	0
	>=12 to <18	0	0	1/ 5 (20.0%)	0	1/12 (8.3%)
Injury, poisoning and procedural complications	1 to <12	2/ 7 (28.6%)	0	2/11 (18.2%)	0	4/19 (21.1%)
	>=12 to <18	2/ 5 (40.0%)	0	1/ 5 (20.0%)	0	3/12 (25.0%)
Infusion related reaction	1 to <12	0	0	0	0	0
	>=12 to <18	1/ 5 (20.0%)	0	0	0	1/12 (8.3%)

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Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Age Group
Safety Analysis Set
Subgroup Factor: Age (Year)

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Wound	1 to <12	0	0	0	0	0
	>=12 to <18	0	0	1/ 5 (20.0%)	0	1/12 (8.3%)
Limb injury	1 to <12	0	0	0	0	0
	>=12 to <18	0	0	1/ 5 (20.0%)	0	1/12 (8.3%)
Skeletal injury	1 to <12	0	0	0	0	0
	>=12 to <18	0	0	1/ 5 (20.0%)	0	1/12 (8.3%)
Procedural hypotension	1 to <12	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Procedural pain	1 to <12	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Skin abrasion	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Allergic transfusion reaction	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Procedural haemorrhage	1 to <12	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0

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Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
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Treatment-Emergent Adverse Event (MedDRA v23.0) by Age Group
Safety Analysis Set
Subgroup Factor: Age (Year)

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Vascular access site pain	1 to <12	0	0	0	0	0
	>=12 to <18	1/ 5 (20.0%)	0	0	0	1/12 (8.3%)
Investigations	1 to <12	1/ 7 (14.3%)	0	5/11 (45.5%)	0	6/19 (31.6%)
	>=12 to <18	3/ 5 (60.0%)	1/ 1 (100.0%)	2/ 5 (40.0%)	1/ 1 (100.0%)	7/12 (58.3%)
Transaminases increased	1 to <12	1/ 7 (14.3%)	0	1/11 (9.1%)	0	2/19 (10.5%)
	>=12 to <18	0	0	0	0	0
QRS axis abnormal	1 to <12	0	0	2/11 (18.2%)	0	2/19 (10.5%)
	>=12 to <18	0	0	0	0	0
Alanine aminotransferase increased	1 to <12	0	0	0	0	0
	>=12 to <18	1/ 5 (20.0%)	0	0	0	1/12 (8.3%)
Aspartate aminotransferase increased	1 to <12	0	0	0	0	0
	>=12 to <18	1/ 5 (20.0%)	0	0	0	1/12 (8.3%)
Blood bilirubin increased	1 to <12	0	0	0	0	0
	>=12 to <18	0	1/ 1 (100.0%)	0	0	1/12 (8.3%)

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Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
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Treatment-Emergent Adverse Event (MedDRA v23.0) by Age Group
Safety Analysis Set
Subgroup Factor: Age (Year)

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Blood fibrinogen increased	1 to <12	0	0	0	0	0
	>=12 to <18	1/ 5 (20.0%)	0	0	0	1/12 (8.3%)
Blood potassium decreased	1 to <12	0	0	0	0	0
	>=12 to <18	1/ 5 (20.0%)	0	0	0	1/12 (8.3%)
C-reactive protein increased	1 to <12	0	0	0	0	0
	>=12 to <18	0	0	0	1/ 1 (100.0%)	1/12 (8.3%)
Electrocardiogram QT prolonged	1 to <12	0	0	0	0	0
	>=12 to <18	0	0	1/ 5 (20.0%)	0	1/12 (8.3%)
Electrocardiogram T wave inversion	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Gamma-glutamyltransferase increased	1 to <12	0	0	0	0	0
	>=12 to <18	0	0	1/ 5 (20.0%)	0	1/12 (8.3%)
Blood urine present	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0

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Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Age Group
Safety Analysis Set
Subgroup Factor: Age (Year)

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Heart rate increased	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Iron binding capacity total decreased	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Neutrophil count decreased	1 to <12	0	0	0	0	0
	>=12 to <18	1/ 5 (20.0%)	0	0	0	1/12 (8.3%)
Oxygen saturation decreased	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Platelet count decreased	1 to <12	0	0	0	0	0
	>=12 to <18	0	0	1/ 5 (20.0%)	0	1/12 (8.3%)
Serum ferritin increased	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
White blood cell count decreased	1 to <12	0	0	0	0	0
	>=12 to <18	0	0	1/ 5 (20.0%)	0	1/12 (8.3%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Age Group
Safety Analysis Set
Subgroup Factor: Age (Year)

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Electrocardiogram T wave abnormal	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Urine output decreased	1 to <12	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Hepatic enzyme increased	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Double stranded DNA antibody positive	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Clostridium test positive	1 to <12	0	0	0	0	0
	>=12 to <18	1/ 5 (20.0%)	0	0	0	1/12 (8.3%)
Human rhinovirus test	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Metabolism and nutrition disorders	1 to <12	1/ 7 (14.3%)	0	5/11 (45.5%)	0	6/19 (31.6%)
	>=12 to <18	2/ 5 (40.0%)	1/ 1 (100.0%)	3/ 5 (60.0%)	0	6/12 (50.0%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Age Group
Safety Analysis Set
Subgroup Factor: Age (Year)

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Hypoalbuminaemia	1 to <12	0	0	3/11 (27.3%)	0	3/19 (15.8%)
	>=12 to <18	0	0	1/ 5 (20.0%)	0	1/12 (8.3%)
Hypokalaemia	1 to <12	0	0	2/11 (18.2%)	0	2/19 (10.5%)
	>=12 to <18	1/ 5 (20.0%)	1/ 1 (100.0%)	0	0	2/12 (16.7%)
Hyperkalaemia	1 to <12	1/ 7 (14.3%)	0	1/11 (9.1%)	0	2/19 (10.5%)
	>=12 to <18	0	0	0	0	0
Hypophosphataemia	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	1/ 5 (20.0%)	0	1/12 (8.3%)
Alkalosis	1 to <12	0	0	0	0	0
	>=12 to <18	0	0	1/ 5 (20.0%)	0	1/12 (8.3%)
Fluid overload	1 to <12	0	0	0	0	0
	>=12 to <18	0	0	1/ 5 (20.0%)	0	1/12 (8.3%)
Hyperglycaemia	1 to <12	0	0	0	0	0
	>=12 to <18	1/ 5 (20.0%)	0	0	0	1/12 (8.3%)
Hyperphosphataemia	1 to <12	0	0	0	0	0
	>=12 to <18	0	1/ 1 (100.0%)	0	0	1/12 (8.3%)
Hypertriglyceridaemia	1 to <12	0	0	0	0	0
	>=12 to <18	0	0	1/ 5 (20.0%)	0	1/12 (8.3%)
Hypocalcaemia	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Age Group
Safety Analysis Set
Subgroup Factor: Age (Year)

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Hypocalcaemia	>=12 to <18	0	0	0	0	0
Hypochloraemia	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Hypomagnesaemia	1 to <12	0	0	0	0	0
	>=12 to <18	0	0	1/ 5 (20.0%)	0	1/12 (8.3%)
Hypoproteinaemia	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Metabolic acidosis	1 to <12	0	0	0	0	0
	>=12 to <18	1/ 5 (20.0%)	0	0	0	1/12 (8.3%)
Decreased appetite	1 to <12	0	0	0	0	0
	>=12 to <18	0	0	1/ 5 (20.0%)	0	1/12 (8.3%)
Hypophagia	1 to <12	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Iron overload	1 to <12	0	0	0	0	0
	>=12 to <18	1/ 5 (20.0%)	0	0	0	1/12 (8.3%)
Musculoskeletal and connective tissue disorders	1 to <12	3/ 7 (42.9%)	0	3/11 (27.3%)	1/ 1 (100.0%)	7/19 (36.8%)
	>=12 to <18	2/ 5 (40.0%)	0	1/ 5 (20.0%)	0	3/12 (25.0%)
Arthralgia	1 to <12	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Age Group
Safety Analysis Set
Subgroup Factor: Age (Year)

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Arthralgia	>=12 to <18	1/ 5 (20.0%)	0	1/ 5 (20.0%)	0	2/12 (16.7%)
Muscle spasms	1 to <12	0	0	0	0	0
	>=12 to <18	2/ 5 (40.0%)	0	0	0	2/12 (16.7%)
Pain in extremity	1 to <12	1/ 7 (14.3%)	0	0	1/ 1 (100.0%)	2/19 (10.5%)
	>=12 to <18	0	0	0	0	0
Haemarthrosis	1 to <12	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Joint swelling	1 to <12	0	0	0	0	0
	>=12 to <18	0	0	1/ 5 (20.0%)	0	1/12 (8.3%)
Myalgia	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Rhabdomyolysis	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Synovitis	1 to <12	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Systemic lupus erythematosus	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Tendonitis	1 to <12	0	0	0	1/ 1 (100.0%)	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Age Group
Safety Analysis Set
Subgroup Factor: Age (Year)

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Foot deformity	1 to <12	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Nervous system disorders	1 to <12	0	0	2/11 (18.2%)	0	2/19 (10.5%)
	>=12 to <18	2/ 5 (40.0%)	1/ 1 (100.0%)	0	1/ 1 (100.0%)	4/12 (33.3%)
Headache	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	2/ 5 (40.0%)	0	0	0	2/12 (16.7%)
Dysgeusia	1 to <12	0	0	0	0	0
	>=12 to <18	0	0	0	1/ 1 (100.0%)	1/12 (8.3%)
Lethargy	1 to <12	0	0	0	0	0
	>=12 to <18	0	1/ 1 (100.0%)	0	0	1/12 (8.3%)
Seizure	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Psychiatric disorders	1 to <12	0	0	0	0	0
	>=12 to <18	0	0	2/ 5 (40.0%)	0	2/12 (16.7%)
Anxiety	1 to <12	0	0	0	0	0
	>=12 to <18	0	0	1/ 5 (20.0%)	0	1/12 (8.3%)
Confusional state	1 to <12	0	0	0	0	0
	>=12 to <18	0	0	1/ 5 (20.0%)	0	1/12 (8.3%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Age Group
Safety Analysis Set
Subgroup Factor: Age (Year)

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Insomnia	1 to <12	0	0	0	0	0
	>=12 to <18	0	0	1/ 5 (20.0%)	0	1/12 (8.3%)
Renal and urinary disorders	1 to <12	0	0	1/11 (9.1%)	1/ 1 (100.0%)	2/19 (10.5%)
	>=12 to <18	1/ 5 (20.0%)	1/ 1 (100.0%)	1/ 5 (20.0%)	0	3/12 (25.0%)
Anuria	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	1/ 5 (20.0%)	0	1/12 (8.3%)
Dysuria	1 to <12	0	0	0	1/ 1 (100.0%)	1/19 (5.3%)
	>=12 to <18	0	1/ 1 (100.0%)	0	0	1/12 (8.3%)
Azotaemia	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Glomerulonephritis	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Haematuria	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Hypertonic bladder	1 to <12	0	0	0	0	0
	>=12 to <18	0	0	1/ 5 (20.0%)	0	1/12 (8.3%)
Renal impairment	1 to <12	0	0	0	0	0
	>=12 to <18	1/ 5 (20.0%)	0	0	0	1/12 (8.3%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Age Group
Safety Analysis Set
Subgroup Factor: Age (Year)

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Reproductive system and breast disorders	1 to <12	0	0	2/11 (18.2%)	1/ 1 (100.0%)	3/19 (15.8%)
	>=12 to <18	0	0	1/ 5 (20.0%)	0	1/12 (8.3%)
Menorrhagia	1 to <12	0	0	0	0	0
	>=12 to <18	0	0	1/ 5 (20.0%)	0	1/12 (8.3%)
Pelvic pain	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Pruritus genital	1 to <12	0	0	0	1/ 1 (100.0%)	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Vulvovaginal erythema	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Respiratory, thoracic and mediastinal disorders	1 to <12	6/ 7 (85.7%)	0	4/11 (36.4%)	1/ 1 (100.0%)	11/19 (57.9%)
	>=12 to <18	2/ 5 (40.0%)	1/ 1 (100.0%)	3/ 5 (60.0%)	1/ 1 (100.0%)	7/12 (58.3%)
Cough	1 to <12	0	0	2/11 (18.2%)	0	2/19 (10.5%)
	>=12 to <18	0	0	1/ 5 (20.0%)	0	1/12 (8.3%)
Epistaxis	1 to <12	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
	>=12 to <18	0	0	2/ 5 (40.0%)	0	2/12 (16.7%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
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Treatment-Emergent Adverse Event (MedDRA v23.0) by Age Group
Safety Analysis Set
Subgroup Factor: Age (Year)

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Respiratory distress	1 to <12	1/ 7 (14.3%)	0	1/11 (9.1%)	0	2/19 (10.5%)
	>=12 to <18	1/ 5 (20.0%)	0	0	0	1/12 (8.3%)
Rhinorrhoea	1 to <12	2/ 7 (28.6%)	0	0	0	2/19 (10.5%)
	>=12 to <18	0	0	1/ 5 (20.0%)	0	1/12 (8.3%)
Tachypnoea	1 to <12	0	0	0	1/ 1 (100.0%)	1/19 (5.3%)
	>=12 to <18	1/ 5 (20.0%)	0	1/ 5 (20.0%)	0	2/12 (16.7%)
Dyspnoea	1 to <12	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
	>=12 to <18	0	1/ 1 (100.0%)	0	0	1/12 (8.3%)
Haemoptysis	1 to <12	0	0	0	0	0
	>=12 to <18	2/ 5 (40.0%)	0	0	0	2/12 (16.7%)
Hypoxia	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	1/ 1 (100.0%)	1/12 (8.3%)
Pleural effusion	1 to <12	1/ 7 (14.3%)	0	1/11 (9.1%)	0	2/19 (10.5%)
	>=12 to <18	0	0	0	0	0
Pulmonary oedema	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	1/ 5 (20.0%)	0	1/12 (8.3%)
Oropharyngeal pain	1 to <12	2/ 7 (28.6%)	0	0	0	2/19 (10.5%)
	>=12 to <18	0	0	0	0	0
Lung opacity	1 to <12	1/ 7 (14.3%)	0	1/11 (9.1%)	0	2/19 (10.5%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
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Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Age Group
Safety Analysis Set
Subgroup Factor: Age (Year)

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Lung opacity	>=12 to <18	0	0	0	0	0
Aphonia	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Atelectasis	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Dysphonia	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Lung infiltration	1 to <12	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Pneumothorax	1 to <12	0	0	0	0	0
	>=12 to <18	0	1/ 1 (100.0%)	0	0	1/12 (8.3%)
Pulmonary alveolar haemorrhage	1 to <12	0	0	0	0	0
	>=12 to <18	1/ 5 (20.0%)	0	0	0	1/12 (8.3%)
Rales	1 to <12	0	0	0	0	0
	>=12 to <18	0	0	1/ 5 (20.0%)	0	1/12 (8.3%)
Respiratory alkalosis	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0

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Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
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Treatment-Emergent Adverse Event (MedDRA v23.0) by Age Group
Safety Analysis Set
Subgroup Factor: Age (Year)

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Respiratory failure	1 to <12	0	0	0	0	0
	>=12 to <18	1/ 5 (20.0%)	0	0	0	1/12 (8.3%)
Stridor	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Pulmonary mass	1 to <12	0	0	0	0	0
	>=12 to <18	0	0	1/ 5 (20.0%)	0	1/12 (8.3%)
Increased bronchial secretion	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Increased upper airway secretion	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Increased viscosity of upper respiratory secretion	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Skin and subcutaneous tissue disorders	1 to <12	5/ 7 (71.4%)	0	4/11 (36.4%)	0	9/19 (47.4%)
	>=12 to <18	0	0	2/ 5 (40.0%)	0	2/12 (16.7%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Age Group
Safety Analysis Set
Subgroup Factor: Age (Year)

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Dry skin	1 to <12	3/ 7 (42.9%)	0	0	0	3/19 (15.8%)
	>=12 to <18	0	0	0	0	0
Pruritus	1 to <12	3/ 7 (42.9%)	0	0	0	3/19 (15.8%)
	>=12 to <18	0	0	0	0	0
Petechiae	1 to <12	2/ 7 (28.6%)	0	0	0	2/19 (10.5%)
	>=12 to <18	0	0	0	0	0
Rash	1 to <12	1/ 7 (14.3%)	0	1/11 (9.1%)	0	2/19 (10.5%)
	>=12 to <18	0	0	0	0	0
Urticaria	1 to <12	2/ 7 (28.6%)	0	0	0	2/19 (10.5%)
	>=12 to <18	0	0	0	0	0
Blister	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Dermatitis diaper	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Ecchymosis	1 to <12	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Erythema	1 to <12	0	0	0	0	0
	>=12 to <18	0	0	1/ 5 (20.0%)	0	1/12 (8.3%)
Idiopathic urticaria	1 to <12	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Age Group
Safety Analysis Set
Subgroup Factor: Age (Year)

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Idiopathic urticaria	>=12 to <18	0	0	0	0	0
Papule	1 to <12	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Rash maculo-papular	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Skin hyperpigmentation	1 to <12	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Skin toxicity	1 to <12	0	0	0	0	0
	>=12 to <18	0	0	1/ 5 (20.0%)	0	1/12 (8.3%)
Social circumstances	1 to <12	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Social problem	1 to <12	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Surgical and medical procedures	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Age Group
Safety Analysis Set
Subgroup Factor: Age (Year)

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Allogenic stem cell transplantation	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Vascular disorders	1 to <12	2/ 7 (28.6%)	0	1/11 (9.1%)	0	3/19 (15.8%)
	>=12 to <18	1/ 5 (20.0%)	1/ 1 (100.0%)	2/ 5 (40.0%)	0	4/12 (33.3%)
Hypertension	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	1/ 1 (100.0%)	1/ 5 (20.0%)	0	2/12 (16.7%)
Hypotension	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	2/ 5 (40.0%)	0	2/12 (16.7%)
Pallor	1 to <12	2/ 7 (28.6%)	0	0	0	2/19 (10.5%)
	>=12 to <18	0	0	0	0	0
Circulatory collapse	1 to <12	0	0	0	0	0
	>=12 to <18	1/ 5 (20.0%)	0	0	0	1/12 (8.3%)
Haematoma	1 to <12	0	0	0	0	0
	>=12 to <18	0	0	1/ 5 (20.0%)	0	1/12 (8.3%)
Labile blood pressure	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Age Group
Safety Analysis Set
Subgroup Factor: Age (Year)

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Peripheral venous disease	1 to <12	0	0	0	0	0
	>=12 to <18	0	0	1/ 5 (20.0%)	0	1/12 (8.3%)
Product issues	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Device leakage	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Gender
Safety Analysis Set
Subgroup Factor: Gender

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Overall	Male	2/ 2 (100.0%)	1/ 1 (100.0%)	3/ 3 (100.0%)	0	6/ 6 (100.0%)
	Female	9/10 (90.0%)	0	12/13 (92.3%)	2/ 2 (100.0%)	23/25 (92.0%)
Blood and lymphatic system disorders	Male	0	0	1/ 3 (33.3%)	0	1/ 6 (16.7%)
	Female	6/10 (60.0%)	0	4/13 (30.8%)	1/ 2 (50.0%)	11/25 (44.0%)
Anaemia	Male	0	0	1/ 3 (33.3%)	0	1/ 6 (16.7%)
	Female	2/10 (20.0%)	0	0	0	2/25 (8.0%)
Febrile neutropenia	Male	0	0	0	0	0
	Female	3/10 (30.0%)	0	0	0	3/25 (12.0%)
Lymphopenia	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	1/13 (7.7%)	1/ 2 (50.0%)	3/25 (12.0%)
Thrombocytopenia	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	2/13 (15.4%)	0	3/25 (12.0%)
Neutropenia	Male	0	0	1/ 3 (33.3%)	0	1/ 6 (16.7%)
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
Coagulopathy	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Leukocytosis	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Gender
Safety Analysis Set
Subgroup Factor: Gender

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Leukopenia	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
Thrombocytosis	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Immune thrombocytopenia	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
Cardiac disorders	Male	0	0	1/ 3 (33.3%)	0	1/ 6 (16.7%)
	Female	1/10 (10.0%)	0	4/13 (30.8%)	0	5/25 (20.0%)
Tachycardia	Male	0	0	1/ 3 (33.3%)	0	1/ 6 (16.7%)
	Female	1/10 (10.0%)	0	1/13 (7.7%)	0	2/25 (8.0%)
Arrhythmia supraventricular	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Cardiac failure	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
Cardio-respiratory arrest	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Gender
Safety Analysis Set
Subgroup Factor: Gender

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Pericardial effusion	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Sinus arrhythmia	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Ventricular hypokinesia	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Right atrial enlargement	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Ear and labyrinth disorders	Male	0	0	0	0	0
	Female	2/10 (20.0%)	0	0	0	2/25 (8.0%)
Ear pain	Male	0	0	0	0	0
	Female	2/10 (20.0%)	0	0	0	2/25 (8.0%)
Endocrine disorders	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	1/ 2 (50.0%)	2/25 (8.0%)
Cushingoid	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Thyroid cyst	Male	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Gender
Safety Analysis Set
Subgroup Factor: Gender

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Thyroid cyst	Female	0	0	0	1/ 2 (50.0%)	1/25 (4.0%)
Eye disorders	Male	1/ 2 (50.0%)	0	0	0	1/ 6 (16.7%)
	Female	1/10 (10.0%)	0	2/13 (15.4%)	1/ 2 (50.0%)	4/25 (16.0%)
Episcleritis	Male	0	0	0	0	0
	Female	0	0	0	1/ 2 (50.0%)	1/25 (4.0%)
Eye pain	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
Mydriasis	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Pupils unequal	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Strabismus	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Swelling of eyelid	Male	1/ 2 (50.0%)	0	0	0	1/ 6 (16.7%)
	Female	0	0	0	0	0
Meibomian gland dysfunction	Male	0	0	0	0	0
	Female	0	0	0	1/ 2 (50.0%)	1/25 (4.0%)
Gastrointestinal disorders	Male	1/ 2 (50.0%)	1/ 1 (100.0%)	2/ 3 (66.7%)	0	4/ 6 (66.7%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Gender
Safety Analysis Set
Subgroup Factor: Gender

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Gastrointestinal disorders	Female	7/10 (70.0%)	0	8/13 (61.5%)	2/ 2 (100.0%)	17/25 (68.0%)
Diarrhoea	Male	0	1/ 1 (100.0%)	0	0	1/ 6 (16.7%)
	Female	4/10 (40.0%)	0	3/13 (23.1%)	0	7/25 (28.0%)
Vomiting	Male	0	0	2/ 3 (66.7%)	0	2/ 6 (33.3%)
	Female	4/10 (40.0%)	0	1/13 (7.7%)	0	5/25 (20.0%)
Stomatitis	Male	0	0	0	0	0
	Female	2/10 (20.0%)	0	2/13 (15.4%)	1/ 2 (50.0%)	5/25 (20.0%)
Abdominal distension	Male	1/ 2 (50.0%)	0	0	0	1/ 6 (16.7%)
	Female	1/10 (10.0%)	0	2/13 (15.4%)	0	3/25 (12.0%)
Aphthous ulcer	Male	1/ 2 (50.0%)	0	1/ 3 (33.3%)	0	2/ 6 (33.3%)
	Female	2/10 (20.0%)	0	0	0	2/25 (8.0%)
Nausea	Male	0	0	1/ 3 (33.3%)	0	1/ 6 (16.7%)
	Female	2/10 (20.0%)	0	1/13 (7.7%)	0	3/25 (12.0%)
Abdominal pain	Male	0	0	0	0	0
	Female	0	0	2/13 (15.4%)	1/ 2 (50.0%)	3/25 (12.0%)
Constipation	Male	0	0	0	0	0
	Female	2/10 (20.0%)	0	0	1/ 2 (50.0%)	3/25 (12.0%)

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Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Gender
Safety Analysis Set
Subgroup Factor: Gender

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Abdominal pain upper	Male	0	0	0	0	0
	Female	0	0	0	1/ 2 (50.0%)	1/25 (4.0%)
Dental caries	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
Dysphagia	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Gastrointestinal haemorrhage	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Gingival bleeding	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Haematochezia	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Lip dry	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
Lip ulceration	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Mouth haemorrhage	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)

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Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Gender
Safety Analysis Set
Subgroup Factor: Gender

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Oral pain	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
Rectal haemorrhage	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Anal inflammation	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
Oral pruritus	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
General disorders and administration site conditions	Male	2/ 2 (100.0%)	1/ 1 (100.0%)	1/ 3 (33.3%)	0	4/ 6 (66.7%)
	Female	6/10 (60.0%)	0	6/13 (46.2%)	2/ 2 (100.0%)	14/25 (56.0%)
Pyrexia	Male	0	0	1/ 3 (33.3%)	0	1/ 6 (16.7%)
	Female	3/10 (30.0%)	0	4/13 (30.8%)	1/ 2 (50.0%)	8/25 (32.0%)
Non-cardiac chest pain	Male	1/ 2 (50.0%)	0	0	0	1/ 6 (16.7%)
	Female	1/10 (10.0%)	0	2/13 (15.4%)	1/ 2 (50.0%)	4/25 (16.0%)
Chills	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	1/13 (7.7%)	0	2/25 (8.0%)
Pain	Male	0	1/ 1 (100.0%)	0	0	1/ 6 (16.7%)
	Female	0	0	0	1/ 2 (50.0%)	1/25 (4.0%)

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Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
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Treatment-Emergent Adverse Event (MedDRA v23.0) by Gender
Safety Analysis Set
Subgroup Factor: Gender

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Infusion site pain	Male	1/ 2 (50.0%)	0	0	0	1/ 6 (16.7%)
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
Chest pain	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
Influenza like illness	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
Injection site reaction	Male	1/ 2 (50.0%)	0	0	0	1/ 6 (16.7%)
	Female	0	0	0	0	0
Malaise	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
Oedema	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Oedema peripheral	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Catheter site haemorrhage	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Infusion site pruritus	Male	1/ 2 (50.0%)	0	0	0	1/ 6 (16.7%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
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Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Gender
Safety Analysis Set
Subgroup Factor: Gender

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Infusion site pruritus	Female	0	0	0	0	0
Infusion site extravasation	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
Mucosal induration	Male	0	0	0	0	0
	Female	0	0	0	1/ 2 (50.0%)	1/25 (4.0%)
Catheter site ulcer	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Hepatobiliary disorders	Male	0	0	0	0	0
	Female	0	0	2/13 (15.4%)	0	2/25 (8.0%)
Jaundice	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Liver disorder	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Venoocclusive liver disease	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)

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Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Gender
Safety Analysis Set
Subgroup Factor: Gender

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Hypertransaminasaemia	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Immune system disorders	Male	0	0	0	0	0
	Female	2/10 (20.0%)	0	2/13 (15.4%)	0	4/25 (16.0%)
Drug hypersensitivity	Male	0	0	0	0	0
	Female	2/10 (20.0%)	0	0	0	2/25 (8.0%)
Graft versus host disease	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Hypogammaglobulinaemia	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Infections and infestations	Male	1/ 2 (50.0%)	0	1/ 3 (33.3%)	0	2/ 6 (33.3%)
	Female	7/10 (70.0%)	0	9/13 (69.2%)	0	16/25 (64.0%)
Rhinitis	Male	1/ 2 (50.0%)	0	0	0	1/ 6 (16.7%)
	Female	0	0	2/13 (15.4%)	0	2/25 (8.0%)
Septic shock	Male	0	0	0	0	0
	Female	0	0	3/13 (23.1%)	0	3/25 (12.0%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Gender
Safety Analysis Set
Subgroup Factor: Gender

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Folliculitis	Male	0	0	0	0	0
	Female	2/10 (20.0%)	0	0	0	2/25 (8.0%)
Pneumonia	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	1/13 (7.7%)	0	2/25 (8.0%)
Oral herpes	Male	0	0	0	0	0
	Female	2/10 (20.0%)	0	0	0	2/25 (8.0%)
COVID-19	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	1/13 (7.7%)	0	2/25 (8.0%)
Bacteraemia	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Brain abscess	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Cryptosporidiosis infection	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Epstein-Barr virus infection	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
Escherichia sepsis	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)

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Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Gender
Safety Analysis Set
Subgroup Factor: Gender

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Gingivitis	Male	1/ 2 (50.0%)	0	0	0	1/ 6 (16.7%)
	Female	0	0	0	0	0
Herpes simplex	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Influenza	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
Nasopharyngitis	Male	1/ 2 (50.0%)	0	0	0	1/ 6 (16.7%)
	Female	0	0	0	0	0
Pneumonia pseudomonal	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Sepsis	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Sinusitis	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
Subcutaneous abscess	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Streptococcal sepsis	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)

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Treatment-Emergent Adverse Event (MedDRA v23.0) by Gender
Safety Analysis Set
Subgroup Factor: Gender

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Staphylococcal bacteraemia	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Bacterial sepsis	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
Pneumococcal sepsis	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Urinary tract infection bacterial	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Clostridium difficile infection	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Klebsiella bacteraemia	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Enterobacter bacteraemia	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Gender
Safety Analysis Set
Subgroup Factor: Gender

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Pseudomonal bacteraemia	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
Respiratory tract infection bacterial	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
Herpes dermatitis	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Device related infection	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Vascular device infection	Male	0	0	1/ 3 (33.3%)	0	1/ 6 (16.7%)
	Female	0	0	0	0	0
Injury, poisoning and procedural complications	Male	1/ 2 (50.0%)	0	0	0	1/ 6 (16.7%)
	Female	3/10 (30.0%)	0	3/13 (23.1%)	0	6/25 (24.0%)
Infusion related reaction	Male	1/ 2 (50.0%)	0	0	0	1/ 6 (16.7%)
	Female	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Gender
Safety Analysis Set
Subgroup Factor: Gender

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Wound	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Limb injury	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Skeletal injury	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Procedural hypotension	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
Procedural pain	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
Skin abrasion	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Allergic transfusion reaction	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Procedural haemorrhage	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Gender
Safety Analysis Set
Subgroup Factor: Gender

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Vascular access site pain	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
Investigations	Male	0	1/ 1 (100.0%)	1/ 3 (33.3%)	0	2/ 6 (33.3%)
	Female	4/10 (40.0%)	0	6/13 (46.2%)	1/ 2 (50.0%)	11/25 (44.0%)
Transaminases increased	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	1/13 (7.7%)	0	2/25 (8.0%)
QRS axis abnormal	Male	0	0	0	0	0
	Female	0	0	2/13 (15.4%)	0	2/25 (8.0%)
Alanine aminotransferase increased	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
Aspartate aminotransferase increased	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
Blood bilirubin increased	Male	0	1/ 1 (100.0%)	0	0	1/ 6 (16.7%)
	Female	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
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Treatment-Emergent Adverse Event (MedDRA v23.0) by Gender
Safety Analysis Set
Subgroup Factor: Gender

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Blood fibrinogen increased	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
Blood potassium decreased	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
C-reactive protein increased	Male	0	0	0	0	0
	Female	0	0	0	1/ 2 (50.0%)	1/25 (4.0%)
Electrocardiogram QT prolonged	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Electrocardiogram T wave inversion	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Gamma-glutamyltransferase increased	Male	0	0	1/ 3 (33.3%)	0	1/ 6 (16.7%)
	Female	0	0	0	0	0
Blood urine present	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)

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Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Gender
Safety Analysis Set
Subgroup Factor: Gender

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Heart rate increased	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Iron binding capacity total decreased	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Neutrophil count decreased	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
Oxygen saturation decreased	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Platelet count decreased	Male	0	0	1/ 3 (33.3%)	0	1/ 6 (16.7%)
	Female	0	0	0	0	0
Serum ferritin increased	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
White blood cell count decreased	Male	0	0	1/ 3 (33.3%)	0	1/ 6 (16.7%)
	Female	0	0	0	0	0

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Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Gender
Safety Analysis Set
Subgroup Factor: Gender

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Electrocardiogram T wave abnormal	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Urine output decreased	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
Hepatic enzyme increased	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Double stranded DNA antibody positive	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Clostridium test positive	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
Human rhinovirus test	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Metabolism and nutrition disorders	Male	0	1/ 1 (100.0%)	1/ 3 (33.3%)	0	2/ 6 (33.3%)
	Female	3/10 (30.0%)	0	7/13 (53.8%)	0	10/25 (40.0%)

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Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Gender
Safety Analysis Set
Subgroup Factor: Gender

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Hypoalbuminaemia	Male	0	0	1/ 3 (33.3%)	0	1/ 6 (16.7%)
	Female	0	0	3/13 (23.1%)	0	3/25 (12.0%)
Hypokalaemia	Male	0	1/ 1 (100.0%)	0	0	1/ 6 (16.7%)
	Female	1/10 (10.0%)	0	2/13 (15.4%)	0	3/25 (12.0%)
Hyperkalaemia	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	1/13 (7.7%)	0	2/25 (8.0%)
Hypophosphataemia	Male	0	0	0	0	0
	Female	0	0	2/13 (15.4%)	0	2/25 (8.0%)
Alkalosis	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Fluid overload	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Hyperglycaemia	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
Hyperphosphataemia	Male	0	1/ 1 (100.0%)	0	0	1/ 6 (16.7%)
	Female	0	0	0	0	0
Hypertriglyceridaemia	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Hypocalcaemia	Male	0	0	0	0	0

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Treatment-Emergent Adverse Event (MedDRA v23.0) by Gender
Safety Analysis Set
Subgroup Factor: Gender

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Hypocalcaemia	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Hypochloraemia	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Hypomagnesaemia	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Hypoproteinaemia	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Metabolic acidosis	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
Decreased appetite	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Hypophagia	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
Iron overload	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
Musculoskeletal and connective tissue disorders	Male	1/ 2 (50.0%)	0	1/ 3 (33.3%)	0	2/ 6 (33.3%)
	Female	4/10 (40.0%)	0	3/13 (23.1%)	1/ 2 (50.0%)	8/25 (32.0%)
Arthralgia	Male	0	0	1/ 3 (33.3%)	0	1/ 6 (16.7%)

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In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Gender
Safety Analysis Set
Subgroup Factor: Gender

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Arthralgia	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
Muscle spasms	Male	0	0	0	0	0
	Female	2/10 (20.0%)	0	0	0	2/25 (8.0%)
Pain in extremity	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	1/ 2 (50.0%)	2/25 (8.0%)
Haemarthrosis	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
Joint swelling	Male	0	0	1/ 3 (33.3%)	0	1/ 6 (16.7%)
	Female	0	0	0	0	0
Myalgia	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Rhabdomyolysis	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Synovitis	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
Systemic lupus erythematosus	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Tendonitis	Male	0	0	0	0	0
	Female	0	0	0	1/ 2 (50.0%)	1/25 (4.0%)

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Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Gender
Safety Analysis Set
Subgroup Factor: Gender

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Foot deformity	Male	1/ 2 (50.0%)	0	0	0	1/ 6 (16.7%)
	Female	0	0	0	0	0
Nervous system disorders	Male	0	1/ 1 (100.0%)	0	0	1/ 6 (16.7%)
	Female	2/10 (20.0%)	0	2/13 (15.4%)	1/ 2 (50.0%)	5/25 (20.0%)
Headache	Male	0	0	0	0	0
	Female	2/10 (20.0%)	0	1/13 (7.7%)	0	3/25 (12.0%)
Dysgeusia	Male	0	0	0	0	0
	Female	0	0	0	1/ 2 (50.0%)	1/25 (4.0%)
Lethargy	Male	0	1/ 1 (100.0%)	0	0	1/ 6 (16.7%)
	Female	0	0	0	0	0
Seizure	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Psychiatric disorders	Male	0	0	0	0	0
	Female	0	0	2/13 (15.4%)	0	2/25 (8.0%)
Anxiety	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Confusional state	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)

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Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Gender
Safety Analysis Set
Subgroup Factor: Gender

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Insomnia	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Renal and urinary disorders	Male	0	1/ 1 (100.0%)	0	0	1/ 6 (16.7%)
	Female	1/10 (10.0%)	0	2/13 (15.4%)	1/ 2 (50.0%)	4/25 (16.0%)
Anuria	Male	0	0	0	0	0
	Female	0	0	2/13 (15.4%)	0	2/25 (8.0%)
Dysuria	Male	0	1/ 1 (100.0%)	0	0	1/ 6 (16.7%)
	Female	0	0	0	1/ 2 (50.0%)	1/25 (4.0%)
Azotaemia	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Glomerulonephritis	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Haematuria	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Hypertonic bladder	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Renal impairment	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)

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Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Gender
Safety Analysis Set
Subgroup Factor: Gender

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Reproductive system and breast disorders	Male	0	0	0	0	0
	Female	0	0	3/13 (23.1%)	1/ 2 (50.0%)	4/25 (16.0%)
Menorrhagia	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Pelvic pain	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Pruritus genital	Male	0	0	0	0	0
	Female	0	0	0	1/ 2 (50.0%)	1/25 (4.0%)
Vulvovaginal erythema	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Respiratory, thoracic and mediastinal disorders	Male	1/ 2 (50.0%)	1/ 1 (100.0%)	0	0	2/ 6 (33.3%)
	Female	7/10 (70.0%)	0	7/13 (53.8%)	2/ 2 (100.0%)	16/25 (64.0%)
Cough	Male	0	0	0	0	0
	Female	0	0	3/13 (23.1%)	0	3/25 (12.0%)
Epistaxis	Male	1/ 2 (50.0%)	0	0	0	1/ 6 (16.7%)
	Female	0	0	2/13 (15.4%)	0	2/25 (8.0%)

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Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Gender
Safety Analysis Set
Subgroup Factor: Gender

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Respiratory distress	Male	0	0	0	0	0
	Female	2/10 (20.0%)	0	1/13 (7.7%)	0	3/25 (12.0%)
Rhinorrhoea	Male	0	0	0	0	0
	Female	2/10 (20.0%)	0	1/13 (7.7%)	0	3/25 (12.0%)
Tachypnoea	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	1/13 (7.7%)	1/ 2 (50.0%)	3/25 (12.0%)
Dyspnoea	Male	0	1/ 1 (100.0%)	0	0	1/ 6 (16.7%)
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
Haemoptysis	Male	0	0	0	0	0
	Female	2/10 (20.0%)	0	0	0	2/25 (8.0%)
Hypoxia	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	1/ 2 (50.0%)	2/25 (8.0%)
Pleural effusion	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	1/13 (7.7%)	0	2/25 (8.0%)
Pulmonary oedema	Male	0	0	0	0	0
	Female	0	0	2/13 (15.4%)	0	2/25 (8.0%)
Oropharyngeal pain	Male	0	0	0	0	0
	Female	2/10 (20.0%)	0	0	0	2/25 (8.0%)
Lung opacity	Male	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Gender
Safety Analysis Set
Subgroup Factor: Gender

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Lung opacity	Female	1/10 (10.0%)	0	1/13 (7.7%)	0	2/25 (8.0%)
Aphonia	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Atelectasis	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Dysphonia	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Lung infiltration	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
Pneumothorax	Male	0	1/ 1 (100.0%)	0	0	1/ 6 (16.7%)
	Female	0	0	0	0	0
Pulmonary alveolar haemorrhage	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
Rales	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Respiratory alkalosis	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Gender
Safety Analysis Set
Subgroup Factor: Gender

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Respiratory failure	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
Stridor	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Pulmonary mass	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Increased bronchial secretion	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Increased upper airway secretion	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Increased viscosity of upper respiratory secretion	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Skin and subcutaneous tissue disorders	Male	1/ 2 (50.0%)	0	1/ 3 (33.3%)	0	2/ 6 (33.3%)
	Female	4/10 (40.0%)	0	5/13 (38.5%)	0	9/25 (36.0%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Gender
Safety Analysis Set
Subgroup Factor: Gender

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Dry skin	Male	1/ 2 (50.0%)	0	0	0	1/ 6 (16.7%)
	Female	2/10 (20.0%)	0	0	0	2/25 (8.0%)
Pruritus	Male	1/ 2 (50.0%)	0	0	0	1/ 6 (16.7%)
	Female	2/10 (20.0%)	0	0	0	2/25 (8.0%)
Petechiae	Male	1/ 2 (50.0%)	0	0	0	1/ 6 (16.7%)
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
Rash	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	1/13 (7.7%)	0	2/25 (8.0%)
Urticaria	Male	1/ 2 (50.0%)	0	0	0	1/ 6 (16.7%)
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
Blister	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Dermatitis diaper	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Ecchymosis	Male	1/ 2 (50.0%)	0	0	0	1/ 6 (16.7%)
	Female	0	0	0	0	0
Erythema	Male	0	0	1/ 3 (33.3%)	0	1/ 6 (16.7%)
	Female	0	0	0	0	0
Idiopathic urticaria	Male	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Gender
Safety Analysis Set
Subgroup Factor: Gender

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Idiopathic urticaria	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
Papule	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
Rash maculo-papular	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Skin hyperpigmentation	Male	1/ 2 (50.0%)	0	0	0	1/ 6 (16.7%)
	Female	0	0	0	0	0
Skin toxicity	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Social circumstances	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
Social problem	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
Surgical and medical procedures	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Gender
Safety Analysis Set
Subgroup Factor: Gender

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Allogenic stem cell transplantation	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Vascular disorders	Male	1/ 2 (50.0%)	1/ 1 (100.0%)	0	0	2/ 6 (33.3%)
	Female	2/10 (20.0%)	0	3/13 (23.1%)	0	5/25 (20.0%)
Hypertension	Male	0	1/ 1 (100.0%)	0	0	1/ 6 (16.7%)
	Female	0	0	2/13 (15.4%)	0	2/25 (8.0%)
Hypotension	Male	0	0	0	0	0
	Female	0	0	3/13 (23.1%)	0	3/25 (12.0%)
Pallor	Male	1/ 2 (50.0%)	0	0	0	1/ 6 (16.7%)
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
Circulatory collapse	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
Haematoma	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Labile blood pressure	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Gender
Safety Analysis Set
Subgroup Factor: Gender

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Peripheral venous disease	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Product issues	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Device leakage	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Overall	White	3/ 4 (75.0%)	1/ 1 (100.0%)	12/13 (92.3%)	1/ 1 (100.0%)	17/19 (89.5%)
	Black or African American	0	0	1/ 1 (100.0%)	0	1/ 1 (100.0%)
	Asian	4/ 4 (100.0%)	0	1/ 1 (100.0%)	0	5/ 5 (100.0%)
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	2/ 2 (100.0%)	0	1/ 1 (100.0%)	1/ 1 (100.0%)	4/ 4 (100.0%)
Blood and lymphatic system disorders	White	1/ 4 (25.0%)	0	3/13 (23.1%)	0	4/19 (21.1%)
	Black or African American	0	0	1/ 1 (100.0%)	0	1/ 1 (100.0%)
	Asian	2/ 4 (50.0%)	0	1/ 1 (100.0%)	0	3/ 5 (60.0%)
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	1/ 2 (50.0%)	0	0	1/ 1 (100.0%)	2/ 4 (50.0%)
Anaemia	White	1/ 4 (25.0%)	0	1/13 (7.7%)	0	2/19 (10.5%)
	Black or African American	0	0	0	0	0
	Asian	1/ 4 (25.0%)	0	0	0	1/ 5 (20.0%)
	American Indian or Alaska Native	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Anaemia	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Febrile neutropenia	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	1/ 4 (25.0%)	0	0	0	1/ 5 (20.0%)
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	1/ 2 (50.0%)	0	0	0	1/ 4 (25.0%)
Lymphopenia	White	1/ 4 (25.0%)	0	1/13 (7.7%)	0	2/19 (10.5%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	1/ 1 (100.0%)	1/ 4 (25.0%)
Thrombocytopenia	White	1/ 4 (25.0%)	0	1/13 (7.7%)	0	2/19 (10.5%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Thrombocytopenia	Black or African American	0	0	1/ 1 (100.0%)	0	1/ 1 (100.0%)
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Neutropenia	White	1/ 4 (25.0%)	0	1/13 (7.7%)	0	2/19 (10.5%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Coagulopathy	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Coagulopathy	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Leukocytosis	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Leukopenia	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Thrombocytosis	White	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Thrombocytosis	Black or African American	0	0	0	0	0
	Asian	0	0	1/ 1 (100.0%)	0	1/ 5 (20.0%)
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Immune thrombocytopenia	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Cardiac disorders	White	1/ 4 (25.0%)	0	4/13 (30.8%)	0	5/19 (26.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	1/ 1 (100.0%)	0	1/ 5 (20.0%)
	American Indian or Alaska Native	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Cardiac disorders	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Tachycardia	White	1/ 4 (25.0%)	0	2/13 (15.4%)	0	3/19 (15.8%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Arrhythmia supraventricular	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	0	0	1/ 1 (100.0%)	0	1/ 5 (20.0%)
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Cardiac failure	White	1/ 4 (25.0%)	0	0	0	1/19 (5.3%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Cardiac failure	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Cardio-respiratory arrest	White	1/ 4 (25.0%)	0	0	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Pericardial effusion	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Pericardial effusion	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Sinus arrhythmia	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Ventricular hypokinesia	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Right atrial enlargement	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Ear and labyrinth disorders	White	1/ 4 (25.0%)	0	0	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	1/ 4 (25.0%)	0	0	0	1/ 5 (20.0%)
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Ear pain	White	1/ 4 (25.0%)	0	0	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	1/ 4 (25.0%)	0	0	0	1/ 5 (20.0%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Ear pain	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Endocrine disorders	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	1/ 1 (100.0%)	1/ 4 (25.0%)
Cushingoid	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Thyroid cyst	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	1/ 1 (100.0%)	1/ 4 (25.0%)
Eye disorders	White	0	0	2/13 (15.4%)	0	2/19 (10.5%)
	Black or African American	0	0	0	0	0
	Asian	2/ 4 (50.0%)	0	0	0	2/ 5 (40.0%)
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	1/ 1 (100.0%)	1/ 4 (25.0%)
Episcleritis	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Episcleritis	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	1/ 1 (100.0%)	1/ 4 (25.0%)
Eye pain	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	1/ 4 (25.0%)	0	0	0	1/ 5 (20.0%)
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Mydriasis	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Pupils unequal	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Pupils unequal	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Strabismus	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Swelling of eyelid	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	1/ 4 (25.0%)	0	0	0	1/ 5 (20.0%)
	American Indian or Alaska Native	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Swelling of eyelid	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Meibomian gland dysfunction	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	1/ 1 (100.0%)	1/ 4 (25.0%)
Gastrointestinal disorders	White	2/ 4 (50.0%)	1/ 1 (100.0%)	8/13 (61.5%)	1/ 1 (100.0%)	12/19 (63.2%)
	Black or African American	0	0	1/ 1 (100.0%)	0	1/ 1 (100.0%)
	Asian	3/ 4 (75.0%)	0	1/ 1 (100.0%)	0	4/ 5 (80.0%)
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	1/ 2 (50.0%)	0	0	1/ 1 (100.0%)	2/ 4 (50.0%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Diarrhoea	White	1/ 4 (25.0%)	1/ 1 (100.0%)	2/13 (15.4%)	0	4/19 (21.1%)
	Black or African American	0	0	0	0	0
	Asian	1/ 4 (25.0%)	0	1/ 1 (100.0%)	0	2/ 5 (40.0%)
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	1/ 2 (50.0%)	0	0	0	1/ 4 (25.0%)
Vomiting	White	0	0	3/13 (23.1%)	0	3/19 (15.8%)
	Black or African American	0	0	0	0	0
	Asian	2/ 4 (50.0%)	0	0	0	2/ 5 (40.0%)
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	1/ 2 (50.0%)	0	0	0	1/ 4 (25.0%)
Stomatitis	White	0	0	2/13 (15.4%)	1/ 1 (100.0%)	3/19 (15.8%)
	Black or African American	0	0	0	0	0
	Asian	2/ 4 (50.0%)	0	0	0	2/ 5 (40.0%)
	American Indian or Alaska Native	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Stomatitis	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Abdominal distension	White	1/ 4 (25.0%)	0	2/13 (15.4%)	0	3/19 (15.8%)
	Black or African American	0	0	0	0	0
	Asian	1/ 4 (25.0%)	0	0	0	1/ 5 (20.0%)
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Aphthous ulcer	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	2/ 4 (50.0%)	0	0	0	2/ 5 (40.0%)
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	1/ 2 (50.0%)	0	0	0	1/ 4 (25.0%)
Nausea	White	0	0	2/13 (15.4%)	0	2/19 (10.5%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Nausea	Black or African American	0	0	0	0	0
	Asian	1/ 4 (25.0%)	0	0	0	1/ 5 (20.0%)
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Abdominal pain	White	0	0	2/13 (15.4%)	1/ 1 (100.0%)	3/19 (15.8%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Constipation	White	1/ 4 (25.0%)	0	0	1/ 1 (100.0%)	2/19 (10.5%)
	Black or African American	0	0	0	0	0
	Asian	1/ 4 (25.0%)	0	0	0	1/ 5 (20.0%)
	American Indian or Alaska Native	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Constipation	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Abdominal pain upper	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	1/ 1 (100.0%)	1/ 4 (25.0%)
Dental caries	White	1/ 4 (25.0%)	0	0	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Dysphagia	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Dysphagia	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Gastrointestinal haemorrhage	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Gingival bleeding	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Gingival bleeding	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Haematochezia	White	0	0	0	0	0
	Black or African American	0	0	1/ 1 (100.0%)	0	1/ 1 (100.0%)
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Lip dry	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	1/ 4 (25.0%)	0	0	0	1/ 5 (20.0%)
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Lip ulceration	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Lip ulceration	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Mouth haemorrhage	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	1/ 2 (50.0%)	0	0	0	1/ 4 (25.0%)
Oral pain	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Oral pain	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	1/ 2 (50.0%)	0	0	0	1/ 4 (25.0%)
Rectal haemorrhage	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Anal inflammation	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	1/ 2 (50.0%)	0	0	0	1/ 4 (25.0%)
Oral pruritus	White	1/ 4 (25.0%)	0	0	0	1/19 (5.3%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Oral pruritus	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
General disorders and administration site conditions	White	2/ 4 (50.0%)	1/ 1 (100.0%)	5/13 (38.5%)	1/ 1 (100.0%)	9/19 (47.4%)
	Black or African American	0	0	1/ 1 (100.0%)	0	1/ 1 (100.0%)
	Asian	4/ 4 (100.0%)	0	0	0	4/ 5 (80.0%)
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	2/ 2 (100.0%)	0	1/ 1 (100.0%)	1/ 1 (100.0%)	4/ 4 (100.0%)
Pyrexia	White	2/ 4 (50.0%)	0	3/13 (23.1%)	0	5/19 (26.3%)
	Black or African American	0	0	1/ 1 (100.0%)	0	1/ 1 (100.0%)
	Asian	1/ 4 (25.0%)	0	0	0	1/ 5 (20.0%)
	American Indian or Alaska Native	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Pyrexia	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	1/ 1 (100.0%)	1/ 1 (100.0%)	2/ 4 (50.0%)
Non-cardiac chest pain	White	0	0	2/13 (15.4%)	1/ 1 (100.0%)	3/19 (15.8%)
	Black or African American	0	0	0	0	0
	Asian	2/ 4 (50.0%)	0	0	0	2/ 5 (40.0%)
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Chills	White	1/ 4 (25.0%)	0	1/13 (7.7%)	0	2/19 (10.5%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Pain	White	0	1/ 1 (100.0%)	0	1/ 1 (100.0%)	2/19 (10.5%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Pain	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Infusion site pain	White	1/ 4 (25.0%)	0	0	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	1/ 2 (50.0%)	0	0	0	1/ 4 (25.0%)
Chest pain	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	1/ 4 (25.0%)	0	0	0	1/ 5 (20.0%)
	American Indian or Alaska Native	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Chest pain	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Influenza like illness	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	1/ 4 (25.0%)	0	0	0	1/ 5 (20.0%)
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Injection site reaction	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	1/ 2 (50.0%)	0	0	0	1/ 4 (25.0%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Malaise	White	1/ 4 (25.0%)	0	0	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Oedema	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Oedema peripheral	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Oedema peripheral	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Catheter site haemorrhage	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Infusion site pruritus	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	1/ 2 (50.0%)	0	0	0	1/ 4 (25.0%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Infusion site extravasation	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	1/ 2 (50.0%)	0	0	0	1/ 4 (25.0%)
Mucosal induration	White	0	0	0	1/ 1 (100.0%)	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Catheter site ulcer	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Catheter site ulcer	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Hepatobiliary disorders	White	0	0	2/13 (15.4%)	0	2/19 (10.5%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Jaundice	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Liver disorder	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Venoocclusive liver disease	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Hypertransaminasaemia	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Hypertransaminasaemia	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Immune system disorders	White	0	0	2/13 (15.4%)	0	2/19 (10.5%)
	Black or African American	0	0	0	0	0
	Asian	2/ 4 (50.0%)	0	0	0	2/ 5 (40.0%)
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Drug hypersensitivity	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	2/ 4 (50.0%)	0	0	0	2/ 5 (40.0%)
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Drug hypersensitivity	Other	0	0	0	0	0
Graft versus host disease	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Hypogammaglobulinaemia	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Infections and infestations	White	3/ 4 (75.0%)	0	9/13 (69.2%)	0	12/19 (63.2%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Infections and infestations	Black or African American	0	0	1/ 1 (100.0%)	0	1/ 1 (100.0%)
	Asian	3/ 4 (75.0%)	0	0	0	3/ 5 (60.0%)
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	1/ 2 (50.0%)	0	0	0	1/ 4 (25.0%)
Rhinitis	White	0	0	2/13 (15.4%)	0	2/19 (10.5%)
	Black or African American	0	0	0	0	0
	Asian	1/ 4 (25.0%)	0	0	0	1/ 5 (20.0%)
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Septic shock	White	0	0	3/13 (23.1%)	0	3/19 (15.8%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Septic shock	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Folliculitis	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	1/ 4 (25.0%)	0	0	0	1/ 5 (20.0%)
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	1/ 2 (50.0%)	0	0	0	1/ 4 (25.0%)
Pneumonia	White	1/ 4 (25.0%)	0	1/13 (7.7%)	0	2/19 (10.5%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Oral herpes	White	1/ 4 (25.0%)	0	0	0	1/19 (5.3%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Oral herpes	Black or African American	0	0	0	0	0
	Asian	1/ 4 (25.0%)	0	0	0	1/ 5 (20.0%)
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
COVID-19	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Bacteraemia	White	0	0	0	0	0
	Black or African American	0	0	1/ 1 (100.0%)	0	1/ 1 (100.0%)
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Bacteraemia	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Brain abscess	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Cryptosporidiosis infection	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Epstein-Barr virus infection	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Escherichia sepsis	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Gingivitis	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	1/ 4 (25.0%)	0	0	0	1/ 5 (20.0%)
	American Indian or Alaska Native	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Gingivitis	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Herpes simplex	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Influenza	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	1/ 2 (50.0%)	0	0	0	1/ 4 (25.0%)
Nasopharyngitis	White	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Nasopharyngitis	Black or African American	0	0	0	0	0
	Asian	1/ 4 (25.0%)	0	0	0	1/ 5 (20.0%)
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Pneumonia pseudomonal	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Sepsis	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Sepsis	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Sinusitis	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	1/ 2 (50.0%)	0	0	0	1/ 4 (25.0%)
Subcutaneous abscess	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Streptococcal sepsis	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Staphylococcal bacteraemia	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Bacterial sepsis	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	1/ 4 (25.0%)	0	0	0	1/ 5 (20.0%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Bacterial sepsis	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Pneumococcal sepsis	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Urinary tract infection bacterial	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Urinary tract infection bacterial	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Clostridium difficile infection	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Klebsiella bacteraemia	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Enterobacter bacteraemia	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Pseudomonal bacteraemia	White	1/ 4 (25.0%)	0	0	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Respiratory tract infection bacterial	White	1/ 4 (25.0%)	0	0	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Respiratory tract infection bacterial	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Herpes dermatitis	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Device related infection	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Device related infection	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Vascular device infection	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Injury, poisoning and procedural complications	White	2/ 4 (50.0%)	0	3/13 (23.1%)	0	5/19 (26.3%)
	Black or African American	0	0	0	0	0
	Asian	1/ 4 (25.0%)	0	0	0	1/ 5 (20.0%)
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	1/ 2 (50.0%)	0	0	0	1/ 4 (25.0%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Infusion related reaction	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	1/ 2 (50.0%)	0	0	0	1/ 4 (25.0%)
Wound	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Limb injury	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Limb injury	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Skeletal injury	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Procedural hypotension	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	1/ 4 (25.0%)	0	0	0	1/ 5 (20.0%)
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Procedural pain	White	1/ 4 (25.0%)	0	0	0	1/19 (5.3%)

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Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Procedural pain	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Skin abrasion	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Allergic transfusion reaction	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Allergic transfusion reaction	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Procedural haemorrhage	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	1/ 4 (25.0%)	0	0	0	1/ 5 (20.0%)
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Vascular access site pain	White	1/ 4 (25.0%)	0	0	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Investigations	White	2/ 4 (50.0%)	1/ 1 (100.0%)	5/13 (38.5%)	0	8/19 (42.1%)
	Black or African American	0	0	0	0	0
	Asian	0	0	1/ 1 (100.0%)	0	1/ 5 (20.0%)
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	1/ 1 (100.0%)	1/ 1 (100.0%)	2/ 4 (50.0%)
Transaminases increased	White	1/ 4 (25.0%)	0	1/13 (7.7%)	0	2/19 (10.5%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
QRS axis abnormal	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	1/ 1 (100.0%)	0	1/ 5 (20.0%)
	American Indian or Alaska Native	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
QRS axis abnormal	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Alanine aminotransferase increased	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Aspartate aminotransferase increased	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Aspartate aminotransferase increased	Other	0	0	0	0	0
Blood bilirubin increased	White	0	1/ 1 (100.0%)	0	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Blood fibrinogen increased	White	1/ 4 (25.0%)	0	0	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Blood potassium decreased	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
C-reactive protein increased	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	1/ 1 (100.0%)	1/ 4 (25.0%)
Electrocardiogram QT prolonged	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Electrocardiogram QT prolonged	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Electrocardiogram T wave inversion	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Gamma-glutamyltransferase increased	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Gamma-glutamyltransferase increased	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Blood urine present	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Heart rate increased	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	1/ 1 (100.0%)	0	1/ 4 (25.0%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Iron binding capacity total decreased	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Neutrophil count decreased	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Oxygen saturation decreased	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Oxygen saturation decreased	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Platelet count decreased	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Serum ferritin increased	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Serum ferritin increased	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
White blood cell count decreased	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Electrocardiogram T wave abnormal	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	0	0	1/ 1 (100.0%)	0	1/ 5 (20.0%)
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Urine output decreased	White	1/ 4 (25.0%)	0	0	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Hepatic enzyme increased	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Double stranded DNA antibody positive	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Double stranded DNA antibody positive	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Clostridium test positive	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Human rhinovirus test	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Human rhinovirus test	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Metabolism and nutrition disorders	White	2/ 4 (50.0%)	1/ 1 (100.0%)	7/13 (53.8%)	0	10/19 (52.6%)
	Black or African American	0	0	0	0	0
	Asian	0	0	1/ 1 (100.0%)	0	1/ 5 (20.0%)
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Hypoalbuminaemia	White	0	0	4/13 (30.8%)	0	4/19 (21.1%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Hypokalaemia	White	0	1/ 1 (100.0%)	2/13 (15.4%)	0	3/19 (15.8%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Hypokalaemia	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Hyperkalaemia	White	1/ 4 (25.0%)	0	1/13 (7.7%)	0	2/19 (10.5%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Hypophosphataemia	White	0	0	2/13 (15.4%)	0	2/19 (10.5%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Hypophosphataemia	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Alkalosis	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Fluid overload	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Hyperglycaemia	White	1/ 4 (25.0%)	0	0	0	1/19 (5.3%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Hyperglycaemia	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Hyperphosphataemia	White	0	1/ 1 (100.0%)	0	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Hypertriglyceridaemia	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Hypertriglyceridaemia	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Hypocalcaemia	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Hypochloraemia	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	0	0	1/ 1 (100.0%)	0	1/ 5 (20.0%)
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Hypomagnesaemia	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Hypomagnesaemia	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Hypoproteinaemia	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Metabolic acidosis	White	1/ 4 (25.0%)	0	0	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Metabolic acidosis	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Decreased appetite	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Hypophagia	White	1/ 4 (25.0%)	0	0	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Iron overload	White	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Iron overload	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Musculoskeletal and connective tissue disorders	White	1/ 4 (25.0%)	0	4/13 (30.8%)	1/ 1 (100.0%)	6/19 (31.6%)
	Black or African American	0	0	0	0	0
	Asian	3/ 4 (75.0%)	0	0	0	3/ 5 (60.0%)
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Arthralgia	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Arthralgia	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Muscle spasms	White	1/ 4 (25.0%)	0	0	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Pain in extremity	White	0	0	0	1/ 1 (100.0%)	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	1/ 4 (25.0%)	0	0	0	1/ 5 (20.0%)
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Haemarthrosis	White	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Haemarthrosis	Black or African American	0	0	0	0	0
	Asian	1/ 4 (25.0%)	0	0	0	1/ 5 (20.0%)
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Joint swelling	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Myalgia	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Myalgia	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Rhabdomyolysis	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Synovitis	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	1/ 4 (25.0%)	0	0	0	1/ 5 (20.0%)
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Systemic lupus erythematosus	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Systemic lupus erythematosus	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Tendonitis	White	0	0	0	1/ 1 (100.0%)	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Foot deformity	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	1/ 4 (25.0%)	0	0	0	1/ 5 (20.0%)
	American Indian or Alaska Native	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Foot deformity	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Nervous system disorders	White	1/ 4 (25.0%)	1/ 1 (100.0%)	2/13 (15.4%)	0	4/19 (21.1%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	1/ 1 (100.0%)	1/ 4 (25.0%)
Headache	White	1/ 4 (25.0%)	0	1/13 (7.7%)	0	2/19 (10.5%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Dysgeusia	White	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Dysgeusia	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	1/ 1 (100.0%)	1/ 4 (25.0%)
Lethargy	White	0	1/ 1 (100.0%)	0	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Seizure	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Seizure	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Psychiatric disorders	White	0	0	2/13 (15.4%)	0	2/19 (10.5%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Anxiety	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Confusional state	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)

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Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Confusional state	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Insomnia	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Renal and urinary disorders	White	1/ 4 (25.0%)	1/ 1 (100.0%)	2/13 (15.4%)	1/ 1 (100.0%)	5/19 (26.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0

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Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Renal and urinary disorders	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Anuria	White	0	0	2/13 (15.4%)	0	2/19 (10.5%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Dysuria	White	0	1/ 1 (100.0%)	0	1/ 1 (100.0%)	2/19 (10.5%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Azotaemia	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Azotaemia	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Glomerulonephritis	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Haematuria	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Haematuria	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Hypertonic bladder	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Renal impairment	White	1/ 4 (25.0%)	0	0	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Reproductive system and breast disorders	White	0	0	3/13 (23.1%)	1/ 1 (100.0%)	4/19 (21.1%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Menorrhagia	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Pelvic pain	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0

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Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Pelvic pain	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Pruritus genital	White	0	0	0	1/ 1 (100.0%)	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Vulvovaginal erythema	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Respiratory, thoracic and mediastinal disorders	White	2/ 4 (50.0%)	1/ 1 (100.0%)	7/13 (53.8%)	1/ 1 (100.0%)	11/19 (57.9%)
	Black or African American	0	0	0	0	0
	Asian	4/ 4 (100.0%)	0	0	0	4/ 5 (80.0%)
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	1/ 2 (50.0%)	0	0	1/ 1 (100.0%)	2/ 4 (50.0%)
Cough	White	0	0	3/13 (23.1%)	0	3/19 (15.8%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Epistaxis	White	0	0	2/13 (15.4%)	0	2/19 (10.5%)
	Black or African American	0	0	0	0	0
	Asian	1/ 4 (25.0%)	0	0	0	1/ 5 (20.0%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Epistaxis	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Respiratory distress	White	1/ 4 (25.0%)	0	1/13 (7.7%)	0	2/19 (10.5%)
	Black or African American	0	0	0	0	0
	Asian	1/ 4 (25.0%)	0	0	0	1/ 5 (20.0%)
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Rhinorrhoea	White	1/ 4 (25.0%)	0	1/13 (7.7%)	0	2/19 (10.5%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	1/ 2 (50.0%)	0	0	0	1/ 4 (25.0%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Tachypnoea	White	1/ 4 (25.0%)	0	1/13 (7.7%)	1/ 1 (100.0%)	3/19 (15.8%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Dyspnoea	White	0	1/ 1 (100.0%)	0	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	1/ 4 (25.0%)	0	0	0	1/ 5 (20.0%)
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Haemoptysis	White	1/ 4 (25.0%)	0	0	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Haemoptysis	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Hypoxia	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	1/ 1 (100.0%)	1/ 4 (25.0%)
Pleural effusion	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	1/ 4 (25.0%)	0	0	0	1/ 5 (20.0%)
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Pulmonary oedema	White	0	0	2/13 (15.4%)	0	2/19 (10.5%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Pulmonary oedema	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Oropharyngeal pain	White	1/ 4 (25.0%)	0	0	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	1/ 4 (25.0%)	0	0	0	1/ 5 (20.0%)
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Lung opacity	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	1/ 4 (25.0%)	0	0	0	1/ 5 (20.0%)
	American Indian or Alaska Native	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Lung opacity	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Aphonia	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Atelectasis	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Dysphonia	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Dysphonia	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Lung infiltration	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	1/ 2 (50.0%)	0	0	0	1/ 4 (25.0%)
Pneumothorax	White	0	1/ 1 (100.0%)	0	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Pneumothorax	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Pulmonary alveolar haemorrhage	White	1/ 4 (25.0%)	0	0	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Rales	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Respiratory alkalosis	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Respiratory failure	White	1/ 4 (25.0%)	0	0	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Stridor	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Stridor	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Pulmonary mass	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Increased bronchial secretion	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Increased bronchial secretion	Other	0	0	0	0	0
Increased upper airway secretion	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Increased viscosity of upper respiratory secretion	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Skin and subcutaneous tissue disorders	White	1/ 4 (25.0%)	0	6/13 (46.2%)	0	7/19 (36.8%)
	Black or African American	0	0	0	0	0
	Asian	3/ 4 (75.0%)	0	0	0	3/ 5 (60.0%)
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	1/ 2 (50.0%)	0	0	0	1/ 4 (25.0%)
Dry skin	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	2/ 4 (50.0%)	0	0	0	2/ 5 (40.0%)
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	1/ 2 (50.0%)	0	0	0	1/ 4 (25.0%)
Pruritus	White	1/ 4 (25.0%)	0	0	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	2/ 4 (50.0%)	0	0	0	2/ 5 (40.0%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Pruritus	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Petechiae	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	2/ 4 (50.0%)	0	0	0	2/ 5 (40.0%)
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Rash	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	1/ 4 (25.0%)	0	0	0	1/ 5 (20.0%)
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Urticaria	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	2/ 4 (50.0%)	0	0	0	2/ 5 (40.0%)
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Blister	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Dermatitis diaper	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Dermatitis diaper	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Ecchymosis	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	1/ 4 (25.0%)	0	0	0	1/ 5 (20.0%)
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Erythema	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Idiopathic urticaria	White	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Idiopathic urticaria	Black or African American	0	0	0	0	0
	Asian	1/ 4 (25.0%)	0	0	0	1/ 5 (20.0%)
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Papule	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	1/ 2 (50.0%)	0	0	0	1/ 4 (25.0%)
Rash maculo-papular	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Rash maculo-papular	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Skin hyperpigmentation	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	1/ 4 (25.0%)	0	0	0	1/ 5 (20.0%)
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Skin toxicity	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Social circumstances	White	1/ 4 (25.0%)	0	0	0	1/19 (5.3%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Social circumstances	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Social problem	White	1/ 4 (25.0%)	0	0	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Surgical and medical procedures	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Surgical and medical procedures	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Allogenic stem cell transplantation	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Vascular disorders	White	1/ 4 (25.0%)	1/ 1 (100.0%)	3/13 (23.1%)	0	5/19 (26.3%)
	Black or African American	0	0	0	0	0
	Asian	2/ 4 (50.0%)	0	0	0	2/ 5 (40.0%)
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Hypertension	White	0	1/ 1 (100.0%)	2/13 (15.4%)	0	3/19 (15.8%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Hypotension	White	0	0	3/13 (23.1%)	0	3/19 (15.8%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Pallor	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	2/ 4 (50.0%)	0	0	0	2/ 5 (40.0%)
	American Indian or Alaska Native	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Pallor	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Circulatory collapse	White	1/ 4 (25.0%)	0	0	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Haematoma	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Labile blood pressure	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Peripheral venous disease	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Product issues	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Product issues	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Device leakage	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Ethnicity
Safety Analysis Set
Subgroup Factor: Ethnicity

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Overall	Hispanic or Latino	3/ 3 (100.0%)	1/ 1 (100.0%)	4/ 4 (100.0%)	2/ 2 (100.0%)	10/10 (100.0%)
	Not Hispanic or Latino	6/ 7 (85.7%)	0	11/12 (91.7%)	0	17/19 (89.5%)
Blood and lymphatic system disorders	Hispanic or Latino	1/ 3 (33.3%)	0	2/ 4 (50.0%)	1/ 2 (50.0%)	4/10 (40.0%)
	Not Hispanic or Latino	3/ 7 (42.9%)	0	3/12 (25.0%)	0	6/19 (31.6%)
Anaemia	Hispanic or Latino	1/ 3 (33.3%)	0	0	0	1/10 (10.0%)
	Not Hispanic or Latino	1/ 7 (14.3%)	0	1/12 (8.3%)	0	2/19 (10.5%)
Febrile neutropenia	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	2/ 7 (28.6%)	0	0	0	2/19 (10.5%)
Lymphopenia	Hispanic or Latino	1/ 3 (33.3%)	0	1/ 4 (25.0%)	1/ 2 (50.0%)	3/10 (30.0%)
	Not Hispanic or Latino	0	0	0	0	0
Thrombocytopenia	Hispanic or Latino	1/ 3 (33.3%)	0	1/ 4 (25.0%)	0	2/10 (20.0%)
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Neutropenia	Hispanic or Latino	1/ 3 (33.3%)	0	0	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Ethnicity
Safety Analysis Set
Subgroup Factor: Ethnicity

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Coagulopathy	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Leukocytosis	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Leukopenia	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	0	0	0
Thrombocytosis	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Immune thrombocytopenia	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	0	0	0
Cardiac disorders	Hispanic or Latino	1/ 3 (33.3%)	0	1/ 4 (25.0%)	0	2/10 (20.0%)
	Not Hispanic or Latino	0	0	4/12 (33.3%)	0	4/19 (21.1%)
Tachycardia	Hispanic or Latino	1/ 3 (33.3%)	0	0	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	2/12 (16.7%)	0	2/19 (10.5%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Ethnicity
Safety Analysis Set
Subgroup Factor: Ethnicity

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Arrhythmia supraventricular	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Cardiac failure	Hispanic or Latino	1/ 3 (33.3%)	0	0	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Cardio-respiratory arrest	Hispanic or Latino	1/ 3 (33.3%)	0	0	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Pericardial effusion	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Sinus arrhythmia	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Ventricular hypokinesia	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Ethnicity
Safety Analysis Set
Subgroup Factor: Ethnicity

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Right atrial enlargement	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Ear and labyrinth disorders	Hispanic or Latino	1/ 3 (33.3%)	0	0	0	1/10 (10.0%)
	Not Hispanic or Latino	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
Ear pain	Hispanic or Latino	1/ 3 (33.3%)	0	0	0	1/10 (10.0%)
	Not Hispanic or Latino	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
Endocrine disorders	Hispanic or Latino	0	0	1/ 4 (25.0%)	1/ 2 (50.0%)	2/10 (20.0%)
	Not Hispanic or Latino	0	0	0	0	0
Cushingoid	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Thyroid cyst	Hispanic or Latino	0	0	0	1/ 2 (50.0%)	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Eye disorders	Hispanic or Latino	0	0	1/ 4 (25.0%)	1/ 2 (50.0%)	2/10 (20.0%)
	Not Hispanic or Latino	2/ 7 (28.6%)	0	1/12 (8.3%)	0	3/19 (15.8%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Ethnicity
Safety Analysis Set
Subgroup Factor: Ethnicity

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Episcleritis	Hispanic or Latino	0	0	0	1/ 2 (50.0%)	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Eye pain	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
Mydriasis	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Pupils unequal	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Strabismus	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Swelling of eyelid	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
Meibomian gland dysfunction	Hispanic or Latino	0	0	0	1/ 2 (50.0%)	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Ethnicity
Safety Analysis Set
Subgroup Factor: Ethnicity

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Gastrointestinal disorders	Hispanic or Latino	2/ 3 (66.7%)	1/ 1 (100.0%)	2/ 4 (50.0%)	2/ 2 (100.0%)	7/10 (70.0%)
	Not Hispanic or Latino	4/ 7 (57.1%)	0	8/12 (66.7%)	0	12/19 (63.2%)
Diarrhoea	Hispanic or Latino	1/ 3 (33.3%)	1/ 1 (100.0%)	0	0	2/10 (20.0%)
	Not Hispanic or Latino	2/ 7 (28.6%)	0	3/12 (25.0%)	0	5/19 (26.3%)
Vomiting	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	3/ 7 (42.9%)	0	3/12 (25.0%)	0	6/19 (31.6%)
Stomatitis	Hispanic or Latino	0	0	0	1/ 2 (50.0%)	1/10 (10.0%)
	Not Hispanic or Latino	2/ 7 (28.6%)	0	2/12 (16.7%)	0	4/19 (21.1%)
Abdominal distension	Hispanic or Latino	1/ 3 (33.3%)	0	1/ 4 (25.0%)	0	2/10 (20.0%)
	Not Hispanic or Latino	1/ 7 (14.3%)	0	1/12 (8.3%)	0	2/19 (10.5%)
Aphthous ulcer	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	3/ 7 (42.9%)	0	1/12 (8.3%)	0	4/19 (21.1%)
Nausea	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	1/ 7 (14.3%)	0	2/12 (16.7%)	0	3/19 (15.8%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
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Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Ethnicity
Safety Analysis Set
Subgroup Factor: Ethnicity

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Abdominal pain	Hispanic or Latino	0	0	1/ 4 (25.0%)	1/ 2 (50.0%)	2/10 (20.0%)
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Constipation	Hispanic or Latino	1/ 3 (33.3%)	0	0	1/ 2 (50.0%)	2/10 (20.0%)
	Not Hispanic or Latino	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
Abdominal pain upper	Hispanic or Latino	0	0	0	1/ 2 (50.0%)	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Dental caries	Hispanic or Latino	1/ 3 (33.3%)	0	0	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Dysphagia	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Gastrointestinal haemorrhage	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Gingival bleeding	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Ethnicity
Safety Analysis Set
Subgroup Factor: Ethnicity

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Haematochezia	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Lip dry	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
Lip ulceration	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Mouth haemorrhage	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
Oral pain	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
Rectal haemorrhage	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Anal inflammation	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
Oral pruritus	Hispanic or Latino	1/ 3 (33.3%)	0	0	0	1/10 (10.0%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
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Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Ethnicity
Safety Analysis Set
Subgroup Factor: Ethnicity

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Oral pruritus	Not Hispanic or Latino	0	0	0	0	0
General disorders and administration site conditions	Hispanic or Latino	3/ 3 (100.0%)	1/ 1 (100.0%)	2/ 4 (50.0%)	2/ 2 (100.0%)	8/10 (80.0%)
	Not Hispanic or Latino	5/ 7 (71.4%)	0	5/12 (41.7%)	0	10/19 (52.6%)
Pyrexia	Hispanic or Latino	2/ 3 (66.7%)	0	2/ 4 (50.0%)	1/ 2 (50.0%)	5/10 (50.0%)
	Not Hispanic or Latino	1/ 7 (14.3%)	0	3/12 (25.0%)	0	4/19 (21.1%)
Non-cardiac chest pain	Hispanic or Latino	0	0	0	1/ 2 (50.0%)	1/10 (10.0%)
	Not Hispanic or Latino	2/ 7 (28.6%)	0	2/12 (16.7%)	0	4/19 (21.1%)
Chills	Hispanic or Latino	1/ 3 (33.3%)	0	0	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Pain	Hispanic or Latino	0	1/ 1 (100.0%)	0	1/ 2 (50.0%)	2/10 (20.0%)
	Not Hispanic or Latino	0	0	0	0	0
Infusion site pain	Hispanic or Latino	2/ 3 (66.7%)	0	0	0	2/10 (20.0%)
	Not Hispanic or Latino	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Ethnicity
Safety Analysis Set
Subgroup Factor: Ethnicity

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Chest pain	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
Influenza like illness	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
Injection site reaction	Hispanic or Latino	1/ 3 (33.3%)	0	0	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Malaise	Hispanic or Latino	1/ 3 (33.3%)	0	0	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Oedema	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Oedema peripheral	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Catheter site haemorrhage	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
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Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
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Treatment-Emergent Adverse Event (MedDRA v23.0) by Ethnicity
Safety Analysis Set
Subgroup Factor: Ethnicity

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Catheter site haemorrhage	Not Hispanic or Latino	0	0	0	0	0
Infusion site pruritus	Hispanic or Latino	1/ 3 (33.3%)	0	0	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Infusion site extravasation	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
Mucosal induration	Hispanic or Latino	0	0	0	1/ 2 (50.0%)	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Catheter site ulcer	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Hepatobiliary disorders	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Jaundice	Hispanic or Latino	0	0	0	0	0

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Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
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Treatment-Emergent Adverse Event (MedDRA v23.0) by Ethnicity
Safety Analysis Set
Subgroup Factor: Ethnicity

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Jaundice	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Liver disorder	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Venoocclusive liver disease	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Hypertransaminasaemia	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Immune system disorders	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	2/ 7 (28.6%)	0	1/12 (8.3%)	0	3/19 (15.8%)
Drug hypersensitivity	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	2/ 7 (28.6%)	0	0	0	2/19 (10.5%)
Graft versus host disease	Hispanic or Latino	0	0	0	0	0

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Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Ethnicity
Safety Analysis Set
Subgroup Factor: Ethnicity

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Graft versus host disease	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Hypogammaglobulinaemia	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Infections and infestations	Hispanic or Latino	2/ 3 (66.7%)	0	3/ 4 (75.0%)	0	5/10 (50.0%)
	Not Hispanic or Latino	5/ 7 (71.4%)	0	7/12 (58.3%)	0	12/19 (63.2%)
Rhinitis	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	1/ 7 (14.3%)	0	2/12 (16.7%)	0	3/19 (15.8%)
Septic shock	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	2/12 (16.7%)	0	2/19 (10.5%)
Folliculitis	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	2/ 7 (28.6%)	0	0	0	2/19 (10.5%)
Pneumonia	Hispanic or Latino	1/ 3 (33.3%)	0	1/ 4 (25.0%)	0	2/10 (20.0%)
	Not Hispanic or Latino	0	0	0	0	0

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Treatment-Emergent Adverse Event (MedDRA v23.0) by Ethnicity
Safety Analysis Set
Subgroup Factor: Ethnicity

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Oral herpes	Hispanic or Latino	1/ 3 (33.3%)	0	0	0	1/10 (10.0%)
	Not Hispanic or Latino	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
COVID-19	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Bacteraemia	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Brain abscess	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Cryptosporidiosis infection	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Epstein-Barr virus infection	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	0	0	0
Escherichia sepsis	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0

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Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
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Treatment-Emergent Adverse Event (MedDRA v23.0) by Ethnicity
Safety Analysis Set
Subgroup Factor: Ethnicity

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Gingivitis	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
Herpes simplex	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Influenza	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
Nasopharyngitis	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
Pneumonia pseudomonal	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Sepsis	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Sinusitis	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)

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Treatment-Emergent Adverse Event (MedDRA v23.0) by Ethnicity
Safety Analysis Set
Subgroup Factor: Ethnicity

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Subcutaneous abscess	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Streptococcal sepsis	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Staphylococcal bacteraemia	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Bacterial sepsis	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
Pneumococcal sepsis	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Urinary tract infection bacterial	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0

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Treatment-Emergent Adverse Event (MedDRA v23.0) by Ethnicity
Safety Analysis Set
Subgroup Factor: Ethnicity

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Clostridium difficile infection	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Klebsiella bacteraemia	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Enterobacter bacteraemia	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Pseudomonal bacteraemia	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
Respiratory tract infection bacterial	Hispanic or Latino	1/ 3 (33.3%)	0	0	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Herpes dermatitis	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)

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Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
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Treatment-Emergent Adverse Event (MedDRA v23.0) by Ethnicity
Safety Analysis Set
Subgroup Factor: Ethnicity

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Herpes dermatitis	Not Hispanic or Latino	0	0	0	0	0
Device related infection	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Vascular device infection	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Injury, poisoning and procedural complications	Hispanic or Latino	3/ 3 (100.0%)	0	1/ 4 (25.0%)	0	4/10 (40.0%)
	Not Hispanic or Latino	1/ 7 (14.3%)	0	2/12 (16.7%)	0	3/19 (15.8%)
Infusion related reaction	Hispanic or Latino	1/ 3 (33.3%)	0	0	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Wound	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Limb injury	Hispanic or Latino	0	0	0	0	0

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Treatment-Emergent Adverse Event (MedDRA v23.0) by Ethnicity
Safety Analysis Set
Subgroup Factor: Ethnicity

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Limb injury	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Skeletal injury	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Procedural hypotension	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
Procedural pain	Hispanic or Latino	1/ 3 (33.3%)	0	0	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Skin abrasion	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Allergic transfusion reaction	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Procedural haemorrhage	Hispanic or Latino	0	0	0	0	0

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Treatment-Emergent Adverse Event (MedDRA v23.0) by Ethnicity
Safety Analysis Set
Subgroup Factor: Ethnicity

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Procedural haemorrhage	Not Hispanic or Latino	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
Vascular access site pain	Hispanic or Latino	1/ 3 (33.3%)	0	0	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Investigations	Hispanic or Latino	2/ 3 (66.7%)	1/ 1 (100.0%)	3/ 4 (75.0%)	1/ 2 (50.0%)	7/10 (70.0%)
	Not Hispanic or Latino	0	0	4/12 (33.3%)	0	4/19 (21.1%)
Transaminases increased	Hispanic or Latino	1/ 3 (33.3%)	0	1/ 4 (25.0%)	0	2/10 (20.0%)
	Not Hispanic or Latino	0	0	0	0	0
QRS axis abnormal	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Alanine aminotransferase increased	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	0	0	0

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Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Ethnicity
Safety Analysis Set
Subgroup Factor: Ethnicity

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Aspartate aminotransferase increased	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	0	0	0
Blood bilirubin increased	Hispanic or Latino	0	1/ 1 (100.0%)	0	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Blood fibrinogen increased	Hispanic or Latino	1/ 3 (33.3%)	0	0	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Blood potassium decreased	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	0	0	0
C-reactive protein increased	Hispanic or Latino	0	0	0	1/ 2 (50.0%)	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Electrocardiogram QT prolonged	Hispanic or Latino	0	0	0	0	0

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Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
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Treatment-Emergent Adverse Event (MedDRA v23.0) by Ethnicity
Safety Analysis Set
Subgroup Factor: Ethnicity

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Electrocardiogram QT prolonged	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Electrocardiogram T wave inversion	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Gamma-glutamyltransferase increased	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Blood urine present	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Heart rate increased	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Iron binding capacity total decreased	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0

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Treatment-Emergent Adverse Event (MedDRA v23.0) by Ethnicity
Safety Analysis Set
Subgroup Factor: Ethnicity

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Neutrophil count decreased	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	0	0	0
Oxygen saturation decreased	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Platelet count decreased	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Serum ferritin increased	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
White blood cell count decreased	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Electrocardiogram T wave abnormal	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)

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Treatment-Emergent Adverse Event (MedDRA v23.0) by Ethnicity
Safety Analysis Set
Subgroup Factor: Ethnicity

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Urine output decreased	Hispanic or Latino	1/ 3 (33.3%)	0	0	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Hepatic enzyme increased	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Double stranded DNA antibody positive	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Clostridium test positive	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	0	0	0
Human rhinovirus test	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Metabolism and nutrition disorders	Hispanic or Latino	2/ 3 (66.7%)	1/ 1 (100.0%)	3/ 4 (75.0%)	0	6/10 (60.0%)

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Treatment-Emergent Adverse Event (MedDRA v23.0) by Ethnicity
Safety Analysis Set
Subgroup Factor: Ethnicity

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Metabolism and nutrition disorders	Not Hispanic or Latino	0	0	5/12 (41.7%)	0	5/19 (26.3%)
Hypoalbuminaemia	Hispanic or Latino	0	0	2/ 4 (50.0%)	0	2/10 (20.0%)
	Not Hispanic or Latino	0	0	2/12 (16.7%)	0	2/19 (10.5%)
Hypokalaemia	Hispanic or Latino	0	1/ 1 (100.0%)	2/ 4 (50.0%)	0	3/10 (30.0%)
	Not Hispanic or Latino	0	0	0	0	0
Hyperkalaemia	Hispanic or Latino	1/ 3 (33.3%)	0	1/ 4 (25.0%)	0	2/10 (20.0%)
	Not Hispanic or Latino	0	0	0	0	0
Hypophosphataemia	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Alkalosis	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Fluid overload	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Hyperglycaemia	Hispanic or Latino	1/ 3 (33.3%)	0	0	0	1/10 (10.0%)

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Treatment-Emergent Adverse Event (MedDRA v23.0) by Ethnicity
Safety Analysis Set
Subgroup Factor: Ethnicity

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Hyperglycaemia	Not Hispanic or Latino	0	0	0	0	0
Hyperphosphataemia	Hispanic or Latino	0	1/ 1 (100.0%)	0	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Hypertriglyceridaemia	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Hypocalcaemia	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Hypochloraemia	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Hypomagnesaemia	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Hypoproteinaemia	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Metabolic acidosis	Hispanic or Latino	1/ 3 (33.3%)	0	0	0	1/10 (10.0%)

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Treatment-Emergent Adverse Event (MedDRA v23.0) by Ethnicity
Safety Analysis Set
Subgroup Factor: Ethnicity

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Metabolic acidosis	Not Hispanic or Latino	0	0	0	0	0
Decreased appetite	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Hypophagia	Hispanic or Latino	1/ 3 (33.3%)	0	0	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Iron overload	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	0	0	0
Musculoskeletal and connective tissue disorders	Hispanic or Latino	0	0	2/ 4 (50.0%)	1/ 2 (50.0%)	3/10 (30.0%)
	Not Hispanic or Latino	4/ 7 (57.1%)	0	2/12 (16.7%)	0	6/19 (31.6%)
Arthralgia	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Muscle spasms	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)

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Treatment-Emergent Adverse Event (MedDRA v23.0) by Ethnicity
Safety Analysis Set
Subgroup Factor: Ethnicity

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Pain in extremity	Hispanic or Latino	0	0	0	1/ 2 (50.0%)	1/10 (10.0%)
	Not Hispanic or Latino	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
Haemarthrosis	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
Joint swelling	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Myalgia	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Rhabdomyolysis	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Synovitis	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
Systemic lupus erythematosus	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0

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Treatment-Emergent Adverse Event (MedDRA v23.0) by Ethnicity
Safety Analysis Set
Subgroup Factor: Ethnicity

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Tendonitis	Hispanic or Latino	0	0	0	1/ 2 (50.0%)	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Foot deformity	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
Nervous system disorders	Hispanic or Latino	1/ 3 (33.3%)	1/ 1 (100.0%)	2/ 4 (50.0%)	1/ 2 (50.0%)	5/10 (50.0%)
	Not Hispanic or Latino	0	0	0	0	0
Headache	Hispanic or Latino	1/ 3 (33.3%)	0	1/ 4 (25.0%)	0	2/10 (20.0%)
	Not Hispanic or Latino	0	0	0	0	0
Dysgeusia	Hispanic or Latino	0	0	0	1/ 2 (50.0%)	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Lethargy	Hispanic or Latino	0	1/ 1 (100.0%)	0	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Seizure	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0

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Treatment-Emergent Adverse Event (MedDRA v23.0) by Ethnicity
Safety Analysis Set
Subgroup Factor: Ethnicity

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Psychiatric disorders	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	2/12 (16.7%)	0	2/19 (10.5%)
Anxiety	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Confusional state	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Insomnia	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Renal and urinary disorders	Hispanic or Latino	1/ 3 (33.3%)	1/ 1 (100.0%)	1/ 4 (25.0%)	1/ 2 (50.0%)	4/10 (40.0%)
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Anuria	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Dysuria	Hispanic or Latino	0	1/ 1 (100.0%)	0	1/ 2 (50.0%)	2/10 (20.0%)
	Not Hispanic or Latino	0	0	0	0	0

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Treatment-Emergent Adverse Event (MedDRA v23.0) by Ethnicity
Safety Analysis Set
Subgroup Factor: Ethnicity

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Azotaemia	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Glomerulonephritis	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Haematuria	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Hypertonic bladder	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Renal impairment	Hispanic or Latino	1/ 3 (33.3%)	0	0	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Reproductive system and breast disorders	Hispanic or Latino	0	0	1/ 4 (25.0%)	1/ 2 (50.0%)	2/10 (20.0%)
	Not Hispanic or Latino	0	0	2/12 (16.7%)	0	2/19 (10.5%)
Menorrhagia	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)

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Treatment-Emergent Adverse Event (MedDRA v23.0) by Ethnicity
Safety Analysis Set
Subgroup Factor: Ethnicity

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Pelvic pain	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Pruritus genital	Hispanic or Latino	0	0	0	1/ 2 (50.0%)	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Vulvovaginal erythema	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Respiratory, thoracic and mediastinal disorders	Hispanic or Latino	2/ 3 (66.7%)	1/ 1 (100.0%)	2/ 4 (50.0%)	2/ 2 (100.0%)	7/10 (70.0%)
	Not Hispanic or Latino	5/ 7 (71.4%)	0	5/12 (41.7%)	0	10/19 (52.6%)
Cough	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	2/12 (16.7%)	0	2/19 (10.5%)
Epistaxis	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	1/ 7 (14.3%)	0	2/12 (16.7%)	0	3/19 (15.8%)

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Treatment-Emergent Adverse Event (MedDRA v23.0) by Ethnicity
Safety Analysis Set
Subgroup Factor: Ethnicity

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Respiratory distress	Hispanic or Latino	1/ 3 (33.3%)	0	1/ 4 (25.0%)	0	2/10 (20.0%)
	Not Hispanic or Latino	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
Rhinorrhoea	Hispanic or Latino	1/ 3 (33.3%)	0	0	0	1/10 (10.0%)
	Not Hispanic or Latino	1/ 7 (14.3%)	0	1/12 (8.3%)	0	2/19 (10.5%)
Tachypnoea	Hispanic or Latino	1/ 3 (33.3%)	0	0	1/ 2 (50.0%)	2/10 (20.0%)
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Dyspnoea	Hispanic or Latino	0	1/ 1 (100.0%)	0	0	1/10 (10.0%)
	Not Hispanic or Latino	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
Haemoptysis	Hispanic or Latino	1/ 3 (33.3%)	0	0	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Hypoxia	Hispanic or Latino	0	0	1/ 4 (25.0%)	1/ 2 (50.0%)	2/10 (20.0%)
	Not Hispanic or Latino	0	0	0	0	0
Pleural effusion	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	1/ 7 (14.3%)	0	1/12 (8.3%)	0	2/19 (10.5%)

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Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Ethnicity
Safety Analysis Set
Subgroup Factor: Ethnicity

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Pulmonary oedema	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Oropharyngeal pain	Hispanic or Latino	1/ 3 (33.3%)	0	0	0	1/10 (10.0%)
	Not Hispanic or Latino	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
Lung opacity	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
Aphonia	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Atelectasis	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Dysphonia	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Lung infiltration	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
Pneumothorax	Hispanic or Latino	0	1/ 1 (100.0%)	0	0	1/10 (10.0%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Ethnicity
Safety Analysis Set
Subgroup Factor: Ethnicity

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Pneumothorax	Not Hispanic or Latino	0	0	0	0	0
Pulmonary alveolar haemorrhage	Hispanic or Latino	1/ 3 (33.3%)	0	0	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Rales	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Respiratory alkalosis	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Respiratory failure	Hispanic or Latino	1/ 3 (33.3%)	0	0	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Stridor	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Pulmonary mass	Hispanic or Latino	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Ethnicity
Safety Analysis Set
Subgroup Factor: Ethnicity

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Pulmonary mass	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Increased bronchial secretion	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Increased upper airway secretion	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Increased viscosity of upper respiratory secretion	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Skin and subcutaneous tissue disorders	Hispanic or Latino	1/ 3 (33.3%)	0	2/ 4 (50.0%)	0	3/10 (30.0%)
	Not Hispanic or Latino	4/ 7 (57.1%)	0	4/12 (33.3%)	0	8/19 (42.1%)
Dry skin	Hispanic or Latino	0	0	0	0	0

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Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Ethnicity
Safety Analysis Set
Subgroup Factor: Ethnicity

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Dry skin	Not Hispanic or Latino	3/ 7 (42.9%)	0	0	0	3/19 (15.8%)
Pruritus	Hispanic or Latino	1/ 3 (33.3%)	0	0	0	1/10 (10.0%)
	Not Hispanic or Latino	2/ 7 (28.6%)	0	0	0	2/19 (10.5%)
Petechiae	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	2/ 7 (28.6%)	0	0	0	2/19 (10.5%)
Rash	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
Urticaria	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	2/ 7 (28.6%)	0	0	0	2/19 (10.5%)
Blister	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Dermatitis diaper	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Ecchymosis	Hispanic or Latino	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Ethnicity
Safety Analysis Set
Subgroup Factor: Ethnicity

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Ecchymosis	Not Hispanic or Latino	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
Erythema	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Idiopathic urticaria	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
Papule	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
Rash maculo-papular	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Skin hyperpigmentation	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
Skin toxicity	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)

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Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
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Treatment-Emergent Adverse Event (MedDRA v23.0) by Ethnicity
Safety Analysis Set
Subgroup Factor: Ethnicity

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Social circumstances	Hispanic or Latino	1/ 3 (33.3%)	0	0	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Social problem	Hispanic or Latino	1/ 3 (33.3%)	0	0	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Surgical and medical procedures	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Allogenic stem cell transplantation	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Vascular disorders	Hispanic or Latino	0	1/ 1 (100.0%)	1/ 4 (25.0%)	0	2/10 (20.0%)
	Not Hispanic or Latino	3/ 7 (42.9%)	0	2/12 (16.7%)	0	5/19 (26.3%)
Hypertension	Hispanic or Latino	0	1/ 1 (100.0%)	1/ 4 (25.0%)	0	2/10 (20.0%)
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Hypotension	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Ethnicity
Safety Analysis Set
Subgroup Factor: Ethnicity

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Hypotension	Not Hispanic or Latino	0	0	2/12 (16.7%)	0	2/19 (10.5%)
Pallor	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	2/ 7 (28.6%)	0	0	0	2/19 (10.5%)
Circulatory collapse	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
Haematoma	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Labile blood pressure	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Peripheral venous disease	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Product issues	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0

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Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Ethnicity
Safety Analysis Set
Subgroup Factor: Ethnicity

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Device leakage	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0

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Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
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Treatment-Emergent Adverse Event (MedDRA v23.0) by Baseline Neutropenic Status
Safety Analysis Set
Subgroup Factor: Baseline Neutropenic Status

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Overall	Yes	7/ 8 (87.5%)	1/ 1 (100.0%)	10/10 (100.0%)	1/ 1 (100.0%)	19/20 (95.0%)
	No	4/ 4 (100.0%)	0	5/ 6 (83.3%)	1/ 1 (100.0%)	10/11 (90.9%)
Blood and lymphatic system disorders	Yes	3/ 8 (37.5%)	0	2/10 (20.0%)	0	5/20 (25.0%)
	No	3/ 4 (75.0%)	0	3/ 6 (50.0%)	1/ 1 (100.0%)	7/11 (63.6%)
Anaemia	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	2/ 4 (50.0%)	0	0	0	2/11 (18.2%)
Febrile neutropenia	Yes	3/ 8 (37.5%)	0	0	0	3/20 (15.0%)
	No	0	0	0	0	0
Lymphopenia	Yes	0	0	0	0	0
	No	1/ 4 (25.0%)	0	1/ 6 (16.7%)	1/ 1 (100.0%)	3/11 (27.3%)
Thrombocytopenia	Yes	0	0	0	0	0
	No	1/ 4 (25.0%)	0	2/ 6 (33.3%)	0	3/11 (27.3%)
Neutropenia	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	1/ 4 (25.0%)	0	0	0	1/11 (9.1%)
Coagulopathy	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Leukocytosis	Yes	0	0	0	0	0
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)

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Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Baseline Neutropenic Status
Safety Analysis Set
Subgroup Factor: Baseline Neutropenic Status

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Leukopenia	Yes	0	0	0	0	0
	No	1/ 4 (25.0%)	0	0	0	1/11 (9.1%)
Thrombocytosis	Yes	0	0	0	0	0
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Immune thrombocytopenia	Yes	0	0	0	0	0
	No	1/ 4 (25.0%)	0	0	0	1/11 (9.1%)
Cardiac disorders	Yes	0	0	2/10 (20.0%)	0	2/20 (10.0%)
	No	1/ 4 (25.0%)	0	3/ 6 (50.0%)	0	4/11 (36.4%)
Tachycardia	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	1/ 4 (25.0%)	0	1/ 6 (16.7%)	0	2/11 (18.2%)
Arrhythmia supraventricular	Yes	0	0	0	0	0
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Cardiac failure	Yes	0	0	0	0	0
	No	1/ 4 (25.0%)	0	0	0	1/11 (9.1%)
Cardio-respiratory arrest	Yes	0	0	0	0	0
	No	1/ 4 (25.0%)	0	0	0	1/11 (9.1%)

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Investigator assessment of IFD diagnosis is used.
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Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Baseline Neutropenic Status
Safety Analysis Set
Subgroup Factor: Baseline Neutropenic Status

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Pericardial effusion	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Sinus arrhythmia	Yes	0	0	0	0	0
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Ventricular hypokinesia	Yes	0	0	0	0	0
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Right atrial enlargement	Yes	0	0	0	0	0
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Ear and labyrinth disorders	Yes	2/ 8 (25.0%)	0	0	0	2/20 (10.0%)
	No	0	0	0	0	0
Ear pain	Yes	2/ 8 (25.0%)	0	0	0	2/20 (10.0%)
	No	0	0	0	0	0
Endocrine disorders	Yes	0	0	0	0	0
	No	0	0	1/ 6 (16.7%)	1/ 1 (100.0%)	2/11 (18.2%)
Cushingoid	Yes	0	0	0	0	0
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Thyroid cyst	Yes	0	0	0	0	0

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Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Baseline Neutropenic Status
Safety Analysis Set
Subgroup Factor: Baseline Neutropenic Status

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Thyroid cyst	No	0	0	0	1/ 1 (100.0%)	1/11 (9.1%)
Eye disorders	Yes	2/ 8 (25.0%)	0	1/10 (10.0%)	0	3/20 (15.0%)
	No	0	0	1/ 6 (16.7%)	1/ 1 (100.0%)	2/11 (18.2%)
Episcleritis	Yes	0	0	0	0	0
	No	0	0	0	1/ 1 (100.0%)	1/11 (9.1%)
Eye pain	Yes	1/ 8 (12.5%)	0	0	0	1/20 (5.0%)
	No	0	0	0	0	0
Mydriasis	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Pupils unequal	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Strabismus	Yes	0	0	0	0	0
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Swelling of eyelid	Yes	1/ 8 (12.5%)	0	0	0	1/20 (5.0%)
	No	0	0	0	0	0
Meibomian gland dysfunction	Yes	0	0	0	0	0
	No	0	0	0	1/ 1 (100.0%)	1/11 (9.1%)
Gastrointestinal disorders	Yes	6/ 8 (75.0%)	1/ 1 (100.0%)	6/10 (60.0%)	1/ 1 (100.0%)	14/20 (70.0%)

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Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Baseline Neutropenic Status
Safety Analysis Set
Subgroup Factor: Baseline Neutropenic Status

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Gastrointestinal disorders	No	2/ 4 (50.0%)	0	4/ 6 (66.7%)	1/ 1 (100.0%)	7/11 (63.6%)
Diarrhoea	Yes	4/ 8 (50.0%)	1/ 1 (100.0%)	2/10 (20.0%)	0	7/20 (35.0%)
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Vomiting	Yes	3/ 8 (37.5%)	0	2/10 (20.0%)	0	5/20 (25.0%)
	No	1/ 4 (25.0%)	0	1/ 6 (16.7%)	0	2/11 (18.2%)
Stomatitis	Yes	2/ 8 (25.0%)	0	2/10 (20.0%)	1/ 1 (100.0%)	5/20 (25.0%)
	No	0	0	0	0	0
Abdominal distension	Yes	1/ 8 (12.5%)	0	2/10 (20.0%)	0	3/20 (15.0%)
	No	1/ 4 (25.0%)	0	0	0	1/11 (9.1%)
Aphthous ulcer	Yes	3/ 8 (37.5%)	0	1/10 (10.0%)	0	4/20 (20.0%)
	No	0	0	0	0	0
Nausea	Yes	1/ 8 (12.5%)	0	1/10 (10.0%)	0	2/20 (10.0%)
	No	1/ 4 (25.0%)	0	1/ 6 (16.7%)	0	2/11 (18.2%)
Abdominal pain	Yes	0	0	1/10 (10.0%)	1/ 1 (100.0%)	2/20 (10.0%)
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Constipation	Yes	2/ 8 (25.0%)	0	0	1/ 1 (100.0%)	3/20 (15.0%)
	No	0	0	0	0	0

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Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Baseline Neutropenic Status
Safety Analysis Set
Subgroup Factor: Baseline Neutropenic Status

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Abdominal pain upper	Yes	0	0	0	0	0
	No	0	0	0	1/ 1 (100.0%)	1/11 (9.1%)
Dental caries	Yes	1/ 8 (12.5%)	0	0	0	1/20 (5.0%)
	No	0	0	0	0	0
Dysphagia	Yes	0	0	0	0	0
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Gastrointestinal haemorrhage	Yes	0	0	0	0	0
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Gingival bleeding	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Haematochezia	Yes	0	0	0	0	0
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Lip dry	Yes	1/ 8 (12.5%)	0	0	0	1/20 (5.0%)
	No	0	0	0	0	0
Lip ulceration	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Mouth haemorrhage	Yes	1/ 8 (12.5%)	0	0	0	1/20 (5.0%)
	No	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Baseline Neutropenic Status
Safety Analysis Set
Subgroup Factor: Baseline Neutropenic Status

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Oral pain	Yes	1/ 8 (12.5%)	0	0	0	1/20 (5.0%)
	No	0	0	0	0	0
Rectal haemorrhage	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Anal inflammation	Yes	1/ 8 (12.5%)	0	0	0	1/20 (5.0%)
	No	0	0	0	0	0
Oral pruritus	Yes	1/ 8 (12.5%)	0	0	0	1/20 (5.0%)
	No	0	0	0	0	0
General disorders and administration site conditions	Yes	5/ 8 (62.5%)	1/ 1 (100.0%)	4/10 (40.0%)	1/ 1 (100.0%)	11/20 (55.0%)
	No	3/ 4 (75.0%)	0	3/ 6 (50.0%)	1/ 1 (100.0%)	7/11 (63.6%)
Pyrexia	Yes	2/ 8 (25.0%)	0	2/10 (20.0%)	0	4/20 (20.0%)
	No	1/ 4 (25.0%)	0	3/ 6 (50.0%)	1/ 1 (100.0%)	5/11 (45.5%)
Non-cardiac chest pain	Yes	1/ 8 (12.5%)	0	2/10 (20.0%)	1/ 1 (100.0%)	4/20 (20.0%)
	No	1/ 4 (25.0%)	0	0	0	1/11 (9.1%)
Chills	Yes	1/ 8 (12.5%)	0	1/10 (10.0%)	0	2/20 (10.0%)
	No	0	0	0	0	0
Pain	Yes	0	1/ 1 (100.0%)	0	1/ 1 (100.0%)	2/20 (10.0%)
	No	0	0	0	0	0

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Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
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Treatment-Emergent Adverse Event (MedDRA v23.0) by Baseline Neutropenic Status
Safety Analysis Set
Subgroup Factor: Baseline Neutropenic Status

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Infusion site pain	Yes	0	0	0	0	0
	No	2/ 4 (50.0%)	0	0	0	2/11 (18.2%)
Chest pain	Yes	1/ 8 (12.5%)	0	0	0	1/20 (5.0%)
	No	0	0	0	0	0
Influenza like illness	Yes	1/ 8 (12.5%)	0	0	0	1/20 (5.0%)
	No	0	0	0	0	0
Injection site reaction	Yes	0	0	0	0	0
	No	1/ 4 (25.0%)	0	0	0	1/11 (9.1%)
Malaise	Yes	0	0	0	0	0
	No	1/ 4 (25.0%)	0	0	0	1/11 (9.1%)
Oedema	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Oedema peripheral	Yes	0	0	0	0	0
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Catheter site haemorrhage	Yes	0	0	0	0	0
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Infusion site pruritus	Yes	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
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Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
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Treatment-Emergent Adverse Event (MedDRA v23.0) by Baseline Neutropenic Status
Safety Analysis Set
Subgroup Factor: Baseline Neutropenic Status

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Infusion site pruritus	No	1/ 4 (25.0%)	0	0	0	1/11 (9.1%)
Infusion site extravasation	Yes	1/ 8 (12.5%)	0	0	0	1/20 (5.0%)
	No	0	0	0	0	0
Mucosal induration	Yes	0	0	0	1/ 1 (100.0%)	1/20 (5.0%)
	No	0	0	0	0	0
Catheter site ulcer	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Hepatobiliary disorders	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Jaundice	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Liver disorder	Yes	0	0	0	0	0
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Venoocclusive liver disease	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0

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Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
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Treatment-Emergent Adverse Event (MedDRA v23.0) by Baseline Neutropenic Status
Safety Analysis Set
Subgroup Factor: Baseline Neutropenic Status

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Hypertransaminasaemia	Yes	0	0	0	0	0
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Immune system disorders	Yes	2/ 8 (25.0%)	0	1/10 (10.0%)	0	3/20 (15.0%)
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Drug hypersensitivity	Yes	2/ 8 (25.0%)	0	0	0	2/20 (10.0%)
	No	0	0	0	0	0
Graft versus host disease	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Hypogammaglobulinaemia	Yes	0	0	0	0	0
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Infections and infestations	Yes	6/ 8 (75.0%)	0	6/10 (60.0%)	0	12/20 (60.0%)
	No	2/ 4 (50.0%)	0	4/ 6 (66.7%)	0	6/11 (54.5%)
Rhinitis	Yes	1/ 8 (12.5%)	0	2/10 (20.0%)	0	3/20 (15.0%)
	No	0	0	0	0	0
Septic shock	Yes	0	0	2/10 (20.0%)	0	2/20 (10.0%)
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)

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Treatment-Emergent Adverse Event (MedDRA v23.0) by Baseline Neutropenic Status
Safety Analysis Set
Subgroup Factor: Baseline Neutropenic Status

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Folliculitis	Yes	2/ 8 (25.0%)	0	0	0	2/20 (10.0%)
	No	0	0	0	0	0
Pneumonia	Yes	0	0	0	0	0
	No	1/ 4 (25.0%)	0	1/ 6 (16.7%)	0	2/11 (18.2%)
Oral herpes	Yes	2/ 8 (25.0%)	0	0	0	2/20 (10.0%)
	No	0	0	0	0	0
COVID-19	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	1/ 4 (25.0%)	0	0	0	1/11 (9.1%)
Bacteraemia	Yes	0	0	0	0	0
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Brain abscess	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Cryptosporidiosis infection	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Epstein-Barr virus infection	Yes	0	0	0	0	0
	No	1/ 4 (25.0%)	0	0	0	1/11 (9.1%)
Escherichia sepsis	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0

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Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
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Treatment-Emergent Adverse Event (MedDRA v23.0) by Baseline Neutropenic Status
Safety Analysis Set
Subgroup Factor: Baseline Neutropenic Status

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Gingivitis	Yes	1/ 8 (12.5%)	0	0	0	1/20 (5.0%)
	No	0	0	0	0	0
Herpes simplex	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Influenza	Yes	1/ 8 (12.5%)	0	0	0	1/20 (5.0%)
	No	0	0	0	0	0
Nasopharyngitis	Yes	1/ 8 (12.5%)	0	0	0	1/20 (5.0%)
	No	0	0	0	0	0
Pneumonia pseudomonal	Yes	0	0	0	0	0
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Sepsis	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Sinusitis	Yes	1/ 8 (12.5%)	0	0	0	1/20 (5.0%)
	No	0	0	0	0	0
Subcutaneous abscess	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Streptococcal sepsis	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0

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Treatment-Emergent Adverse Event (MedDRA v23.0) by Baseline Neutropenic Status
Safety Analysis Set
Subgroup Factor: Baseline Neutropenic Status

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Staphylococcal bacteraemia	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Bacterial sepsis	Yes	1/ 8 (12.5%)	0	0	0	1/20 (5.0%)
	No	0	0	0	0	0
Pneumococcal sepsis	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Urinary tract infection bacterial	Yes	0	0	0	0	0
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Clostridium difficile infection	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Klebsiella bacteraemia	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Enterobacter bacteraemia	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0

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Treatment-Emergent Adverse Event (MedDRA v23.0) by Baseline Neutropenic Status
Safety Analysis Set
Subgroup Factor: Baseline Neutropenic Status

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Pseudomonal bacteraemia	Yes	1/ 8 (12.5%)	0	0	0	1/20 (5.0%)
	No	0	0	0	0	0
Respiratory tract infection bacterial	Yes	0	0	0	0	0
	No	1/ 4 (25.0%)	0	0	0	1/11 (9.1%)
Herpes dermatitis	Yes	0	0	0	0	0
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Device related infection	Yes	0	0	0	0	0
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Vascular device infection	Yes	0	0	0	0	0
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Injury, poisoning and procedural complications	Yes	1/ 8 (12.5%)	0	3/10 (30.0%)	0	4/20 (20.0%)
	No	3/ 4 (75.0%)	0	0	0	3/11 (27.3%)
Infusion related reaction	Yes	0	0	0	0	0
	No	1/ 4 (25.0%)	0	0	0	1/11 (9.1%)

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Treatment-Emergent Adverse Event (MedDRA v23.0) by Baseline Neutropenic Status
Safety Analysis Set
Subgroup Factor: Baseline Neutropenic Status

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Wound	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Limb injury	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Skeletal injury	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Procedural hypotension	Yes	0	0	0	0	0
	No	1/ 4 (25.0%)	0	0	0	1/11 (9.1%)
Procedural pain	Yes	1/ 8 (12.5%)	0	0	0	1/20 (5.0%)
	No	0	0	0	0	0
Skin abrasion	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Allergic transfusion reaction	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Procedural haemorrhage	Yes	0	0	0	0	0
	No	1/ 4 (25.0%)	0	0	0	1/11 (9.1%)

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Treatment-Emergent Adverse Event (MedDRA v23.0) by Baseline Neutropenic Status
Safety Analysis Set
Subgroup Factor: Baseline Neutropenic Status

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Vascular access site pain	Yes	0	0	0	0	0
	No	1/ 4 (25.0%)	0	0	0	1/11 (9.1%)
Investigations	Yes	2/ 8 (25.0%)	1/ 1 (100.0%)	5/10 (50.0%)	0	8/20 (40.0%)
	No	2/ 4 (50.0%)	0	2/ 6 (33.3%)	1/ 1 (100.0%)	5/11 (45.5%)
Transaminases increased	Yes	1/ 8 (12.5%)	0	1/10 (10.0%)	0	2/20 (10.0%)
	No	0	0	0	0	0
QRS axis abnormal	Yes	0	0	0	0	0
	No	0	0	2/ 6 (33.3%)	0	2/11 (18.2%)
Alanine aminotransferase increased	Yes	0	0	0	0	0
	No	1/ 4 (25.0%)	0	0	0	1/11 (9.1%)
Aspartate aminotransferase increased	Yes	0	0	0	0	0
	No	1/ 4 (25.0%)	0	0	0	1/11 (9.1%)
Blood bilirubin increased	Yes	0	1/ 1 (100.0%)	0	0	1/20 (5.0%)
	No	0	0	0	0	0

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Treatment-Emergent Adverse Event (MedDRA v23.0) by Baseline Neutropenic Status
Safety Analysis Set
Subgroup Factor: Baseline Neutropenic Status

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Blood fibrinogen increased	Yes	0	0	0	0	0
	No	1/ 4 (25.0%)	0	0	0	1/11 (9.1%)
Blood potassium decreased	Yes	0	0	0	0	0
	No	1/ 4 (25.0%)	0	0	0	1/11 (9.1%)
C-reactive protein increased	Yes	0	0	0	0	0
	No	0	0	0	1/ 1 (100.0%)	1/11 (9.1%)
Electrocardiogram QT prolonged	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Electrocardiogram T wave inversion	Yes	0	0	0	0	0
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Gamma-glutamyltransferase increased	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Blood urine present	Yes	0	0	0	0	0
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)

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Treatment-Emergent Adverse Event (MedDRA v23.0) by Baseline Neutropenic Status
Safety Analysis Set
Subgroup Factor: Baseline Neutropenic Status

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Heart rate increased	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Iron binding capacity total decreased	Yes	0	0	0	0	0
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Neutrophil count decreased	Yes	1/ 8 (12.5%)	0	0	0	1/20 (5.0%)
	No	0	0	0	0	0
Oxygen saturation decreased	Yes	0	0	0	0	0
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Platelet count decreased	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Serum ferritin increased	Yes	0	0	0	0	0
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
White blood cell count decreased	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Baseline Neutropenic Status
Safety Analysis Set
Subgroup Factor: Baseline Neutropenic Status

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Electrocardiogram T wave abnormal	Yes	0	0	0	0	0
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Urine output decreased	Yes	1/ 8 (12.5%)	0	0	0	1/20 (5.0%)
	No	0	0	0	0	0
Hepatic enzyme increased	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Double stranded DNA antibody positive	Yes	0	0	0	0	0
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Clostridium test positive	Yes	1/ 8 (12.5%)	0	0	0	1/20 (5.0%)
	No	0	0	0	0	0
Human rhinovirus test	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Metabolism and nutrition disorders	Yes	2/ 8 (25.0%)	1/ 1 (100.0%)	5/10 (50.0%)	0	8/20 (40.0%)
	No	1/ 4 (25.0%)	0	3/ 6 (50.0%)	0	4/11 (36.4%)

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Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
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Treatment-Emergent Adverse Event (MedDRA v23.0) by Baseline Neutropenic Status
Safety Analysis Set
Subgroup Factor: Baseline Neutropenic Status

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Hypoalbuminaemia	Yes	0	0	3/10 (30.0%)	0	3/20 (15.0%)
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Hypokalaemia	Yes	1/ 8 (12.5%)	1/ 1 (100.0%)	1/10 (10.0%)	0	3/20 (15.0%)
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Hyperkalaemia	Yes	1/ 8 (12.5%)	0	0	0	1/20 (5.0%)
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Hypophosphataemia	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Alkalosis	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Fluid overload	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Hyperglycaemia	Yes	0	0	0	0	0
	No	1/ 4 (25.0%)	0	0	0	1/11 (9.1%)
Hyperphosphataemia	Yes	0	1/ 1 (100.0%)	0	0	1/20 (5.0%)
	No	0	0	0	0	0
Hypertriglyceridaemia	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Hypocalcaemia	Yes	0	0	0	0	0

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Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
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Treatment-Emergent Adverse Event (MedDRA v23.0) by Baseline Neutropenic Status
Safety Analysis Set
Subgroup Factor: Baseline Neutropenic Status

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Hypocalcaemia	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Hypochloraemia	Yes	0	0	0	0	0
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Hypomagnesaemia	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Hypoproteinaemia	Yes	0	0	0	0	0
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Metabolic acidosis	Yes	0	0	0	0	0
	No	1/ 4 (25.0%)	0	0	0	1/11 (9.1%)
Decreased appetite	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Hypophagia	Yes	1/ 8 (12.5%)	0	0	0	1/20 (5.0%)
	No	0	0	0	0	0
Iron overload	Yes	1/ 8 (12.5%)	0	0	0	1/20 (5.0%)
	No	0	0	0	0	0
Musculoskeletal and connective tissue disorders	Yes	4/ 8 (50.0%)	0	2/10 (20.0%)	1/ 1 (100.0%)	7/20 (35.0%)
	No	1/ 4 (25.0%)	0	2/ 6 (33.3%)	0	3/11 (27.3%)
Arthralgia	Yes	0	0	0	0	0

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Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
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Treatment-Emergent Adverse Event (MedDRA v23.0) by Baseline Neutropenic Status
Safety Analysis Set
Subgroup Factor: Baseline Neutropenic Status

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Arthralgia	No	1/ 4 (25.0%)	0	1/ 6 (16.7%)	0	2/11 (18.2%)
Muscle spasms	Yes	1/ 8 (12.5%)	0	0	0	1/20 (5.0%)
	No	1/ 4 (25.0%)	0	0	0	1/11 (9.1%)
Pain in extremity	Yes	1/ 8 (12.5%)	0	0	1/ 1 (100.0%)	2/20 (10.0%)
	No	0	0	0	0	0
Haemarthrosis	Yes	1/ 8 (12.5%)	0	0	0	1/20 (5.0%)
	No	0	0	0	0	0
Joint swelling	Yes	0	0	0	0	0
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Myalgia	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Rhabdomyolysis	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Synovitis	Yes	1/ 8 (12.5%)	0	0	0	1/20 (5.0%)
	No	0	0	0	0	0
Systemic lupus erythematosus	Yes	0	0	0	0	0
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Tendonitis	Yes	0	0	0	1/ 1 (100.0%)	1/20 (5.0%)
	No	0	0	0	0	0

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Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
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Treatment-Emergent Adverse Event (MedDRA v23.0) by Baseline Neutropenic Status
Safety Analysis Set
Subgroup Factor: Baseline Neutropenic Status

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Foot deformity	Yes	1/ 8 (12.5%)	0	0	0	1/20 (5.0%)
	No	0	0	0	0	0
Nervous system disorders	Yes	1/ 8 (12.5%)	1/ 1 (100.0%)	1/10 (10.0%)	0	3/20 (15.0%)
	No	1/ 4 (25.0%)	0	1/ 6 (16.7%)	1/ 1 (100.0%)	3/11 (27.3%)
Headache	Yes	1/ 8 (12.5%)	0	0	0	1/20 (5.0%)
	No	1/ 4 (25.0%)	0	1/ 6 (16.7%)	0	2/11 (18.2%)
Dysgeusia	Yes	0	0	0	0	0
	No	0	0	0	1/ 1 (100.0%)	1/11 (9.1%)
Lethargy	Yes	0	1/ 1 (100.0%)	0	0	1/20 (5.0%)
	No	0	0	0	0	0
Seizure	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Psychiatric disorders	Yes	0	0	2/10 (20.0%)	0	2/20 (10.0%)
	No	0	0	0	0	0
Anxiety	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Confusional state	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0

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Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
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Treatment-Emergent Adverse Event (MedDRA v23.0) by Baseline Neutropenic Status
Safety Analysis Set
Subgroup Factor: Baseline Neutropenic Status

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Insomnia	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Renal and urinary disorders	Yes	0	1/ 1 (100.0%)	1/10 (10.0%)	1/ 1 (100.0%)	3/20 (15.0%)
	No	1/ 4 (25.0%)	0	1/ 6 (16.7%)	0	2/11 (18.2%)
Anuria	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Dysuria	Yes	0	1/ 1 (100.0%)	0	1/ 1 (100.0%)	2/20 (10.0%)
	No	0	0	0	0	0
Azotaemia	Yes	0	0	0	0	0
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Glomerulonephritis	Yes	0	0	0	0	0
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Haematuria	Yes	0	0	0	0	0
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Hypertonic bladder	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Renal impairment	Yes	0	0	0	0	0
	No	1/ 4 (25.0%)	0	0	0	1/11 (9.1%)

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Treatment-Emergent Adverse Event (MedDRA v23.0) by Baseline Neutropenic Status
Safety Analysis Set
Subgroup Factor: Baseline Neutropenic Status

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Reproductive system and breast disorders	Yes	0	0	3/10 (30.0%)	1/ 1 (100.0%)	4/20 (20.0%)
	No	0	0	0	0	0
Menorrhagia	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Pelvic pain	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Pruritus genital	Yes	0	0	0	1/ 1 (100.0%)	1/20 (5.0%)
	No	0	0	0	0	0
Vulvovaginal erythema	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Respiratory, thoracic and mediastinal disorders	Yes	6/ 8 (75.0%)	1/ 1 (100.0%)	6/10 (60.0%)	1/ 1 (100.0%)	14/20 (70.0%)
	No	2/ 4 (50.0%)	0	1/ 6 (16.7%)	1/ 1 (100.0%)	4/11 (36.4%)
Cough	Yes	0	0	3/10 (30.0%)	0	3/20 (15.0%)
	No	0	0	0	0	0
Epistaxis	Yes	1/ 8 (12.5%)	0	2/10 (20.0%)	0	3/20 (15.0%)
	No	0	0	0	0	0

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Treatment-Emergent Adverse Event (MedDRA v23.0) by Baseline Neutropenic Status
Safety Analysis Set
Subgroup Factor: Baseline Neutropenic Status

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Respiratory distress	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	2/ 4 (50.0%)	0	0	0	2/11 (18.2%)
Rhinorrhoea	Yes	2/ 8 (25.0%)	0	1/10 (10.0%)	0	3/20 (15.0%)
	No	0	0	0	0	0
Tachypnoea	Yes	0	0	1/10 (10.0%)	1/ 1 (100.0%)	2/20 (10.0%)
	No	1/ 4 (25.0%)	0	0	0	1/11 (9.1%)
Dyspnoea	Yes	1/ 8 (12.5%)	1/ 1 (100.0%)	0	0	2/20 (10.0%)
	No	0	0	0	0	0
Haemoptysis	Yes	1/ 8 (12.5%)	0	0	0	1/20 (5.0%)
	No	1/ 4 (25.0%)	0	0	0	1/11 (9.1%)
Hypoxia	Yes	0	0	0	0	0
	No	0	0	1/ 6 (16.7%)	1/ 1 (100.0%)	2/11 (18.2%)
Pleural effusion	Yes	1/ 8 (12.5%)	0	1/10 (10.0%)	0	2/20 (10.0%)
	No	0	0	0	0	0
Pulmonary oedema	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Oropharyngeal pain	Yes	2/ 8 (25.0%)	0	0	0	2/20 (10.0%)
	No	0	0	0	0	0
Lung opacity	Yes	1/ 8 (12.5%)	0	0	0	1/20 (5.0%)

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Treatment-Emergent Adverse Event (MedDRA v23.0) by Baseline Neutropenic Status
Safety Analysis Set
Subgroup Factor: Baseline Neutropenic Status

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Lung opacity	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Aphonia	Yes	0	0	0	0	0
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Atelectasis	Yes	0	0	0	0	0
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Dysphonia	Yes	0	0	0	0	0
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Lung infiltration	Yes	1/ 8 (12.5%)	0	0	0	1/20 (5.0%)
	No	0	0	0	0	0
Pneumothorax	Yes	0	1/ 1 (100.0%)	0	0	1/20 (5.0%)
	No	0	0	0	0	0
Pulmonary alveolar haemorrhage	Yes	0	0	0	0	0
	No	1/ 4 (25.0%)	0	0	0	1/11 (9.1%)
Rales	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Respiratory alkalosis	Yes	0	0	0	0	0
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)

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Treatment-Emergent Adverse Event (MedDRA v23.0) by Baseline Neutropenic Status
Safety Analysis Set
Subgroup Factor: Baseline Neutropenic Status

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Respiratory failure	Yes	0	0	0	0	0
	No	1/ 4 (25.0%)	0	0	0	1/11 (9.1%)
Stridor	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Pulmonary mass	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Increased bronchial secretion	Yes	0	0	0	0	0
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Increased upper airway secretion	Yes	0	0	0	0	0
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Increased viscosity of upper respiratory secretion	Yes	0	0	0	0	0
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Skin and subcutaneous tissue disorders	Yes	5/ 8 (62.5%)	0	4/10 (40.0%)	0	9/20 (45.0%)
	No	0	0	2/ 6 (33.3%)	0	2/11 (18.2%)

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Treatment-Emergent Adverse Event (MedDRA v23.0) by Baseline Neutropenic Status
Safety Analysis Set
Subgroup Factor: Baseline Neutropenic Status

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Dry skin	Yes	3/ 8 (37.5%)	0	0	0	3/20 (15.0%)
	No	0	0	0	0	0
Pruritus	Yes	3/ 8 (37.5%)	0	0	0	3/20 (15.0%)
	No	0	0	0	0	0
Petechiae	Yes	2/ 8 (25.0%)	0	0	0	2/20 (10.0%)
	No	0	0	0	0	0
Rash	Yes	1/ 8 (12.5%)	0	1/10 (10.0%)	0	2/20 (10.0%)
	No	0	0	0	0	0
Urticaria	Yes	2/ 8 (25.0%)	0	0	0	2/20 (10.0%)
	No	0	0	0	0	0
Blister	Yes	0	0	0	0	0
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Dermatitis diaper	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Ecchymosis	Yes	1/ 8 (12.5%)	0	0	0	1/20 (5.0%)
	No	0	0	0	0	0
Erythema	Yes	0	0	0	0	0
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Idiopathic urticaria	Yes	1/ 8 (12.5%)	0	0	0	1/20 (5.0%)

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Treatment-Emergent Adverse Event (MedDRA v23.0) by Baseline Neutropenic Status
Safety Analysis Set
Subgroup Factor: Baseline Neutropenic Status

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Idiopathic urticaria	No	0	0	0	0	0
Papule	Yes	1/ 8 (12.5%)	0	0	0	1/20 (5.0%)
	No	0	0	0	0	0
Rash maculo-papular	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Skin hyperpigmentation	Yes	1/ 8 (12.5%)	0	0	0	1/20 (5.0%)
	No	0	0	0	0	0
Skin toxicity	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Social circumstances	Yes	1/ 8 (12.5%)	0	0	0	1/20 (5.0%)
	No	0	0	0	0	0
Social problem	Yes	1/ 8 (12.5%)	0	0	0	1/20 (5.0%)
	No	0	0	0	0	0
Surgical and medical procedures	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Baseline Neutropenic Status
Safety Analysis Set
Subgroup Factor: Baseline Neutropenic Status

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Allogenic stem cell transplantation	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Vascular disorders	Yes	3/ 8 (37.5%)	1/ 1 (100.0%)	2/10 (20.0%)	0	6/20 (30.0%)
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Hypertension	Yes	0	1/ 1 (100.0%)	1/10 (10.0%)	0	2/20 (10.0%)
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Hypotension	Yes	0	0	2/10 (20.0%)	0	2/20 (10.0%)
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Pallor	Yes	2/ 8 (25.0%)	0	0	0	2/20 (10.0%)
	No	0	0	0	0	0
Circulatory collapse	Yes	1/ 8 (12.5%)	0	0	0	1/20 (5.0%)
	No	0	0	0	0	0
Haematoma	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Labile blood pressure	Yes	0	0	0	0	0
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Treatment-Emergent Adverse Event (MedDRA v23.0) by Baseline Neutropenic Status
Safety Analysis Set
Subgroup Factor: Baseline Neutropenic Status

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Peripheral venous disease	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Product issues	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Device leakage	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Serious Treatment-Emergent Adverse Event (MedDRA v23.0) by Age Group
Safety Analysis Set
Subgroup Factor: Age (Year)

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Overall	1 to <12	4/ 7 (57.1%)	0	5/11 (45.5%)	0	9/19 (47.4%)
	>=12 to <18	5/ 5 (100.0%)	0	4/ 5 (80.0%)	0	9/12 (75.0%)
Blood and lymphatic system disorders	1 to <12	2/ 7 (28.6%)	0	0	0	2/19 (10.5%)
	>=12 to <18	0	0	0	0	0
Febrile neutropenia	1 to <12	2/ 7 (28.6%)	0	0	0	2/19 (10.5%)
	>=12 to <18	0	0	0	0	0
Cardiac disorders	1 to <12	0	0	0	0	0
	>=12 to <18	1/ 5 (20.0%)	0	1/ 5 (20.0%)	0	2/12 (16.7%)
Cardio-respiratory arrest	1 to <12	0	0	0	0	0
	>=12 to <18	1/ 5 (20.0%)	0	0	0	1/12 (8.3%)
Pericardial effusion	1 to <12	0	0	0	0	0
	>=12 to <18	0	0	1/ 5 (20.0%)	0	1/12 (8.3%)
Ear and labyrinth disorders	1 to <12	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Ear pain	1 to <12	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Serious Treatment-Emergent Adverse Event (MedDRA v23.0) by Age Group
Safety Analysis Set
Subgroup Factor: Age (Year)

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Gastrointestinal disorders	1 to <12	2/ 7 (28.6%)	0	0	0	2/19 (10.5%)
	>=12 to <18	0	0	1/ 5 (20.0%)	0	1/12 (8.3%)
Stomatitis	1 to <12	2/ 7 (28.6%)	0	0	0	2/19 (10.5%)
	>=12 to <18	0	0	0	0	0
Abdominal distension	1 to <12	0	0	0	0	0
	>=12 to <18	0	0	1/ 5 (20.0%)	0	1/12 (8.3%)
General disorders and administration site conditions	1 to <12	0	0	0	0	0
	>=12 to <18	1/ 5 (20.0%)	0	0	0	1/12 (8.3%)
Injection site reaction	1 to <12	0	0	0	0	0
	>=12 to <18	1/ 5 (20.0%)	0	0	0	1/12 (8.3%)
Infusion site pain	1 to <12	0	0	0	0	0
	>=12 to <18	1/ 5 (20.0%)	0	0	0	1/12 (8.3%)
Infusion site pruritus	1 to <12	0	0	0	0	0
	>=12 to <18	1/ 5 (20.0%)	0	0	0	1/12 (8.3%)
Hepatobiliary disorders	1 to <12	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Serious Treatment-Emergent Adverse Event (MedDRA v23.0) by Age Group
Safety Analysis Set
Subgroup Factor: Age (Year)

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Hepatobiliary disorders	>=12 to <18	0	0	1/ 5 (20.0%)	0	1/12 (8.3%)
Venoocclusive liver disease	1 to <12	0	0	0	0	0
	>=12 to <18	0	0	1/ 5 (20.0%)	0	1/12 (8.3%)
Immune system disorders	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Graft versus host disease	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Infections and infestations	1 to <12	1/ 7 (14.3%)	0	4/11 (36.4%)	0	5/19 (26.3%)
	>=12 to <18	1/ 5 (20.0%)	0	4/ 5 (80.0%)	0	5/12 (41.7%)
Septic shock	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	2/ 5 (40.0%)	0	2/12 (16.7%)
Bacteraemia	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Brain abscess	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Escherichia sepsis	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Serious Treatment-Emergent Adverse Event (MedDRA v23.0) by Age Group
Safety Analysis Set
Subgroup Factor: Age (Year)

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Escherichia sepsis	>=12 to <18	0	0	0	0	0
Pneumonia	1 to <12	0	0	0	0	0
	>=12 to <18	1/ 5 (20.0%)	0	0	0	1/12 (8.3%)
Pneumonia pseudomonal	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Sepsis	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Streptococcal sepsis	1 to <12	0	0	0	0	0
	>=12 to <18	0	0	1/ 5 (20.0%)	0	1/12 (8.3%)
Bacterial sepsis	1 to <12	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Pneumococcal sepsis	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Vascular device infection	1 to <12	0	0	0	0	0
	>=12 to <18	0	0	1/ 5 (20.0%)	0	1/12 (8.3%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Serious Treatment-Emergent Adverse Event (MedDRA v23.0) by Age Group
Safety Analysis Set
Subgroup Factor: Age (Year)

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Injury, poisoning and procedural complications	1 to <12	0	0	0	0	0
	>=12 to <18	1/ 5 (20.0%)	0	0	0	1/12 (8.3%)
Infusion related reaction	1 to <12	0	0	0	0	0
	>=12 to <18	1/ 5 (20.0%)	0	0	0	1/12 (8.3%)
Musculoskeletal and connective tissue disorders	1 to <12	1/ 7 (14.3%)	0	1/11 (9.1%)	0	2/19 (10.5%)
	>=12 to <18	1/ 5 (20.0%)	0	0	0	1/12 (8.3%)
Arthralgia	1 to <12	0	0	0	0	0
	>=12 to <18	1/ 5 (20.0%)	0	0	0	1/12 (8.3%)
Rhabdomyolysis	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Synovitis	1 to <12	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Renal and urinary disorders	1 to <12	0	0	0	0	0
	>=12 to <18	0	0	1/ 5 (20.0%)	0	1/12 (8.3%)
Anuria	1 to <12	0	0	0	0	0
	>=12 to <18	0	0	1/ 5 (20.0%)	0	1/12 (8.3%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Serious Treatment-Emergent Adverse Event (MedDRA v23.0) by Age Group
Safety Analysis Set
Subgroup Factor: Age (Year)

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Respiratory, thoracic and mediastinal disorders	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	2/ 5 (40.0%)	0	0	0	2/12 (16.7%)
Haemoptysis	1 to <12	0	0	0	0	0
	>=12 to <18	1/ 5 (20.0%)	0	0	0	1/12 (8.3%)
Pleural effusion	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Respiratory failure	1 to <12	0	0	0	0	0
	>=12 to <18	1/ 5 (20.0%)	0	0	0	1/12 (8.3%)
Social circumstances	1 to <12	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Social problem	1 to <12	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0
Vascular disorders	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	1/ 5 (20.0%)	0	0	0	1/12 (8.3%)
Circulatory collapse	1 to <12	0	0	0	0	0
	>=12 to <18	1/ 5 (20.0%)	0	0	0	1/12 (8.3%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Serious Treatment-Emergent Adverse Event (MedDRA v23.0) by Age Group
Safety Analysis Set
Subgroup Factor: Age (Year)

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Hypertension	1 to <12	0	0	1/11 (9.1%)	0	1/19 (5.3%)
	>=12 to <18	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Serious Treatment-Emergent Adverse Event (MedDRA v23.0) by Gender
Safety Analysis Set
Subgroup Factor: Gender

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Overall	Male	1/ 2 (50.0%)	0	1/ 3 (33.3%)	0	2/ 6 (33.3%)
	Female	8/10 (80.0%)	0	8/13 (61.5%)	0	16/25 (64.0%)
Blood and lymphatic system disorders	Male	0	0	0	0	0
	Female	2/10 (20.0%)	0	0	0	2/25 (8.0%)
Febrile neutropenia	Male	0	0	0	0	0
	Female	2/10 (20.0%)	0	0	0	2/25 (8.0%)
Cardiac disorders	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	1/13 (7.7%)	0	2/25 (8.0%)
Cardio-respiratory arrest	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
Pericardial effusion	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Ear and labyrinth disorders	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
Ear pain	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Serious Treatment-Emergent Adverse Event (MedDRA v23.0) by Gender
Safety Analysis Set
Subgroup Factor: Gender

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Gastrointestinal disorders	Male	0	0	0	0	0
	Female	2/10 (20.0%)	0	1/13 (7.7%)	0	3/25 (12.0%)
Stomatitis	Male	0	0	0	0	0
	Female	2/10 (20.0%)	0	0	0	2/25 (8.0%)
Abdominal distension	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
General disorders and administration site conditions	Male	1/ 2 (50.0%)	0	0	0	1/ 6 (16.7%)
	Female	0	0	0	0	0
Injection site reaction	Male	1/ 2 (50.0%)	0	0	0	1/ 6 (16.7%)
	Female	0	0	0	0	0
Infusion site pain	Male	1/ 2 (50.0%)	0	0	0	1/ 6 (16.7%)
	Female	0	0	0	0	0
Infusion site pruritus	Male	1/ 2 (50.0%)	0	0	0	1/ 6 (16.7%)
	Female	0	0	0	0	0
Hepatobiliary disorders	Male	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Serious Treatment-Emergent Adverse Event (MedDRA v23.0) by Gender
Safety Analysis Set
Subgroup Factor: Gender

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Hepatobiliary disorders	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Venoocclusive liver disease	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Immune system disorders	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Graft versus host disease	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Infections and infestations	Male	0	0	1/ 3 (33.3%)	0	1/ 6 (16.7%)
	Female	2/10 (20.0%)	0	7/13 (53.8%)	0	9/25 (36.0%)
Septic shock	Male	0	0	0	0	0
	Female	0	0	3/13 (23.1%)	0	3/25 (12.0%)
Bacteraemia	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Brain abscess	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Escherichia sepsis	Male	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Serious Treatment-Emergent Adverse Event (MedDRA v23.0) by Gender
Safety Analysis Set
Subgroup Factor: Gender

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Escherichia sepsis	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Pneumonia	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
Pneumonia pseudomonal	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Sepsis	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Streptococcal sepsis	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Bacterial sepsis	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
Pneumococcal sepsis	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Vascular device infection	Male	0	0	1/ 3 (33.3%)	0	1/ 6 (16.7%)
	Female	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Serious Treatment-Emergent Adverse Event (MedDRA v23.0) by Gender
Safety Analysis Set
Subgroup Factor: Gender

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Injury, poisoning and procedural complications	Male	1/ 2 (50.0%)	0	0	0	1/ 6 (16.7%)
	Female	0	0	0	0	0
Infusion related reaction	Male	1/ 2 (50.0%)	0	0	0	1/ 6 (16.7%)
	Female	0	0	0	0	0
Musculoskeletal and connective tissue disorders	Male	0	0	0	0	0
	Female	2/10 (20.0%)	0	1/13 (7.7%)	0	3/25 (12.0%)
Arthralgia	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
Rhabdomyolysis	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Synovitis	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
Renal and urinary disorders	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Anuria	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Serious Treatment-Emergent Adverse Event (MedDRA v23.0) by Gender
Safety Analysis Set
Subgroup Factor: Gender

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Respiratory, thoracic and mediastinal disorders	Male	0	0	0	0	0
	Female	2/10 (20.0%)	0	1/13 (7.7%)	0	3/25 (12.0%)
Haemoptysis	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
Pleural effusion	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)
Respiratory failure	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
Social circumstances	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
Social problem	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)
Vascular disorders	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	1/13 (7.7%)	0	2/25 (8.0%)
Circulatory collapse	Male	0	0	0	0	0
	Female	1/10 (10.0%)	0	0	0	1/25 (4.0%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Serious Treatment-Emergent Adverse Event (MedDRA v23.0) by Gender
Safety Analysis Set
Subgroup Factor: Gender

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Hypertension	Male	0	0	0	0	0
	Female	0	0	1/13 (7.7%)	0	1/25 (4.0%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Serious Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Overall	White	3/ 4 (75.0%)	0	8/13 (61.5%)	0	11/19 (57.9%)
	Black or African American	0	0	1/ 1 (100.0%)	0	1/ 1 (100.0%)
	Asian	2/ 4 (50.0%)	0	0	0	2/ 5 (40.0%)
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	2/ 2 (100.0%)	0	0	0	2/ 4 (50.0%)
Blood and lymphatic system disorders	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	1/ 4 (25.0%)	0	0	0	1/ 5 (20.0%)
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	1/ 2 (50.0%)	0	0	0	1/ 4 (25.0%)
Febrile neutropenia	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	1/ 4 (25.0%)	0	0	0	1/ 5 (20.0%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Serious Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Febrile neutropenia	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	1/ 2 (50.0%)	0	0	0	1/ 4 (25.0%)
Cardiac disorders	White	1/ 4 (25.0%)	0	1/13 (7.7%)	0	2/19 (10.5%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Cardio-respiratory arrest	White	1/ 4 (25.0%)	0	0	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Serious Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Cardio-respiratory arrest	Other	0	0	0	0	0
Pericardial effusion	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Ear and labyrinth disorders	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	1/ 4 (25.0%)	0	0	0	1/ 5 (20.0%)
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Ear pain	White	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Serious Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Ear pain	Black or African American	0	0	0	0	0
	Asian	1/ 4 (25.0%)	0	0	0	1/ 5 (20.0%)
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Gastrointestinal disorders	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	2/ 4 (50.0%)	0	0	0	2/ 5 (40.0%)
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Stomatitis	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	2/ 4 (50.0%)	0	0	0	2/ 5 (40.0%)
	American Indian or Alaska Native	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Serious Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Stomatitis	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Abdominal distension	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
General disorders and administration site conditions	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	1/ 2 (50.0%)	0	0	0	1/ 4 (25.0%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Serious Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Injection site reaction	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	1/ 2 (50.0%)	0	0	0	1/ 4 (25.0%)
Infusion site pain	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	1/ 2 (50.0%)	0	0	0	1/ 4 (25.0%)
Infusion site pruritus	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Serious Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Infusion site pruritus	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	1/ 2 (50.0%)	0	0	0	1/ 4 (25.0%)
Hepatobiliary disorders	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Venoocclusive liver disease	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Serious Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Venoocclusive liver disease	Other	0	0	0	0	0
Immune system disorders	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Graft versus host disease	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Infections and infestations	White	1/ 4 (25.0%)	0	7/13 (53.8%)	0	8/19 (42.1%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Serious Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Infections and infestations	Black or African American	0	0	1/ 1 (100.0%)	0	1/ 1 (100.0%)
	Asian	1/ 4 (25.0%)	0	0	0	1/ 5 (20.0%)
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Septic shock	White	0	0	3/13 (23.1%)	0	3/19 (15.8%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Bacteraemia	White	0	0	0	0	0
	Black or African American	0	0	1/ 1 (100.0%)	0	1/ 1 (100.0%)
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Serious Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Bacteraemia	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Brain abscess	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Escherichia sepsis	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Pneumonia	White	1/ 4 (25.0%)	0	0	0	1/19 (5.3%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Serious Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Pneumonia	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Pneumonia pseudomonal	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Sepsis	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Serious Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Sepsis	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Streptococcal sepsis	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Bacterial sepsis	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	1/ 4 (25.0%)	0	0	0	1/ 5 (20.0%)
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Serious Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Pneumococcal sepsis	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Vascular device infection	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Injury, poisoning and procedural complications	White	0	0	0	0	0
	Black or African American	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Serious Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Injury, poisoning and procedural complications	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	1/ 2 (50.0%)	0	0	0	1/ 4 (25.0%)
Infusion related reaction	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	1/ 2 (50.0%)	0	0	0	1/ 4 (25.0%)
Musculoskeletal and connective tissue disorders	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	1/ 4 (25.0%)	0	0	0	1/ 5 (20.0%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Serious Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Musculoskeletal and connective tissue disorders	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Arthralgia	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Rhabdomyolysis	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Serious Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Synovitis	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	1/ 4 (25.0%)	0	0	0	1/ 5 (20.0%)
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Renal and urinary disorders	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Anuria	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Serious Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Anuria	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Respiratory, thoracic and mediastinal disorders	White	1/ 4 (25.0%)	0	1/13 (7.7%)	0	2/19 (10.5%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Haemoptysis	White	0	0	0	0	0
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Serious Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Pleural effusion	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Respiratory failure	White	1/ 4 (25.0%)	0	0	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Social circumstances	White	1/ 4 (25.0%)	0	0	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Serious Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Social circumstances	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Social problem	White	1/ 4 (25.0%)	0	0	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Vascular disorders	White	1/ 4 (25.0%)	0	1/13 (7.7%)	0	2/19 (10.5%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Circulatory collapse	White	1/ 4 (25.0%)	0	0	0	1/19 (5.3%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Serious Treatment-Emergent Adverse Event (MedDRA v23.0) by Race
Safety Analysis Set
Subgroup Factor: Race

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Circulatory collapse	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0
Hypertension	White	0	0	1/13 (7.7%)	0	1/19 (5.3%)
	Black or African American	0	0	0	0	0
	Asian	0	0	0	0	0
	American Indian or Alaska Native	0	0	0	0	0
	Native Hawaiian or Other Pacific Islander	0	0	0	0	0
	Other	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Serious Treatment-Emergent Adverse Event (MedDRA v23.0) by Ethnicity
Safety Analysis Set
Subgroup Factor: Ethnicity

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Overall	Hispanic or Latino	3/ 3 (100.0%)	0	2/ 4 (50.0%)	0	5/10 (50.0%)
	Not Hispanic or Latino	4/ 7 (57.1%)	0	7/12 (58.3%)	0	11/19 (57.9%)
Blood and lymphatic system disorders	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	2/ 7 (28.6%)	0	0	0	2/19 (10.5%)
Febrile neutropenia	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	2/ 7 (28.6%)	0	0	0	2/19 (10.5%)
Cardiac disorders	Hispanic or Latino	1/ 3 (33.3%)	0	0	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Cardio-respiratory arrest	Hispanic or Latino	1/ 3 (33.3%)	0	0	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Pericardial effusion	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Serious Treatment-Emergent Adverse Event (MedDRA v23.0) by Ethnicity
Safety Analysis Set
Subgroup Factor: Ethnicity

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Ear and labyrinth disorders	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
Ear pain	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
Gastrointestinal disorders	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	2/ 7 (28.6%)	0	1/12 (8.3%)	0	3/19 (15.8%)
Stomatitis	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	2/ 7 (28.6%)	0	0	0	2/19 (10.5%)
Abdominal distension	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
General disorders and administration site conditions	Hispanic or Latino	1/ 3 (33.3%)	0	0	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0

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Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Serious Treatment-Emergent Adverse Event (MedDRA v23.0) by Ethnicity
Safety Analysis Set
Subgroup Factor: Ethnicity

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Injection site reaction	Hispanic or Latino	1/ 3 (33.3%)	0	0	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Infusion site pain	Hispanic or Latino	1/ 3 (33.3%)	0	0	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Infusion site pruritus	Hispanic or Latino	1/ 3 (33.3%)	0	0	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Hepatobiliary disorders	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Venoocclusive liver disease	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Immune system disorders	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)

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Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Serious Treatment-Emergent Adverse Event (MedDRA v23.0) by Ethnicity
Safety Analysis Set
Subgroup Factor: Ethnicity

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Graft versus host disease	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Infections and infestations	Hispanic or Latino	1/ 3 (33.3%)	0	2/ 4 (50.0%)	0	3/10 (30.0%)
	Not Hispanic or Latino	1/ 7 (14.3%)	0	6/12 (50.0%)	0	7/19 (36.8%)
Septic shock	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	2/12 (16.7%)	0	2/19 (10.5%)
Bacteraemia	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Brain abscess	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Escherichia sepsis	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Pneumonia	Hispanic or Latino	1/ 3 (33.3%)	0	0	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Serious Treatment-Emergent Adverse Event (MedDRA v23.0) by Ethnicity
Safety Analysis Set
Subgroup Factor: Ethnicity

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Pneumonia pseudomonal	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Sepsis	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Streptococcal sepsis	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Bacterial sepsis	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
Pneumococcal sepsis	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Vascular device infection	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
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Serious Treatment-Emergent Adverse Event (MedDRA v23.0) by Ethnicity
Safety Analysis Set
Subgroup Factor: Ethnicity

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Injury, poisoning and procedural complications	Hispanic or Latino	1/ 3 (33.3%)	0	0	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Infusion related reaction	Hispanic or Latino	1/ 3 (33.3%)	0	0	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Musculoskeletal and connective tissue disorders	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
Arthralgia	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	0	0	0
Rhabdomyolysis	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Synovitis	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Serious Treatment-Emergent Adverse Event (MedDRA v23.0) by Ethnicity
Safety Analysis Set
Subgroup Factor: Ethnicity

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Renal and urinary disorders	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Anuria	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Respiratory, thoracic and mediastinal disorders	Hispanic or Latino	1/ 3 (33.3%)	0	0	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Haemoptysis	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	0	0	0
Pleural effusion	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	0	0	1/12 (8.3%)	0	1/19 (5.3%)
Respiratory failure	Hispanic or Latino	1/ 3 (33.3%)	0	0	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Serious Treatment-Emergent Adverse Event (MedDRA v23.0) by Ethnicity
Safety Analysis Set
Subgroup Factor: Ethnicity

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Social circumstances	Hispanic or Latino	1/ 3 (33.3%)	0	0	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Social problem	Hispanic or Latino	1/ 3 (33.3%)	0	0	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0
Vascular disorders	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
Circulatory collapse	Hispanic or Latino	0	0	0	0	0
	Not Hispanic or Latino	1/ 7 (14.3%)	0	0	0	1/19 (5.3%)
Hypertension	Hispanic or Latino	0	0	1/ 4 (25.0%)	0	1/10 (10.0%)
	Not Hispanic or Latino	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
Investigator assessment of IFD diagnosis is used.
Possible IFD: According to EORTC/MSG 2008 criteria; Other IFD: IFDs which are confirmed to not be IA or IM.
Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
Sorting order: ascending order by System Organ Class Code and descending by the number of subjects of Total group by Preferred Term.
In case of ties, ascending order by Preferred Term Code is applied.

Serious Treatment-Emergent Adverse Event (MedDRA v23.0) by Baseline Neutropenic Status
Safety Analysis Set
Subgroup Factor: Baseline Neutropenic Status

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Overall	Yes	6/ 8 (75.0%)	0	6/10 (60.0%)	0	12/20 (60.0%)
	No	3/ 4 (75.0%)	0	3/ 6 (50.0%)	0	6/11 (54.5%)
Blood and lymphatic system disorders	Yes	2/ 8 (25.0%)	0	0	0	2/20 (10.0%)
	No	0	0	0	0	0
Febrile neutropenia	Yes	2/ 8 (25.0%)	0	0	0	2/20 (10.0%)
	No	0	0	0	0	0
Cardiac disorders	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	1/ 4 (25.0%)	0	0	0	1/11 (9.1%)
Cardio-respiratory arrest	Yes	0	0	0	0	0
	No	1/ 4 (25.0%)	0	0	0	1/11 (9.1%)
Pericardial effusion	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Ear and labyrinth disorders	Yes	1/ 8 (12.5%)	0	0	0	1/20 (5.0%)
	No	0	0	0	0	0
Ear pain	Yes	1/ 8 (12.5%)	0	0	0	1/20 (5.0%)
	No	0	0	0	0	0

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Serious Treatment-Emergent Adverse Event (MedDRA v23.0) by Baseline Neutropenic Status
Safety Analysis Set
Subgroup Factor: Baseline Neutropenic Status

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Gastrointestinal disorders	Yes	2/ 8 (25.0%)	0	1/10 (10.0%)	0	3/20 (15.0%)
	No	0	0	0	0	0
Stomatitis	Yes	2/ 8 (25.0%)	0	0	0	2/20 (10.0%)
	No	0	0	0	0	0
Abdominal distension	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
General disorders and administration site conditions	Yes	0	0	0	0	0
	No	1/ 4 (25.0%)	0	0	0	1/11 (9.1%)
Injection site reaction	Yes	0	0	0	0	0
	No	1/ 4 (25.0%)	0	0	0	1/11 (9.1%)
Infusion site pain	Yes	0	0	0	0	0
	No	1/ 4 (25.0%)	0	0	0	1/11 (9.1%)
Infusion site pruritus	Yes	0	0	0	0	0
	No	1/ 4 (25.0%)	0	0	0	1/11 (9.1%)
Hepatobiliary disorders	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)

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Serious Treatment-Emergent Adverse Event (MedDRA v23.0) by Baseline Neutropenic Status
Safety Analysis Set
Subgroup Factor: Baseline Neutropenic Status

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Hepatobiliary disorders	No	0	0	0	0	0
Venoocclusive liver disease	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Immune system disorders	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Graft versus host disease	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Infections and infestations	Yes	1/ 8 (12.5%)	0	5/10 (50.0%)	0	6/20 (30.0%)
	No	1/ 4 (25.0%)	0	3/ 6 (50.0%)	0	4/11 (36.4%)
Septic shock	Yes	0	0	2/10 (20.0%)	0	2/20 (10.0%)
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Bacteraemia	Yes	0	0	0	0	0
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Brain abscess	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Escherichia sepsis	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)

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Serious Treatment-Emergent Adverse Event (MedDRA v23.0) by Baseline Neutropenic Status
Safety Analysis Set
Subgroup Factor: Baseline Neutropenic Status

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Escherichia sepsis	No	0	0	0	0	0
Pneumonia	Yes	0	0	0	0	0
	No	1/ 4 (25.0%)	0	0	0	1/11 (9.1%)
Pneumonia pseudomonal	Yes	0	0	0	0	0
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Sepsis	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Streptococcal sepsis	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Bacterial sepsis	Yes	1/ 8 (12.5%)	0	0	0	1/20 (5.0%)
	No	0	0	0	0	0
Pneumococcal sepsis	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Vascular device infection	Yes	0	0	0	0	0
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)

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Number of subjects with adverse events/number of subjects in the subgroup, and percentage of subjects (%) are shown.
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Serious Treatment-Emergent Adverse Event (MedDRA v23.0) by Baseline Neutropenic Status
Safety Analysis Set
Subgroup Factor: Baseline Neutropenic Status

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Injury, poisoning and procedural complications	Yes	0	0	0	0	0
	No	1/ 4 (25.0%)	0	0	0	1/11 (9.1%)
Infusion related reaction	Yes	0	0	0	0	0
	No	1/ 4 (25.0%)	0	0	0	1/11 (9.1%)
Musculoskeletal and connective tissue disorders	Yes	1/ 8 (12.5%)	0	1/10 (10.0%)	0	2/20 (10.0%)
	No	1/ 4 (25.0%)	0	0	0	1/11 (9.1%)
Arthralgia	Yes	0	0	0	0	0
	No	1/ 4 (25.0%)	0	0	0	1/11 (9.1%)
Rhabdomyolysis	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Synovitis	Yes	1/ 8 (12.5%)	0	0	0	1/20 (5.0%)
	No	0	0	0	0	0
Renal and urinary disorders	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Anuria	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0

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Serious Treatment-Emergent Adverse Event (MedDRA v23.0) by Baseline Neutropenic Status
Safety Analysis Set
Subgroup Factor: Baseline Neutropenic Status

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Respiratory, thoracic and mediastinal disorders	Yes	1/ 8 (12.5%)	0	1/10 (10.0%)	0	2/20 (10.0%)
	No	1/ 4 (25.0%)	0	0	0	1/11 (9.1%)
Haemoptysis	Yes	1/ 8 (12.5%)	0	0	0	1/20 (5.0%)
	No	0	0	0	0	0
Pleural effusion	Yes	0	0	1/10 (10.0%)	0	1/20 (5.0%)
	No	0	0	0	0	0
Respiratory failure	Yes	0	0	0	0	0
	No	1/ 4 (25.0%)	0	0	0	1/11 (9.1%)
Social circumstances	Yes	1/ 8 (12.5%)	0	0	0	1/20 (5.0%)
	No	0	0	0	0	0
Social problem	Yes	1/ 8 (12.5%)	0	0	0	1/20 (5.0%)
	No	0	0	0	0	0
Vascular disorders	Yes	1/ 8 (12.5%)	0	0	0	1/20 (5.0%)
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)
Circulatory collapse	Yes	1/ 8 (12.5%)	0	0	0	1/20 (5.0%)
	No	0	0	0	0	0

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
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Serious Treatment-Emergent Adverse Event (MedDRA v23.0) by Baseline Neutropenic Status
Safety Analysis Set
Subgroup Factor: Baseline Neutropenic Status

System Organ Class Preferred Term	Subgroup	Proven or Probable IA (N=12)	Proven or Probable IM (N=1)	Possible IFD (N=16)	Other IFD (N=2)	Total (N=31)
Hypertension	Yes	0	0	0	0	0
	No	0	0	1/ 6 (16.7%)	0	1/11 (9.1%)

IFD:Invasive Fungal Disease; IA:Invasive Aspergillosis; IM:Invasive Mucormycosis.
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