Anhang 4-G: Unerwünschte Ereignisse

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Anhang 4-G1: UE aller Grade nach SOC und PT - Safety Analyse Set

Tabelle 4-1 (Anhang): Ergebnisse für UE nach SOC und PT aus RCT mit dem zu bewertenden Arzneimittel (SELECTION, Induktionsphase: Kohorte A)

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Table 15.11.2.1.2.1: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Induction Study: Cohort A
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Filgotinib 200 mg (N=245)	Filgotinib 100 mg (N=277)	Placebo (N=137)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	103 (42.0%)	122 (44.0%)	57 (41.6%)
Blood and lymphatic system disorders	13 (5.3%)	16 (5.8%)	10 (7.3%)
Anaemia deficiencies	1 (0.4%)	2 (0.7%)	1 (0.7%)
Iron deficiency anaemia	1 (0.4%)	2 (0.7%)	1 (0.7%)
Anaemias NEC	8 (3.3%)	11 (4.0%)	5 (3.6%)
Anaemia	6 (2.4%)	11 (4.0%)	5 (3.6%)
Hypochromic anaemia	1 (0.4%)	0	0
Microcytic anaemia	1 (0.4%)	0	0
Leukopenias NEC	4 (1.6%)	2 (0.7%)	4 (2.9%)
Lymphopenia	2 (0.8%)	1 (0.4%)	3 (2.2%)
Leukopenia	3 (1.2%)	1 (0.4%)	1 (0.7%)
Monocytopenia	1 (0.4%)	0	0
Marrow depression and hypoplastic anaemias	0	1 (0.4%)	0
Pancytopenia	0	1 (0.4%)	0
Neutropenias	3 (1.2%)	1 (0.4%)	0
Neutropenia	3 (1.2%)	1 (0.4%)	0

TEAE = treatment-emergent adverse event. NEC = Not Elsewhere Classified. Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Induction first dose date up to one day before the Maintenance first dose date or 30 days after the Induction last dose date whichever is earlier, or led to premature discontinuation of Induction study drug.
System organ classes and high level terms (within each system organ class) were presented alphabetically, and preferred terms were presented by descending order of the total frequencies. Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Number (%) of Subjects with Any Treatment-Emergent Adverse Events	103 (42.0%)	122 (44.0%)	57 (41.6%)
Blood and lymphatic system disorders (cont)			
Thrombocytopenias	0	0	1 (0.7%)
Thrombocytopenia	0	0	1 (0.7%)
Thrombocytoses	1 (0.4%)	0	0
Thrombocytosis	1 (0.4%)	0	0
Cardiac disorders	5 (2.0%)	1 (0.4%)	0
Cardiac signs and symptoms NEC	1 (0.4%)	1 (0.4%)	0
Cyanosis	1 (0.4%)	0	0
Palpitations	0	1 (0.4%)	0
Myocardial disorders NEC	1 (0.4%)	0	0
Cardiomegaly	1 (0.4%)	0	0
Noninfectious pericarditis	1 (0.4%)	0	0
Pericarditis	1 (0.4%)	0	0
Rate and rhythm disorders NEC	1 (0.4%)	0	0
Tachycardia	1 (0.4%)	0	0

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Number (%) of Subjects with Any Treatment-Emergent Adverse Events	103 (42.0%)	122 (44.0%)	57 (41.6%)
Cardiac disorders (cont)			
Supraventricular arrhythmias	1 (0.4%)	0	0
Sinus arrhythmia	1 (0.4%)	0	0
Congenital, familial and genetic disorders	0	1 (0.4%)	0
Haemoglobinopathies congenital	0	1 (0.4%)	0
Thalassaemia	0	1 (0.4%)	0
Ear and labyrinth disorders	1 (0.4%)	0	3 (2.2%)
Ear disorders NEC	1 (0.4%)	0	0
Ear pain	1 (0.4%)	0	0
Hearing losses	0	0	1 (0.7%)
Hypoacusis	0	0	1 (0.7%)
Inner ear signs and symptoms	0	0	3 (2.2%)
Vertigo	0	0	2 (1.5%)
Tinnitus	0	0	1 (0.7%)

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Number (%) of Subjects with Any Treatment-Emergent Adverse Events	103 (42.0%)	122 (44.0%)	57 (41.6%)
Endocrine disorders	2 (0.8%)	0	1 (0.7%)
Adrenal cortical hyperfunctions	1 (0.4%)	0	1 (0.7%)
Cushingoid	1 (0.4%)	0	1 (0.7%)
Thyroid hyperfunction disorders	1 (0.4%)	0	0
Basedow's disease	1 (0.4%)	0	0
Eye disorders	3 (1.2%)	1 (0.4%)	0
Conjunctival structural change, deposit and degeneration	1 (0.4%)	0	0
Conjunctival disorder	1 (0.4%)	0	0
Ocular disorders NEC	1 (0.4%)	0	0
Eyelid pain	1 (0.4%)	0	0
Retinal bleeding and vascular disorders (excl retinopathy)	1 (0.4%)	1 (0.4%)	0
Papillophlebitis	1 (0.4%)	0	0
Retinal vascular disorder	0	1 (0.4%)	0
Gastrointestinal disorders	37 (15.1%)	35 (12.6%)	24 (17.5%)

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Number (%) of Subjects with Any Treatment-Emergent Adverse Events	103 (42.0%)	122 (44.0%)	57 (41.6%)
Gastrointestinal disorders (cont)			
Benign neoplasms gastrointestinal (excl oral cavity)	0	3 (1.1%)	2 (1.5%)
Large intestine polyp	0	3 (1.1%)	2 (1.5%)
Rectal polyp	0	1 (0.4%)	0
Colitis (excl infective)	6 (2.4%)	6 (2.2%)	8 (5.8%)
Colitis ulcerative	6 (2.4%)	6 (2.2%)	7 (5.1%)
Pseudopolyposis	0	0	1 (0.7%)
Dental pain and sensation disorders	1 (0.4%)	0	0
Toothache	1 (0.4%)	0	0
Diarrhoea (excl infective)	2 (0.8%)	0	2 (1.5%)
Diarrhoea	2 (0.8%)	0	2 (1.5%)
Dyspeptic signs and symptoms	3 (1.2%)	3 (1.1%)	0
Dyspepsia	3 (1.2%)	3 (1.1%)	0
Flatulence, bloating and distension	1 (0.4%)	2 (0.7%)	0
Flatulence	1 (0.4%)	2 (0.7%)	0

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Number (%) of Subjects with Any Treatment-Emergent Adverse Events	103 (42.0%)	122 (44.0%)	57 (41.6%)
Gastrointestinal disorders (cont)			
Gastritis (excl infective)	0	0	4 (2.9%)
Gastritis	0	0	4 (2.9%)
Gastrointestinal and abdominal pains (excl oral and throat)	4 (1.6%)	5 (1.8%)	4 (2.9%)
Abdominal pain	3 (1.2%)	3 (1.1%)	3 (2.2%)
Abdominal pain upper	0	2 (0.7%)	1 (0.7%)
Abdominal pain lower	1 (0.4%)	0	0
Gastrointestinal atonic and hypomotility disorders NEC	1 (0.4%)	3 (1.1%)	1 (0.7%)
Constipation	1 (0.4%)	2 (0.7%)	1 (0.7%)
Gastrooesophageal reflux disease	0	1 (0.4%)	0
Gastrointestinal disorders NEC	1 (0.4%)	0	0
Gastrointestinal disorder	1 (0.4%)	0	0
Gastrointestinal mucosal dystrophies and secretion disorders	1 (0.4%)	0	0
Colon dysplasia	1 (0.4%)	0	0
Gastrointestinal signs and symptoms NEC	1 (0.4%)	0	0
Breath odour	1 (0.4%)	0	0

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Number (%) of Subjects with Any Treatment-Emergent Adverse Events	103 (42.0%)	122 (44.0%)	57 (41.6%)
Gastrointestinal disorders (cont)			
Gastrointestinal spastic and hypermotility disorders	0	2 (0.7%)	0
Frequent bowel movements	0	2 (0.7%)	0
Haemorrhoids and gastrointestinal varices (excl oesophageal)	3 (1.2%)	2 (0.7%)	1 (0.7%)
Haemorrhoids	3 (1.2%)	1 (0.4%)	0
Haemorrhoidal haemorrhage	0	0	1 (0.7%)
Haemorrhoids thrombosed	0	1 (0.4%)	0
Intestinal haemorrhages	1 (0.4%)	3 (1.1%)	0
Rectal haemorrhage	1 (0.4%)	1 (0.4%)	0
Large intestinal haemorrhage	0	1 (0.4%)	0
Lower gastrointestinal haemorrhage	0	1 (0.4%)	0
Intestinal ulcers and perforation NEC	1 (0.4%)	0	0
Ileal ulcer	1 (0.4%)	0	0
Large intestinal stenosis and obstruction	1 (0.4%)	0	1 (0.7%)
Large intestinal stenosis	1 (0.4%)	0	1 (0.7%)

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Number (%) of Subjects with Any Treatment-Emergent Adverse Events	103 (42.0%)	122 (44.0%)	57 (41.6%)
Gastrointestinal disorders (cont)			
Nausea and vomiting symptoms	12 (4.9%)	6 (2.2%)	5 (3.6%)
Nausea	8 (3.3%)	3 (1.1%)	1 (0.7%)
Vomiting	4 (1.6%)	3 (1.1%)	4 (2.9%)
Non-site specific gastrointestinal haemorrhages	1 (0.4%)	1 (0.4%)	0
Gastrointestinal haemorrhage	1 (0.4%)	0	0
Haematochezia	0	1 (0.4%)	0
Oral dryness and saliva altered	1 (0.4%)	1 (0.4%)	0
Dry mouth	1 (0.4%)	1 (0.4%)	0
Stomatitis and ulceration	2 (0.8%)	4 (1.4%)	1 (0.7%)
Stomatitis	2 (0.8%)	3 (1.1%)	0
Aphthous ulcer	0	0	1 (0.7%)
Mouth ulceration	0	1 (0.4%)	0
General disorders and administration site conditions	9 (3.7%)	6 (2.2%)	9 (6.6%)
Asthenic conditions	3 (1.2%)	2 (0.7%)	3 (2.2%)
Asthenia	2 (0.8%)	1 (0.4%)	3 (2.2%)
Fatigue	1 (0.4%)	1 (0.4%)	0

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Number (%) of Subjects with Any Treatment-Emergent Adverse Events	103 (42.0%)	122 (44.0%)	57 (41.6%)
General disorders and administration site conditions (cont)			
Complications associated with device NEC	1 (0.4%)	0	0
Complication associated with device	1 (0.4%)	0	0
Febrile disorders	5 (2.0%)	1 (0.4%)	1 (0.7%)
Pyrexia	5 (2.0%)	1 (0.4%)	1 (0.7%)
General signs and symptoms NEC	1 (0.4%)	1 (0.4%)	0
Influenza like illness	1 (0.4%)	0	0
Peripheral swelling	0	1 (0.4%)	0
Oedema NEC	0	0	4 (2.9%)
Oedema peripheral	0	0	3 (2.2%)
Oedema	0	0	1 (0.7%)
Pain and discomfort NEC	0	2 (0.7%)	2 (1.5%)
Pain	0	0	2 (1.5%)
Chest discomfort	0	1 (0.4%)	0
Chest pain	0	1 (0.4%)	0
Hepatobiliary disorders	1 (0.4%)	2 (0.7%)	0

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Number (%) of Subjects with Any Treatment-Emergent Adverse Events	103 (42.0%)	122 (44.0%)	57 (41.6%)
Hepatobiliary disorders (cont)			
Cholestasis and jaundice	0	1 (0.4%)	0
Hyperbilirubinaemia	0	1 (0.4%)	0
Hepatic enzymes and function abnormalities	1 (0.4%)	0	0
Hepatic function abnormal	1 (0.4%)	0	0
Hepatobiliary signs and symptoms	0	1 (0.4%)	0
Hepatomegaly	0	1 (0.4%)	0
Immune system disorders	0	2 (0.7%)	0
Allergic conditions NEC	0	1 (0.4%)	0
Type I hypersensitivity	0	1 (0.4%)	0
Allergies to foods, food additives, drugs and other chemicals	0	1 (0.4%)	0
Drug hypersensitivity	0	1 (0.4%)	0
Infections and infestations	27 (11.0%)	27 (9.7%)	8 (5.8%)

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Number (%) of Subjects with Any Treatment-Emergent Adverse Events	103 (42.0%)	122 (44.0%)	57 (41.6%)
Infections and infestations (cont)			
Abdominal and gastrointestinal infections	0	4 (1.4%)	1 (0.7%)
Gastroenteritis	0	2 (0.7%)	0
Appendicitis	0	1 (0.4%)	0
Diverticulitis	0	1 (0.4%)	0
Dysentery	0	0	1 (0.7%)
Bacterial infections NEC	0	1 (0.4%)	1 (0.7%)
Cellulitis	0	1 (0.4%)	1 (0.7%)
Bone and joint infections	0	0	1 (0.7%)
Osteomyelitis	0	0	1 (0.7%)
Candida infections	1 (0.4%)	0	0
Oesophageal candidiasis	1 (0.4%)	0	0
Ear infections	0	2 (0.7%)	1 (0.7%)
Otitis externa	0	1 (0.4%)	1 (0.7%)
Otitis media chronic	0	1 (0.4%)	0

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Number (%) of Subjects with Any Treatment-Emergent Adverse Events	103 (42.0%)	122 (44.0%)	57 (41.6%)
Infections and infestations (cont)			
Eye and eyelid infections	2 (0.8%)	0	0
Conjunctivitis	1 (0.4%)	0	0
Hordeolum	1 (0.4%)	0	0
Flaviviral infections	1 (0.4%)	0	0
Dengue fever	1 (0.4%)	0	0
Fungal infections NEC	1 (0.4%)	0	0
Onychomycosis	1 (0.4%)	0	0
Herpes viral infections	3 (1.2%)	0	0
Herpes zoster	2 (0.8%)	0	0
Oral herpes	1 (0.4%)	0	0
Influenza viral infections	0	0	1 (0.7%)
Influenza	0	0	1 (0.7%)
Lower respiratory tract and lung infections	5 (2.0%)	1 (0.4%)	0
Bronchitis	3 (1.2%)	1 (0.4%)	0
Lower respiratory tract infection	1 (0.4%)	0	0
Pneumonia	1 (0.4%)	0	0

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Table 15.11.2.1.2.1: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Induction Study: Cohort A
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Filgotinib 200 mg (N=245)	Filgotinib 100 mg (N=277)	Placebo (N=137)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	103 (42.0%)	122 (44.0%)	57 (41.6%)
Infections and infestations (cont)			
Nematode infections	0	1 (0.4%)	0
Enterobiasis	0	1 (0.4%)	0
Skin structures and soft tissue infections	0	1 (0.4%)	1 (0.7%)
Folliculitis	0	1 (0.4%)	0
Rash pustular	0	0	1 (0.7%)
Tinea infections	1 (0.4%)	0	1 (0.7%)
Tinea versicolour	1 (0.4%)	0	1 (0.7%)
Upper respiratory tract infections	13 (5.3%)	13 (4.7%)	3 (2.2%)
Nasopharyngitis	7 (2.9%)	9 (3.2%)	2 (1.5%)
Pharyngitis	2 (0.8%)	2 (0.7%)	0
Upper respiratory tract infection	2 (0.8%)	2 (0.7%)	0
Rhinitis	1 (0.4%)	0	1 (0.7%)
Acute sinusitis	1 (0.4%)	0	0
Sinusitis	0	0	1 (0.7%)
Urinary tract infections	2 (0.8%)	2 (0.7%)	1 (0.7%)
Urinary tract infection	2 (0.8%)	0	1 (0.7%)
Cystitis	0	2 (0.7%)	0

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TEAEs are defined as any AEs that began on or after the Induction first dose date up to one day before the Maintenance first dose date or 30 days after the Induction last dose date whichever is earlier, or led to premature discontinuation of Induction study drug.
System organ classes and high level terms (within each system organ class) were presented alphabetically, and preferred terms were presented by descending order of the total frequencies. Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
Source: Listing 16.2.7.1

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Table 15.11.2.1.2.1: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Induction Study: Cohort A
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Filgotinib 200 mg (N=245)	Filgotinib 100 mg (N=277)	Placebo (N=137)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	103 (42.0%)	122 (44.0%)	57 (41.6%)
Infections and infestations (cont)			
Viral infections NEC	4 (1.6%)	3 (1.1%)	1 (0.7%)
Respiratory tract infection viral	2 (0.8%)	2 (0.7%)	0
Viral infection	0	1 (0.4%)	1 (0.7%)
Viral upper respiratory tract infection	2 (0.8%)	0	0
Injury, poisoning and procedural complications	4 (1.6%)	4 (1.4%)	4 (2.9%)
Bone and joint injuries NEC	1 (0.4%)	0	1 (0.7%)
Meniscus injury	0	0	1 (0.7%)
Synovial rupture	1 (0.4%)	0	0
Eye injuries NEC	0	1 (0.4%)	0
Eye injury	0	1 (0.4%)	0
Gastrointestinal and hepatobiliary procedural complications	0	0	1 (0.7%)
Procedural intestinal perforation	0	0	1 (0.7%)
Limb fractures and dislocations	1 (0.4%)	0	0
Foot fracture	1 (0.4%)	0	0

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Induction Study: Cohort A
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System Organ Class High-Level Term Preferred Term	Filgotinib 200 mg (N=245)	Filgotinib 100 mg (N=277)	Placebo (N=137)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	103 (42.0%)	122 (44.0%)	57 (41.6%)
Injury, poisoning and procedural complications (cont)			
Muscle, tendon and ligament injuries	0	1 (0.4%)	1 (0.7%)
Ligament sprain	0	1 (0.4%)	0
Muscle strain	0	0	1 (0.7%)
Non-site specific injuries NEC	0	1 (0.4%)	1 (0.7%)
Animal bite	0	0	1 (0.7%)
Road traffic accident	0	1 (0.4%)	0
Non-site specific procedural complications	1 (0.4%)	0	0
Procedural pain	1 (0.4%)	0	0
Skin injuries NEC	1 (0.4%)	1 (0.4%)	0
Contusion	1 (0.4%)	1 (0.4%)	0
Investigations	7 (2.9%)	16 (5.8%)	9 (6.6%)
Cholesterol analyses	0	1 (0.4%)	1 (0.7%)
Blood cholesterol increased	0	1 (0.4%)	0
High density lipoprotein increased	0	0	1 (0.7%)
Low density lipoprotein increased	0	0	1 (0.7%)

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Induction Study: Cohort A
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Filgotinib 200 mg (N=245)	Filgotinib 100 mg (N=277)	Placebo (N=137)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	103 (42.0%)	122 (44.0%)	57 (41.6%)
Investigations (cont)			
Liver function analyses	1 (0.4%)	2 (0.7%)	0
Alanine aminotransferase increased	1 (0.4%)	2 (0.7%)	0
Aspartate aminotransferase increased	1 (0.4%)	2 (0.7%)	0
Mineral and electrolyte analyses	2 (0.8%)	2 (0.7%)	0
Blood phosphorus decreased	0	2 (0.7%)	0
Blood potassium decreased	2 (0.8%)	0	0
Physical examination procedures and organ system status	1 (0.4%)	1 (0.4%)	3 (2.2%)
Weight decreased	1 (0.4%)	0	1 (0.7%)
Weight increased	0	0	2 (1.5%)
Lymph node palpable	0	1 (0.4%)	0
Platelet analyses	0	2 (0.7%)	0
Platelet count increased	0	2 (0.7%)	0
Red blood cell analyses	0	2 (0.7%)	1 (0.7%)
Haemoglobin abnormal	0	0	1 (0.7%)
Haemoglobin decreased	0	1 (0.4%)	0
Red blood cell count decreased	0	1 (0.4%)	0

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Table 15.11.2.1.2.1: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Induction Study: Cohort A
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Filgotinib 200 mg (N=245)	Filgotinib 100 mg (N=277)	Placebo (N=137)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	103 (42.0%)	122 (44.0%)	57 (41.6%)
Investigations (cont)			
Renal function analyses	0	1 (0.4%)	0
Blood creatine increased	0	1 (0.4%)	0
Skeletal and cardiac muscle analyses	1 (0.4%)	2 (0.7%)	0
Blood creatine phosphokinase increased	1 (0.4%)	2 (0.7%)	0
Vascular tests NEC (incl blood pressure)	0	0	1 (0.7%)
Blood pressure increased	0	0	1 (0.7%)
Virus identification and serology	0	1 (0.4%)	0
Hepatitis B DNA assay positive	0	1 (0.4%)	0
White blood cell analyses	3 (1.2%)	4 (1.4%)	4 (2.9%)
Neutrophil count decreased	0	1 (0.4%)	4 (2.9%)
White blood cell count decreased	1 (0.4%)	2 (0.7%)	1 (0.7%)
Lymphocyte count increased	2 (0.8%)	1 (0.4%)	0
Neutrophil count increased	0	2 (0.7%)	0
White blood cell count increased	0	2 (0.7%)	0
Eosinophil count increased	0	1 (0.4%)	0
Lymphocyte count decreased	0	1 (0.4%)	0

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Table 15.11.2.1.2.1: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Induction Study: Cohort A
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Filgotinib 200 mg (N=245)	Filgotinib 100 mg (N=277)	Placebo (N=137)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	103 (42.0%)	122 (44.0%)	57 (41.6%)
Metabolism and nutrition disorders	5 (2.0%)	3 (1.1%)	3 (2.2%)
Diabetes mellitus (incl subtypes)	1 (0.4%)	1 (0.4%)	0
Diabetes mellitus	1 (0.4%)	1 (0.4%)	0
Elevated cholesterol	1 (0.4%)	0	0
Hypercholesterolaemia	1 (0.4%)	0	0
Elevated triglycerides	0	1 (0.4%)	0
Hypertriglyceridaemia	0	1 (0.4%)	0
General nutritional disorders NEC	0	0	1 (0.7%)
Malnutrition	0	0	1 (0.7%)
Hyperglycaemic conditions NEC	0	0	2 (1.5%)
Hyperglycaemia	0	0	2 (1.5%)
Iron deficiencies	1 (0.4%)	1 (0.4%)	0
Iron deficiency	1 (0.4%)	1 (0.4%)	0
Potassium imbalance	2 (0.8%)	0	0
Hypokalaemia	2 (0.8%)	0	0

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Induction Study: Cohort A
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System Organ Class High-Level Term Preferred Term	Filgotinib 200 mg (N=245)	Filgotinib 100 mg (N=277)	Placebo (N=137)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	103 (42.0%)	122 (44.0%)	57 (41.6%)
Metabolism and nutrition disorders (cont)			
Protein metabolism disorders NEC	0	0	1 (0.7%)
Hypoalbuminaemia	0	0	1 (0.7%)
Musculoskeletal and connective tissue disorders	7 (2.9%)	14 (5.1%)	4 (2.9%)
Bone disorders NEC	1 (0.4%)	0	0
Periostitis	1 (0.4%)	0	0
Joint related signs and symptoms	0	5 (1.8%)	2 (1.5%)
Arthralgia	0	4 (1.4%)	2 (1.5%)
Joint swelling	0	1 (0.4%)	0
Muscle infections and inflammations	0	1 (0.4%)	0
Myositis	0	1 (0.4%)	0
Muscle pains	1 (0.4%)	1 (0.4%)	1 (0.7%)
Myalgia	1 (0.4%)	1 (0.4%)	1 (0.7%)
Muscle related signs and symptoms NEC	0	2 (0.7%)	0
Muscle spasms	0	1 (0.4%)	0
Muscle twitching	0	1 (0.4%)	0

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System Organ Class High-Level Term Preferred Term	Filgotinib 200 mg (N=245)	Filgotinib 100 mg (N=277)	Placebo (N=137)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	103 (42.0%)	122 (44.0%)	57 (41.6%)
Musculoskeletal and connective tissue disorders (cont)			
Musculoskeletal and connective tissue pain and discomfort	4 (1.6%)	4 (1.4%)	2 (1.5%)
Back pain	3 (1.2%)	1 (0.4%)	1 (0.7%)
Musculoskeletal pain	0	2 (0.7%)	0
Musculoskeletal chest pain	1 (0.4%)	0	0
Neck pain	0	1 (0.4%)	0
Pain in extremity	0	0	1 (0.7%)
Osteoarthropathies	0	1 (0.4%)	0
Osteoarthritis	0	1 (0.4%)	0
Tendon disorders	1 (0.4%)	0	0
Tendonitis	1 (0.4%)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.4%)	2 (0.7%)	1 (0.7%)
Colorectal neoplasms malignant	0	1 (0.4%)	0
Colon cancer	0	1 (0.4%)	0
Skin neoplasms benign	1 (0.4%)	1 (0.4%)	0
Skin papilloma	1 (0.4%)	1 (0.4%)	0

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Induction Study: Cohort A
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System Organ Class High-Level Term Preferred Term	Filgotinib 200 mg (N=245)	Filgotinib 100 mg (N=277)	Placebo (N=137)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	103 (42.0%)	122 (44.0%)	57 (41.6%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)			
Skin neoplasms malignant and unspecified (excl melanoma)	0	0	1 (0.7%)
Basal cell carcinoma	0	0	1 (0.7%)
Nervous system disorders	19 (7.8%)	18 (6.5%)	9 (6.6%)
Cortical dysfunction NEC	0	2 (0.7%)	0
Aphasia	0	2 (0.7%)	0
Disturbances in consciousness NEC	1 (0.4%)	0	0
Somnolence	1 (0.4%)	0	0
Headaches NEC	11 (4.5%)	13 (4.7%)	6 (4.4%)
Headache	11 (4.5%)	12 (4.3%)	6 (4.4%)
Sinus headache	0	1 (0.4%)	0
Lumbar spinal cord and nerve root disorders	1 (0.4%)	0	0
Sciatica	1 (0.4%)	0	0
Memory loss (excl dementia)	1 (0.4%)	0	0
Amnesia	1 (0.4%)	0	0

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Number (%) of Subjects with Any Treatment-Emergent Adverse Events	103 (42.0%)	122 (44.0%)	57 (41.6%)
Nervous system disorders (cont)			
Migraine headaches	1 (0.4%)	0	0
Migraine	1 (0.4%)	0	0
Mononeuropathies	1 (0.4%)	0	0
Nerve compression	1 (0.4%)	0	0
Neurological signs and symptoms NEC	3 (1.2%)	3 (1.1%)	2 (1.5%)
Dizziness	2 (0.8%)	3 (1.1%)	2 (1.5%)
Head discomfort	1 (0.4%)	0	0
Paraesthesias and dysaesthesias	1 (0.4%)	1 (0.4%)	1 (0.7%)
Paraesthesia	0	1 (0.4%)	1 (0.7%)
Burning sensation	1 (0.4%)	0	0
Sensory abnormalities NEC	1 (0.4%)	0	0
Taste disorder	1 (0.4%)	0	0
Psychiatric disorders	2 (0.8%)	3 (1.1%)	2 (1.5%)
Anxiety symptoms	1 (0.4%)	0	0
Anxiety	1 (0.4%)	0	0

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Number (%) of Subjects with Any Treatment-Emergent Adverse Events	103 (42.0%)	122 (44.0%)	57 (41.6%)
Psychiatric disorders (cont)			
Disturbances in initiating and maintaining sleep	1 (0.4%)	2 (0.7%)	1 (0.7%)
Insomnia	1 (0.4%)	1 (0.4%)	1 (0.7%)
Initial insomnia	0	1 (0.4%)	0
Mood alterations with depressive symptoms	0	0	1 (0.7%)
Depressed mood	0	0	1 (0.7%)
Sleep disorders NEC	0	1 (0.4%)	0
Sleep disorder	0	1 (0.4%)	0
Renal and urinary disorders	0	5 (1.8%)	0
Bladder and urethral symptoms	0	1 (0.4%)	0
Pollakiuria	0	1 (0.4%)	0
Renal lithiasis	0	1 (0.4%)	0
Nephrolithiasis	0	1 (0.4%)	0
Urinary abnormalities	0	1 (0.4%)	0
Proteinuria	0	1 (0.4%)	0

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Number (%) of Subjects with Any Treatment-Emergent Adverse Events	103 (42.0%)	122 (44.0%)	57 (41.6%)
Renal and urinary disorders (cont)			
Urinary tract lithiasis (excl renal)	0	1 (0.4%)	0
Ureterolithiasis	0	1 (0.4%)	0
Urinary tract signs and symptoms NEC	0	1 (0.4%)	0
Renal colic	0	1 (0.4%)	0
Reproductive system and breast disorders	3 (1.2%)	5 (1.8%)	0
Breast signs and symptoms	1 (0.4%)	2 (0.7%)	0
Breast pain	0	2 (0.7%)	0
Breast tenderness	1 (0.4%)	0	0
Erection and ejaculation conditions and disorders	1 (0.4%)	0	0
Erectile dysfunction	1 (0.4%)	0	0
Menstruation and uterine bleeding NEC	1 (0.4%)	0	0
Metrorrhagia	1 (0.4%)	0	0
Ovarian and fallopian tube cysts and neoplasms	0	1 (0.4%)	0
Ovarian cyst ruptured	0	1 (0.4%)	0

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Table 15.11.2.1.2.1: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Induction Study: Cohort A
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Filgotinib 200 mg (N=245)	Filgotinib 100 mg (N=277)	Placebo (N=137)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	103 (42.0%)	122 (44.0%)	57 (41.6%)
Reproductive system and breast disorders (cont)			
Reproductive tract disorders NEC (excl neoplasms)	0	1 (0.4%)	0
Genital paraesthesia	0	1 (0.4%)	0
Uterine disorders NEC	0	1 (0.4%)	0
Adenomyosis	0	1 (0.4%)	0
Vulvovaginal disorders NEC	1 (0.4%)	0	0
Vaginal haemorrhage	1 (0.4%)	0	0
Respiratory, thoracic and mediastinal disorders	11 (4.5%)	7 (2.5%)	0
Breathing abnormalities	1 (0.4%)	1 (0.4%)	0
Dyspnoea	0	1 (0.4%)	0
Respiratory distress	1 (0.4%)	0	0
Bronchospasm and obstruction	1 (0.4%)	1 (0.4%)	0
Bronchospasm	1 (0.4%)	0	0
Wheezing	0	1 (0.4%)	0

TEAE = treatment-emergent adverse event. NEC = Not Elsewhere Classified. Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Induction first dose date up to one day before the Maintenance first dose date or 30 days after the Induction last dose date whichever is earlier, or led to premature discontinuation of Induction study drug.
System organ classes and high level terms (within each system organ class) were presented alphabetically, and preferred terms were presented by descending order of the total frequencies. Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
Source: Listing 16.2.7.1

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Table 15.11.2.1.2.1: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Induction Study: Cohort A
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Filgotinib 200 mg (N=245)	Filgotinib 100 mg (N=277)	Placebo (N=137)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	103 (42.0%)	122 (44.0%)	57 (41.6%)
Respiratory, thoracic and mediastinal disorders (cont)			
Coughing and associated symptoms	6 (2.4%)	1 (0.4%)	0
Cough	5 (2.0%)	1 (0.4%)	0
Productive cough	1 (0.4%)	0	0
Lower respiratory tract signs and symptoms	0	1 (0.4%)	0
Pleuritic pain	0	1 (0.4%)	0
Nasal congestion and inflammations	0	1 (0.4%)	0
Nasal congestion	0	1 (0.4%)	0
Respiratory tract disorders NEC	0	1 (0.4%)	0
Respiratory disorder	0	1 (0.4%)	0
Upper respiratory tract signs and symptoms	6 (2.4%)	3 (1.1%)	0
Oropharyngeal pain	4 (1.6%)	2 (0.7%)	0
Rhinorrhoea	1 (0.4%)	1 (0.4%)	0
Laryngeal discomfort	1 (0.4%)	0	0
Skin and subcutaneous tissue disorders	9 (3.7%)	11 (4.0%)	7 (5.1%)

TEAE = treatment-emergent adverse event. NEC = Not Elsewhere Classified. Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Induction first dose date up to one day before the Maintenance first dose date or 30 days after the Induction last dose date whichever is earlier, or led to premature discontinuation of Induction study drug.
System organ classes and high level terms (within each system organ class) were presented alphabetically, and preferred terms were presented by descending order of the total frequencies. Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
Source: Listing 16.2.7.1

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Table 15.11.2.1.2.1: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Induction Study: Cohort A
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Filgotinib 200 mg (N=245)	Filgotinib 100 mg (N=277)	Placebo (N=137)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	103 (42.0%)	122 (44.0%)	57 (41.6%)
Skin and subcutaneous tissue disorders (cont)			
Acnes	1 (0.4%)	0	0
Acne	1 (0.4%)	0	0
Alopecias	1 (0.4%)	2 (0.7%)	2 (1.5%)
Alopecia	1 (0.4%)	2 (0.7%)	2 (1.5%)
Apocrine and eccrine gland disorders	2 (0.8%)	0	1 (0.7%)
Hidradenitis	1 (0.4%)	0	0
Hyperhidrosis	0	0	1 (0.7%)
Night sweats	1 (0.4%)	0	0
Dermal and epidermal conditions NEC	1 (0.4%)	0	0
Dry skin	1 (0.4%)	0	0
Erythemas	0	2 (0.7%)	0
Erythema	0	2 (0.7%)	0
Exfoliative conditions	0	1 (0.4%)	0
Skin exfoliation	0	1 (0.4%)	0

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TEAEs are defined as any AEs that began on or after the Induction first dose date up to one day before the Maintenance first dose date or 30 days after the Induction last dose date whichever is earlier, or led to premature discontinuation of Induction study drug.
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Source: Listing 16.2.7.1

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Table 15.11.2.1.2.1: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Induction Study: Cohort A
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Filgotinib 200 mg (N=245)	Filgotinib 100 mg (N=277)	Placebo (N=137)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	103 (42.0%)	122 (44.0%)	57 (41.6%)
Skin and subcutaneous tissue disorders (cont)			
Pruritus NEC	1 (0.4%)	1 (0.4%)	1 (0.7%)
Pruritus	1 (0.4%)	1 (0.4%)	0
Rash pruritic	0	0	1 (0.7%)
Purpura and related conditions	0	0	1 (0.7%)
Purpura	0	0	1 (0.7%)
Rashes, eruptions and exanthems NEC	2 (0.8%)	6 (2.2%)	1 (0.7%)
Rash	1 (0.4%)	5 (1.8%)	1 (0.7%)
Rash papular	0	1 (0.4%)	0
Rash vesicular	1 (0.4%)	0	0
Urticarias	1 (0.4%)	0	1 (0.7%)
Urticaria	1 (0.4%)	0	1 (0.7%)
Vascular disorders	3 (1.2%)	2 (0.7%)	1 (0.7%)
Vascular hypertensive disorders NEC	3 (1.2%)	2 (0.7%)	1 (0.7%)
Hypertension	3 (1.2%)	2 (0.7%)	1 (0.7%)

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TEAEs are defined as any AEs that began on or after the Induction first dose date up to one day before the Maintenance first dose date or 30 days after the Induction last dose date whichever is earlier, or led to premature discontinuation of Induction study drug.
System organ classes and high level terms (within each system organ class) were presented alphabetically, and preferred terms were presented by descending order of the total frequencies. Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Tabelle 4-2 (Anhang): Ergebnisse für UE nach SOC und PT aus RCT mit dem zu bewertenden Arzneimittel (SELECTION, Induktionsphase: Kohorte B)

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Table 15.11.2.1.2.2: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Induction Study: Cohort B
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Filgotinib 200 mg (N=262)	Filgotinib 100 mg (N=285)	Placebo (N=142)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	169 (64.5%)	161 (56.5%)	100 (70.4%)
Blood and lymphatic system disorders	22 (8.4%)	25 (8.8%)	20 (14.1%)
Anaemia deficiencies	2 (0.8%)	2 (0.7%)	3 (2.1%)
Iron deficiency anaemia	2 (0.8%)	2 (0.7%)	3 (2.1%)
Anaemias NEC	13 (5.0%)	11 (3.9%)	11 (7.7%)
Anaemia	13 (5.0%)	11 (3.9%)	10 (7.0%)
Anaemia macrocytic	0	0	1 (0.7%)
Anaemias due to chronic disorders	1 (0.4%)	0	0
Anaemia of chronic disease	1 (0.4%)	0	0
Leukocytoses NEC	0	1 (0.4%)	2 (1.4%)
Leukocytosis	0	1 (0.4%)	1 (0.7%)
Neutrophilia	0	0	2 (1.4%)
Leukopenias NEC	5 (1.9%)	9 (3.2%)	1 (0.7%)
Lymphopenia	3 (1.1%)	7 (2.5%)	1 (0.7%)
Leukopenia	3 (1.1%)	2 (0.7%)	0
Lymphatic system disorders NEC	1 (0.4%)	1 (0.4%)	1 (0.7%)
Lymphadenopathy	1 (0.4%)	1 (0.4%)	1 (0.7%)

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TEAEs are defined as any AEs that began on or after the Induction first dose date up to one day before the Maintenance first dose date or 30 days after the Induction last dose date whichever is earlier, or led to premature discontinuation of Induction study drug.
System organ classes and high level terms (within each system organ class) were presented alphabetically, and preferred terms were presented by descending order of the total frequencies. Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
Source: Listing 16.2.7.1

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Table 15.11.2.1.2.2: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Induction Study: Cohort B
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Filgotinib 200 mg (N=262)	Filgotinib 100 mg (N=285)	Placebo (N=142)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	169 (64.5%)	161 (56.5%)	100 (70.4%)
Blood and lymphatic system disorders (cont)			
Marrow depression and hypoplastic anaemias	1 (0.4%)	0	0
Cytopenia	1 (0.4%)	0	0
Neutropenias	1 (0.4%)	2 (0.7%)	2 (1.4%)
Neutropenia	1 (0.4%)	2 (0.7%)	2 (1.4%)
Thrombocytoses	0	0	2 (1.4%)
Thrombocytosis	0	0	2 (1.4%)
Cardiac disorders	4 (1.5%)	2 (0.7%)	3 (2.1%)
Cardiac conduction disorders	1 (0.4%)	0	2 (1.4%)
Bundle branch block left	1 (0.4%)	0	1 (0.7%)
Atrioventricular block first degree	0	0	1 (0.7%)
Cardiac signs and symptoms NEC	1 (0.4%)	2 (0.7%)	1 (0.7%)
Palpitations	1 (0.4%)	2 (0.7%)	1 (0.7%)
Mitral valvular disorders	1 (0.4%)	0	0
Mitral valve incompetence	1 (0.4%)	0	0

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Table 15.11.2.1.2.2: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Induction Study: Cohort B
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Filgotinib 200 mg (N=262)	Filgotinib 100 mg (N=285)	Placebo (N=142)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	169 (64.5%)	161 (56.5%)	100 (70.4%)
Cardiac disorders (cont)			
Supraventricular arrhythmias	1 (0.4%)	0	0
Sinus arrhythmia	1 (0.4%)	0	0
Ear and labyrinth disorders	5 (1.9%)	0	1 (0.7%)
Hearing losses	1 (0.4%)	0	0
Hypoacusis	1 (0.4%)	0	0
Inner ear signs and symptoms	4 (1.5%)	0	1 (0.7%)
Vertigo	2 (0.8%)	0	1 (0.7%)
Tinnitus	2 (0.8%)	0	0
Endocrine disorders	0	2 (0.7%)	1 (0.7%)
Adrenal cortical hyperfunctions	0	1 (0.4%)	0
Cushingoid	0	1 (0.4%)	0
Adrenal gland disorders NEC	0	1 (0.4%)	0
Adrenal disorder	0	1 (0.4%)	0

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TEAEs are defined as any AEs that began on or after the Induction first dose date up to one day before the Maintenance first dose date or 30 days after the Induction last dose date whichever is earlier, or led to premature discontinuation of Induction study drug.
System organ classes and high level terms (within each system organ class) were presented alphabetically, and preferred terms were presented by descending order of the total frequencies. Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
Source: Listing 16.2.7.1

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Table 15.11.2.1.2.2: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Induction Study: Cohort B
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Filgotinib 200 mg (N=262)	Filgotinib 100 mg (N=285)	Placebo (N=142)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	169 (64.5%)	161 (56.5%)	100 (70.4%)
Endocrine disorders (cont)			
Thyroid hypofunction disorders	0	0	1 (0.7%)
Hypothyroidism	0	0	1 (0.7%)
Eye disorders	6 (2.3%)	4 (1.4%)	3 (2.1%)
Choroid and vitreous structural change, deposit and degeneration	0	0	1 (0.7%)
Vitreous detachment	0	0	1 (0.7%)
Conjunctival and corneal bleeding and vascular disorders	1 (0.4%)	0	1 (0.7%)
Conjunctival haemorrhage	1 (0.4%)	0	0
Corneal bleeding	0	0	1 (0.7%)
Glaucomas (excl congenital)	1 (0.4%)	1 (0.4%)	0
Glaucoma	0	1 (0.4%)	0
Ocular hypertension	1 (0.4%)	0	0
Lid, lash and lacrimal infections, irritations and inflammations	0	1 (0.4%)	0
Eyelid oedema	0	1 (0.4%)	0
Lid, lash and lacrimal structural disorders	0	0	1 (0.7%)
Eyelid skin dryness	0	0	1 (0.7%)

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Table 15.11.2.1.2.2: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Induction Study: Cohort B
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Filgotinib 200 mg (N=262)	Filgotinib 100 mg (N=285)	Placebo (N=142)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	169 (64.5%)	161 (56.5%)	100 (70.4%)
Eye disorders (cont)			
Ocular disorders NEC	1 (0.4%)	0	0
Eye pain	1 (0.4%)	0	0
Ocular infections, inflammations and associated manifestations	1 (0.4%)	0	0
Eye discharge	1 (0.4%)	0	0
Scleral structural change, deposit and degeneration	0	1 (0.4%)	0
Scleral disorder	0	1 (0.4%)	0
Visual disorders NEC	1 (0.4%)	0	0
Vision blurred	1 (0.4%)	0	0
Visual impairment and blindness (excl colour blindness)	1 (0.4%)	1 (0.4%)	0
Visual acuity reduced	1 (0.4%)	1 (0.4%)	0
Gastrointestinal disorders	67 (25.6%)	57 (20.0%)	29 (20.4%)
Abdominal findings abnormal	0	1 (0.4%)	0
Gastrointestinal sounds abnormal	0	1 (0.4%)	0

TEAE = treatment-emergent adverse event. NEC = Not Elsewhere Classified. Adverse events were coded according to MedDRA Version 22.1.
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Table 15.11.2.1.2.2: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Induction Study: Cohort B
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Filgotinib 200 mg (N=262)	Filgotinib 100 mg (N=285)	Placebo (N=142)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	169 (64.5%)	161 (56.5%)	100 (70.4%)
Gastrointestinal disorders (cont)			
Acute and chronic pancreatitis	0	0	1 (0.7%)
Pancreatitis acute	0	0	1 (0.7%)
Anal and rectal disorders NEC	1 (0.4%)	2 (0.7%)	0
Anal fissure	1 (0.4%)	2 (0.7%)	0
Anal and rectal pains	0	0	1 (0.7%)
Proctalgia	0	0	1 (0.7%)
Anal and rectal signs and symptoms	0	2 (0.7%)	0
Anorectal discomfort	0	1 (0.4%)	0
Rectal tenesmus	0	1 (0.4%)	0
Benign neoplasms gastrointestinal (excl oral cavity)	0	1 (0.4%)	1 (0.7%)
Large intestine polyp	0	1 (0.4%)	1 (0.7%)
Colitis (excl infective)	21 (8.0%)	16 (5.6%)	12 (8.5%)
Colitis ulcerative	21 (8.0%)	15 (5.3%)	11 (7.7%)
Colitis	0	1 (0.4%)	1 (0.7%)

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Table 15.11.2.1.2.2: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Induction Study: Cohort B
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Filgotinib 200 mg (N=262)	Filgotinib 100 mg (N=285)	Placebo (N=142)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	169 (64.5%)	161 (56.5%)	100 (70.4%)
Gastrointestinal disorders (cont)			
Dental and periodontal infections and inflammations	2 (0.8%)	0	0
Dental caries	2 (0.8%)	0	0
Dental disorders NEC	1 (0.4%)	0	0
Tooth disorder	1 (0.4%)	0	0
Dental pain and sensation disorders	3 (1.1%)	0	0
Toothache	3 (1.1%)	0	0
Diarrhoea (excl infective)	5 (1.9%)	3 (1.1%)	1 (0.7%)
Diarrhoea	5 (1.9%)	3 (1.1%)	1 (0.7%)
Duodenal ulcers and perforation	1 (0.4%)	0	0
Duodenal ulcer	1 (0.4%)	0	0
Duodenal ulcer haemorrhage	1 (0.4%)	0	0
Dyspeptic signs and symptoms	4 (1.5%)	2 (0.7%)	0
Dyspepsia	4 (1.5%)	2 (0.7%)	0

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Table 15.11.2.1.2.2: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Induction Study: Cohort B
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Filgotinib 200 mg (N=262)	Filgotinib 100 mg (N=285)	Placebo (N=142)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	169 (64.5%)	161 (56.5%)	100 (70.4%)
Gastrointestinal disorders (cont)			
Flatulence, bloating and distension	10 (3.8%)	5 (1.8%)	5 (3.5%)
Flatulence	3 (1.1%)	3 (1.1%)	5 (3.5%)
Abdominal distension	6 (2.3%)	2 (0.7%)	0
Aerophagia	1 (0.4%)	0	0
Gastritis (excl infective)	1 (0.4%)	2 (0.7%)	0
Gastritis	1 (0.4%)	2 (0.7%)	0
Gastrointestinal and abdominal pains (excl oral and throat)	10 (3.8%)	9 (3.2%)	10 (7.0%)
Abdominal pain	9 (3.4%)	7 (2.5%)	9 (6.3%)
Abdominal pain upper	1 (0.4%)	2 (0.7%)	1 (0.7%)
Abdominal pain lower	0	0	1 (0.7%)
Gastrointestinal atonic and hypomotility disorders NEC	2 (0.8%)	7 (2.5%)	2 (1.4%)
Constipation	2 (0.8%)	4 (1.4%)	1 (0.7%)
Gastrooesophageal reflux disease	0	4 (1.4%)	1 (0.7%)
Gastrointestinal disorders NEC	1 (0.4%)	0	0
Appendiceal mucocoele	1 (0.4%)	0	0

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Table 15.11.2.1.2.2: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Induction Study: Cohort B
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Filgotinib 200 mg (N=262)	Filgotinib 100 mg (N=285)	Placebo (N=142)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	169 (64.5%)	161 (56.5%)	100 (70.4%)
Gastrointestinal disorders (cont)			
Gastrointestinal fistulae	1 (0.4%)	0	0
Anal fistula	1 (0.4%)	0	0
Gastrointestinal mucosal dystrophies and secretion disorders	1 (0.4%)	1 (0.4%)	0
Colon dysplasia	0	1 (0.4%)	0
Hyperchlorhydria	1 (0.4%)	0	0
Gastrointestinal signs and symptoms NEC	1 (0.4%)	0	2 (1.4%)
Abdominal discomfort	0	0	1 (0.7%)
Anal incontinence	0	0	1 (0.7%)
Dysphagia	1 (0.4%)	0	0
Gastrointestinal spastic and hypermotility disorders	1 (0.4%)	0	1 (0.7%)
Frequent bowel movements	1 (0.4%)	0	1 (0.7%)
Haemorrhoids and gastrointestinal varices (excl oesophageal)	2 (0.8%)	0	3 (2.1%)
Haemorrhoids	1 (0.4%)	0	3 (2.1%)
Haemorrhoids thrombosed	1 (0.4%)	0	0

TEAE = treatment-emergent adverse event. NEC = Not Elsewhere Classified. Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Induction first dose date up to one day before the Maintenance first dose date or 30 days after the Induction last dose date whichever is earlier, or led to premature discontinuation of Induction study drug.
System organ classes and high level terms (within each system organ class) were presented alphabetically, and preferred terms were presented by descending order of the total frequencies. Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
Source: Listing 16.2.7.1

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Table 15.11.2.1.2.2: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Induction Study: Cohort B
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Filgotinib 200 mg (N=262)	Filgotinib 100 mg (N=285)	Placebo (N=142)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	169 (64.5%)	161 (56.5%)	100 (70.4%)
Gastrointestinal disorders (cont)			
Intestinal haemorrhages	3 (1.1%)	1 (0.4%)	0
Rectal haemorrhage	1 (0.4%)	1 (0.4%)	0
Anal haemorrhage	1 (0.4%)	0	0
Large intestinal haemorrhage	1 (0.4%)	0	0
Nausea and vomiting symptoms	11 (4.2%)	17 (6.0%)	8 (5.6%)
Nausea	7 (2.7%)	16 (5.6%)	6 (4.2%)
Vomiting	4 (1.5%)	4 (1.4%)	4 (2.8%)
Regurgitation	1 (0.4%)	0	0
Oral dryness and saliva altered	0	0	1 (0.7%)
Dry mouth	0	0	1 (0.7%)
Stomatitis and ulceration	2 (0.8%)	1 (0.4%)	0
Mouth ulceration	1 (0.4%)	1 (0.4%)	0
Stomatitis	1 (0.4%)	0	0
General disorders and administration site conditions	23 (8.8%)	16 (5.6%)	18 (12.7%)

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Table 15.11.2.1.2.2: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Induction Study: Cohort B
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Filgotinib 200 mg (N=262)	Filgotinib 100 mg (N=285)	Placebo (N=142)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	169 (64.5%)	161 (56.5%)	100 (70.4%)
General disorders and administration site conditions (cont)			
Asthenic conditions	8 (3.1%)	6 (2.1%)	8 (5.6%)
Asthenia	3 (1.1%)	4 (1.4%)	6 (4.2%)
Fatigue	5 (1.9%)	2 (0.7%)	2 (1.4%)
Febrile disorders	6 (2.3%)	3 (1.1%)	8 (5.6%)
Pyrexia	6 (2.3%)	3 (1.1%)	8 (5.6%)
Feelings and sensations NEC	0	2 (0.7%)	0
Chills	0	1 (0.4%)	0
Feeling of body temperature change	0	1 (0.4%)	0
General signs and symptoms NEC	2 (0.8%)	1 (0.4%)	2 (1.4%)
Influenza like illness	0	1 (0.4%)	1 (0.7%)
Secretion discharge	1 (0.4%)	0	1 (0.7%)
Peripheral swelling	1 (0.4%)	0	0
Implant and catheter site reactions	0	1 (0.4%)	0
Implant site pain	0	1 (0.4%)	0
Inflammations	0	1 (0.4%)	0
Inflammation	0	1 (0.4%)	0

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TEAEs are defined as any AEs that began on or after the Induction first dose date up to one day before the Maintenance first dose date or 30 days after the Induction last dose date whichever is earlier, or led to premature discontinuation of Induction study drug.
System organ classes and high level terms (within each system organ class) were presented alphabetically, and preferred terms were presented by descending order of the total frequencies. Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 15.11.2.1.2.2: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Induction Study: Cohort B
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Filgotinib 200 mg (N=262)	Filgotinib 100 mg (N=285)	Placebo (N=142)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	169 (64.5%)	161 (56.5%)	100 (70.4%)
General disorders and administration site conditions (cont)			
Infusion site reactions	0	0	1 (0.7%)
Infusion site erythema	0	0	1 (0.7%)
Mass conditions NEC	1 (0.4%)	0	0
Cyst	1 (0.4%)	0	0
Mucosal findings abnormal	0	1 (0.4%)	0
Polyp	0	1 (0.4%)	0
Oedema NEC	1 (0.4%)	2 (0.7%)	1 (0.7%)
Oedema peripheral	1 (0.4%)	2 (0.7%)	1 (0.7%)
Pain and discomfort NEC	5 (1.9%)	2 (0.7%)	0
Chest pain	4 (1.5%)	2 (0.7%)	0
Pain	1 (0.4%)	0	0
Hepatobiliary disorders	0	2 (0.7%)	2 (1.4%)
Bile duct infections and inflammations	0	0	1 (0.7%)
Cholangitis sclerosing	0	0	1 (0.7%)

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Table 15.11.2.1.2.2: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Induction Study: Cohort B
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Filgotinib 200 mg (N=262)	Filgotinib 100 mg (N=285)	Placebo (N=142)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	169 (64.5%)	161 (56.5%)	100 (70.4%)
Hepatobiliary disorders (cont)			
Hepatic enzymes and function abnormalities	0	1 (0.4%)	1 (0.7%)
Hepatic function abnormal	0	1 (0.4%)	1 (0.7%)
Hepatocellular damage and hepatitis NEC	0	1 (0.4%)	0
Hepatocellular injury	0	1 (0.4%)	0
Immune system disorders	3 (1.1%)	2 (0.7%)	0
Allergic conditions NEC	1 (0.4%)	2 (0.7%)	0
Allergy to arthropod bite	1 (0.4%)	0	0
Hypersensitivity	0	1 (0.4%)	0
Serum sickness	0	1 (0.4%)	0
Atopic disorders	1 (0.4%)	0	0
Seasonal allergy	1 (0.4%)	0	0
Primary immunodeficiency syndromes	1 (0.4%)	0	0
Selective IgA immunodeficiency	1 (0.4%)	0	0
Infections and infestations	65 (24.8%)	55 (19.3%)	31 (21.8%)

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Table 15.11.2.1.2.2: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Induction Study: Cohort B
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Filgotinib 200 mg (N=262)	Filgotinib 100 mg (N=285)	Placebo (N=142)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	169 (64.5%)	161 (56.5%)	100 (70.4%)
Infections and infestations (cont)			
Abdominal and gastrointestinal infections	3 (1.1%)	4 (1.4%)	2 (1.4%)
Gastroenteritis	3 (1.1%)	3 (1.1%)	2 (1.4%)
Anal abscess	0	1 (0.4%)	0
Bacterial infections NEC	1 (0.4%)	0	1 (0.7%)
Pharyngitis bacterial	0	0	1 (0.7%)
Sinusitis bacterial	1 (0.4%)	0	0
Bone and joint infections	0	1 (0.4%)	0
Joint abscess	0	1 (0.4%)	0
Campylobacter infections	0	0	1 (0.7%)
Campylobacter gastroenteritis	0	0	1 (0.7%)
Candida infections	1 (0.4%)	1 (0.4%)	0
Vulvovaginal candidiasis	1 (0.4%)	1 (0.4%)	0
Clostridia infections	2 (0.8%)	0	0
Clostridium difficile colitis	1 (0.4%)	0	0
Clostridium difficile infection	1 (0.4%)	0	0

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Table 15.11.2.1.2.2: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Induction Study: Cohort B
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Filgotinib 200 mg (N=262)	Filgotinib 100 mg (N=285)	Placebo (N=142)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	169 (64.5%)	161 (56.5%)	100 (70.4%)
Infections and infestations (cont)			
Dental and oral soft tissue infections	4 (1.5%)	0	1 (0.7%)
Pulpitis dental	2 (0.8%)	0	0
Tooth abscess	1 (0.4%)	0	1 (0.7%)
Periodontitis	1 (0.4%)	0	0
Eye and eyelid infections	1 (0.4%)	1 (0.4%)	0
Conjunctivitis	0	1 (0.4%)	0
Hordeolum	1 (0.4%)	0	0
Fungal infections NEC	3 (1.1%)	2 (0.7%)	1 (0.7%)
Fungal infection	1 (0.4%)	0	1 (0.7%)
Fungal skin infection	0	2 (0.7%)	0
Onychomycosis	1 (0.4%)	0	0
Oral fungal infection	1 (0.4%)	0	0
Giardia infections	0	1 (0.4%)	0
Giardiasis	0	1 (0.4%)	0
Herpes viral infections	2 (0.8%)	3 (1.1%)	0
Oral herpes	1 (0.4%)	2 (0.7%)	0
Herpes zoster	1 (0.4%)	1 (0.4%)	0

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Table 15.11.2.1.2.2: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Induction Study: Cohort B
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Filgotinib 200 mg (N=262)	Filgotinib 100 mg (N=285)	Placebo (N=142)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	169 (64.5%)	161 (56.5%)	100 (70.4%)
Infections and infestations (cont)			
Infections NEC	2 (0.8%)	1 (0.4%)	0
Infected bite	1 (0.4%)	0	0
Localised infection	1 (0.4%)	0	0
Respiratory tract infection	0	1 (0.4%)	0
Influenza viral infections	3 (1.1%)	1 (0.4%)	1 (0.7%)
Influenza	3 (1.1%)	1 (0.4%)	1 (0.7%)
Lower respiratory tract and lung infections	2 (0.8%)	1 (0.4%)	1 (0.7%)
Bronchitis	1 (0.4%)	1 (0.4%)	0
Lower respiratory tract infection	0	0	1 (0.7%)
Pneumonia	1 (0.4%)	0	0
Sepsis, bacteraemia, viraemia and fungaemia NEC	0	2 (0.7%)	0
Sepsis	0	2 (0.7%)	0
Bacteraemia	0	1 (0.4%)	0

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Table 15.11.2.1.2.2: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Induction Study: Cohort B
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Filgotinib 200 mg (N=262)	Filgotinib 100 mg (N=285)	Placebo (N=142)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	169 (64.5%)	161 (56.5%)	100 (70.4%)
Infections and infestations (cont)			
Skin structures and soft tissue infections	0	2 (0.7%)	3 (2.1%)
Folliculitis	0	0	2 (1.4%)
Eczema infected	0	0	1 (0.7%)
Paronychia	0	1 (0.4%)	0
Rash pustular	0	1 (0.4%)	0
Staphylococcal infections	2 (0.8%)	2 (0.7%)	0
Furuncle	2 (0.8%)	1 (0.4%)	0
Staphylococcal infection	0	1 (0.4%)	0
Streptococcal infections	1 (0.4%)	0	0
Pharyngitis streptococcal	1 (0.4%)	0	0
Tinea infections	0	1 (0.4%)	0
Tinea pedis	0	1 (0.4%)	0

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Induction Study: Cohort B
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System Organ Class High-Level Term Preferred Term	Filgotinib 200 mg (N=262)	Filgotinib 100 mg (N=285)	Placebo (N=142)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	169 (64.5%)	161 (56.5%)	100 (70.4%)
Infections and infestations (cont)			
Upper respiratory tract infections	36 (13.7%)	31 (10.9%)	19 (13.4%)
Nasopharyngitis	20 (7.6%)	20 (7.0%)	11 (7.7%)
Upper respiratory tract infection	13 (5.0%)	4 (1.4%)	5 (3.5%)
Pharyngitis	2 (0.8%)	3 (1.1%)	1 (0.7%)
Rhinitis	2 (0.8%)	3 (1.1%)	1 (0.7%)
Sinusitis	3 (1.1%)	2 (0.7%)	1 (0.7%)
Acute sinusitis	0	1 (0.4%)	0
Tonsillitis	1 (0.4%)	0	0
Urinary tract infections	5 (1.9%)	2 (0.7%)	2 (1.4%)
Urinary tract infection	3 (1.1%)	2 (0.7%)	2 (1.4%)
Cystitis	2 (0.8%)	0	0
Viral infections NEC	2 (0.8%)	3 (1.1%)	4 (2.8%)
Gastroenteritis viral	1 (0.4%)	3 (1.1%)	1 (0.7%)
Gastrointestinal viral infection	1 (0.4%)	0	1 (0.7%)
Viral rhinitis	0	0	2 (1.4%)
Injury, poisoning and procedural complications	11 (4.2%)	7 (2.5%)	3 (2.1%)

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System Organ Class High-Level Term Preferred Term	Filgotinib 200 mg (N=262)	Filgotinib 100 mg (N=285)	Placebo (N=142)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	169 (64.5%)	161 (56.5%)	100 (70.4%)
Injury, poisoning and procedural complications (cont)			
Bone and joint injuries NEC	1 (0.4%)	1 (0.4%)	0
Joint injury	1 (0.4%)	0	0
Meniscus injury	0	1 (0.4%)	0
Heat injuries (excl thermal burns)	0	0	1 (0.7%)
Heat illness	0	0	1 (0.7%)
Limb fractures and dislocations	0	1 (0.4%)	0
Femur fracture	0	1 (0.4%)	0
Muscle, tendon and ligament injuries	1 (0.4%)	1 (0.4%)	0
Ligament sprain	0	1 (0.4%)	0
Muscle strain	1 (0.4%)	0	0
Non-site specific injuries NEC	0	1 (0.4%)	1 (0.7%)
Fall	0	1 (0.4%)	1 (0.7%)
Non-site specific procedural complications	3 (1.1%)	0	0
Procedural pain	3 (1.1%)	0	0

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Table 15.11.2.1.2.2: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Induction Study: Cohort B
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Filgotinib 200 mg (N=262)	Filgotinib 100 mg (N=285)	Placebo (N=142)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	169 (64.5%)	161 (56.5%)	100 (70.4%)
Injury, poisoning and procedural complications (cont)			
Site specific injuries NEC	2 (0.8%)	1 (0.4%)	1 (0.7%)
Limb injury	1 (0.4%)	1 (0.4%)	1 (0.7%)
Head injury	1 (0.4%)	0	0
Skin injuries NEC	4 (1.5%)	3 (1.1%)	0
Contusion	3 (1.1%)	2 (0.7%)	0
Skin laceration	1 (0.4%)	1 (0.4%)	0
Skin abrasion	0	1 (0.4%)	0
Spinal fractures and dislocations	0	0	1 (0.7%)
Spinal compression fracture	0	0	1 (0.7%)
Thoracic cage fractures and dislocations	0	0	1 (0.7%)
Rib fracture	0	0	1 (0.7%)
Investigations	20 (7.6%)	15 (5.3%)	7 (4.9%)
Carbohydrate tolerance analyses (incl diabetes)	1 (0.4%)	1 (0.4%)	0
Blood glucose increased	1 (0.4%)	1 (0.4%)	0

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Table 15.11.2.1.2.2: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Induction Study: Cohort B
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Filgotinib 200 mg (N=262)	Filgotinib 100 mg (N=285)	Placebo (N=142)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	169 (64.5%)	161 (56.5%)	100 (70.4%)
Investigations (cont)			
Cardiac auscultatory investigations	0	1 (0.4%)	1 (0.7%)
Cardiac murmur	0	1 (0.4%)	1 (0.7%)
Cholesterol analyses	2 (0.8%)	0	0
Blood cholesterol increased	2 (0.8%)	0	0
Low density lipoprotein increased	1 (0.4%)	0	0
Heart rate and pulse investigations	0	0	1 (0.7%)
Heart rate increased	0	0	1 (0.7%)
Immunoglobulin analyses	1 (0.4%)	0	0
Blood immunoglobulin A increased	1 (0.4%)	0	0
Blood immunoglobulin M increased	1 (0.4%)	0	0
Liver function analyses	3 (1.1%)	2 (0.7%)	1 (0.7%)
Alanine aminotransferase increased	2 (0.8%)	1 (0.4%)	0
Aspartate aminotransferase increased	2 (0.8%)	1 (0.4%)	0
Liver function test increased	0	1 (0.4%)	1 (0.7%)
Blood bilirubin increased	0	0	1 (0.7%)
Transaminases increased	1 (0.4%)	0	0

TEAE = treatment-emergent adverse event. NEC = Not Elsewhere Classified. Adverse events were coded according to MedDRA Version 22.1.
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System organ classes and high level terms (within each system organ class) were presented alphabetically, and preferred terms were presented by descending order of the total frequencies. Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
Source: Listing 16.2.7.1

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Table 15.11.2.1.2.2: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Induction Study: Cohort B
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Filgotinib 200 mg (N=262)	Filgotinib 100 mg (N=285)	Placebo (N=142)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	169 (64.5%)	161 (56.5%)	100 (70.4%)
Investigations (cont)			
Mineral and electrolyte analyses	6 (2.3%)	3 (1.1%)	2 (1.4%)
Blood phosphorus decreased	6 (2.3%)	2 (0.7%)	2 (1.4%)
Serum ferritin decreased	0	1 (0.4%)	0
Physical examination procedures and organ system status	0	2 (0.7%)	2 (1.4%)
Weight decreased	0	1 (0.4%)	2 (1.4%)
Weight increased	0	1 (0.4%)	0
Platelet analyses	1 (0.4%)	1 (0.4%)	0
Platelet count increased	1 (0.4%)	1 (0.4%)	0
Protein analyses NEC	1 (0.4%)	0	0
C-reactive protein increased	1 (0.4%)	0	0
Red blood cell analyses	4 (1.5%)	2 (0.7%)	0
Haemoglobin decreased	3 (1.1%)	1 (0.4%)	0
Mean cell volume increased	1 (0.4%)	1 (0.4%)	0
Renal function analyses	1 (0.4%)	0	0
Blood urea increased	1 (0.4%)	0	0

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Table 15.11.2.1.2.2: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Induction Study: Cohort B
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Filgotinib 200 mg (N=262)	Filgotinib 100 mg (N=285)	Placebo (N=142)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	169 (64.5%)	161 (56.5%)	100 (70.4%)
Investigations (cont)			
Skeletal and cardiac muscle analyses	3 (1.1%)	0	0
Blood creatine phosphokinase increased	3 (1.1%)	0	0
Tissue enzyme analyses NEC	0	1 (0.4%)	0
Blood alkaline phosphatase increased	0	1 (0.4%)	0
Urinalysis NEC	0	1 (0.4%)	0
Protein urine present	0	1 (0.4%)	0
Vascular tests NEC (incl blood pressure)	0	1 (0.4%)	1 (0.7%)
Blood pressure increased	0	1 (0.4%)	1 (0.7%)
White blood cell analyses	1 (0.4%)	1 (0.4%)	0
Basophil count increased	1 (0.4%)	0	0
White blood cell count increased	0	1 (0.4%)	0
Metabolism and nutrition disorders	11 (4.2%)	28 (9.8%)	12 (8.5%)
Appetite disorders	1 (0.4%)	0	0
Decreased appetite	1 (0.4%)	0	0

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Table 15.11.2.1.2.2: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Induction Study: Cohort B
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Filgotinib 200 mg (N=262)	Filgotinib 100 mg (N=285)	Placebo (N=142)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	169 (64.5%)	161 (56.5%)	100 (70.4%)
Metabolism and nutrition disorders (cont)			
Calcium metabolism disorders	0	0	2 (1.4%)
Calcium deficiency	0	0	1 (0.7%)
Hypocalcaemia	0	0	1 (0.7%)
Diabetes mellitus (incl subtypes)	1 (0.4%)	0	0
Diabetes mellitus	1 (0.4%)	0	0
Elevated cholesterol	2 (0.8%)	1 (0.4%)	0
Hypercholesterolaemia	2 (0.8%)	1 (0.4%)	0
Elevated triglycerides	0	1 (0.4%)	1 (0.7%)
Hypertriglyceridaemia	0	1 (0.4%)	1 (0.7%)
Fat soluble vitamin deficiencies and disorders	0	0	1 (0.7%)
Vitamin D deficiency	0	0	1 (0.7%)
Fluid intake increased	0	1 (0.4%)	0
Polydipsia	0	1 (0.4%)	0

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Table 15.11.2.1.2.2: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Induction Study: Cohort B
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Filgotinib 200 mg (N=262)	Filgotinib 100 mg (N=285)	Placebo (N=142)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	169 (64.5%)	161 (56.5%)	100 (70.4%)
Metabolism and nutrition disorders (cont)			
Hyperglycaemic conditions NEC	0	3 (1.1%)	1 (0.7%)
Hyperglycaemia	0	2 (0.7%)	1 (0.7%)
Glucose tolerance impaired	0	1 (0.4%)	0
Iron deficiencies	1 (0.4%)	4 (1.4%)	2 (1.4%)
Iron deficiency	1 (0.4%)	4 (1.4%)	2 (1.4%)
Lipid metabolism and deposit disorders NEC	2 (0.8%)	2 (0.7%)	0
Dyslipidaemia	2 (0.8%)	2 (0.7%)	0
Metabolic acidoses (excl diabetic acidoses)	0	1 (0.4%)	0
Metabolic acidosis	0	1 (0.4%)	0
Phosphorus metabolism disorders	5 (1.9%)	9 (3.2%)	5 (3.5%)
Hypophosphataemia	5 (1.9%)	9 (3.2%)	5 (3.5%)
Potassium imbalance	2 (0.8%)	2 (0.7%)	4 (2.8%)
Hypokalaemia	2 (0.8%)	2 (0.7%)	4 (2.8%)
Total fluid volume decreased	0	1 (0.4%)	0
Dehydration	0	1 (0.4%)	0

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Table 15.11.2.1.2.2: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Induction Study: Cohort B
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Filgotinib 200 mg (N=262)	Filgotinib 100 mg (N=285)	Placebo (N=142)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	169 (64.5%)	161 (56.5%)	100 (70.4%)
Metabolism and nutrition disorders (cont)			
Water soluble vitamin deficiencies	0	3 (1.1%)	1 (0.7%)
Folate deficiency	0	2 (0.7%)	1 (0.7%)
Vitamin B12 deficiency	0	2 (0.7%)	0
Musculoskeletal and connective tissue disorders	26 (9.9%)	32 (11.2%)	18 (12.7%)
Arthropathies NEC	1 (0.4%)	0	3 (2.1%)
Arthritis	1 (0.4%)	0	2 (1.4%)
Sacroiliitis	0	0	1 (0.7%)
Bone related signs and symptoms	2 (0.8%)	2 (0.7%)	1 (0.7%)
Bone pain	1 (0.4%)	1 (0.4%)	0
Spinal pain	1 (0.4%)	1 (0.4%)	0
Pain in jaw	0	0	1 (0.7%)
Intervertebral disc disorders NEC	2 (0.8%)	1 (0.4%)	0
Intervertebral disc protrusion	2 (0.8%)	0	0
Intervertebral disc degeneration	0	1 (0.4%)	0

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Table 15.11.2.1.2.2: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Induction Study: Cohort B
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Filgotinib 200 mg (N=262)	Filgotinib 100 mg (N=285)	Placebo (N=142)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	169 (64.5%)	161 (56.5%)	100 (70.4%)
Musculoskeletal and connective tissue disorders (cont)			
Joint related signs and symptoms	8 (3.1%)	11 (3.9%)	7 (4.9%)
Arthralgia	8 (3.1%)	10 (3.5%)	7 (4.9%)
Joint swelling	0	1 (0.4%)	0
Metabolic bone disorders	1 (0.4%)	1 (0.4%)	0
Osteoporosis	1 (0.4%)	1 (0.4%)	0
Muscle pains	1 (0.4%)	3 (1.1%)	0
Myalgia	1 (0.4%)	3 (1.1%)	0
Muscle related signs and symptoms NEC	2 (0.8%)	3 (1.1%)	4 (2.8%)
Muscle spasms	2 (0.8%)	3 (1.1%)	4 (2.8%)
Muscle weakness conditions	2 (0.8%)	1 (0.4%)	0
Muscular weakness	2 (0.8%)	1 (0.4%)	0
Musculoskeletal and connective tissue conditions NEC	0	0	1 (0.7%)
Musculoskeletal stiffness	0	0	1 (0.7%)

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Table 15.11.2.1.2.2: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Induction Study: Cohort B
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Filgotinib 200 mg (N=262)	Filgotinib 100 mg (N=285)	Placebo (N=142)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	169 (64.5%)	161 (56.5%)	100 (70.4%)
Musculoskeletal and connective tissue disorders (cont)			
Musculoskeletal and connective tissue pain and discomfort	10 (3.8%)	14 (4.9%)	5 (3.5%)
Back pain	5 (1.9%)	6 (2.1%)	3 (2.1%)
Musculoskeletal pain	1 (0.4%)	2 (0.7%)	1 (0.7%)
Pain in extremity	1 (0.4%)	2 (0.7%)	1 (0.7%)
Musculoskeletal chest pain	1 (0.4%)	2 (0.7%)	0
Musculoskeletal discomfort	0	2 (0.7%)	0
Flank pain	0	1 (0.4%)	0
Limb discomfort	1 (0.4%)	0	0
Neck pain	1 (0.4%)	0	0
Osteoarthropathies	0	1 (0.4%)	0
Osteoarthritis	0	1 (0.4%)	0
Tendon disorders	2 (0.8%)	0	1 (0.7%)
Tendonitis	2 (0.8%)	0	1 (0.7%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4 (1.5%)	0	0
Breast and nipple neoplasms malignant	1 (0.4%)	0	0
Breast cancer	1 (0.4%)	0	0

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Table 15.11.2.1.2.2: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Induction Study: Cohort B
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Filgotinib 200 mg (N=262)	Filgotinib 100 mg (N=285)	Placebo (N=142)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	169 (64.5%)	161 (56.5%)	100 (70.4%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)			
Skin neoplasms benign	1 (0.4%)	0	0
Skin papilloma	1 (0.4%)	0	0
Skin neoplasms malignant and unspecified (excl melanoma)	2 (0.8%)	0	0
Basal cell carcinoma	1 (0.4%)	0	0
Bowen's disease	1 (0.4%)	0	0
Nervous system disorders	27 (10.3%)	24 (8.4%)	17 (12.0%)
Central nervous system haemorrhages and cerebrovascular accidents	0	0	1 (0.7%)
Cerebrovascular accident	0	0	1 (0.7%)
Disturbances in consciousness NEC	2 (0.8%)	1 (0.4%)	0
Syncope	2 (0.8%)	0	0
Lethargy	0	1 (0.4%)	0
Headaches NEC	19 (7.3%)	11 (3.9%)	9 (6.3%)
Headache	19 (7.3%)	11 (3.9%)	9 (6.3%)
Lumbar spinal cord and nerve root disorders	0	0	2 (1.4%)
Sciatica	0	0	2 (1.4%)

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Table 15.11.2.1.2.2: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Induction Study: Cohort B
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Filgotinib 200 mg (N=262)	Filgotinib 100 mg (N=285)	Placebo (N=142)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	169 (64.5%)	161 (56.5%)	100 (70.4%)
Nervous system disorders (cont)			
Mental impairment (excl dementia and memory loss)	0	1 (0.4%)	0
Disturbance in attention	0	1 (0.4%)	0
Migraine headaches	1 (0.4%)	1 (0.4%)	1 (0.7%)
Migraine	1 (0.4%)	0	1 (0.7%)
Migraine with aura	0	1 (0.4%)	0
Mononeuropathies	0	1 (0.4%)	0
Nerve compression	0	1 (0.4%)	0
Nervous system disorders NEC	0	1 (0.4%)	0
Nervous system disorder	0	1 (0.4%)	0
Neurological signs and symptoms NEC	2 (0.8%)	5 (1.8%)	2 (1.4%)
Dizziness	2 (0.8%)	4 (1.4%)	2 (1.4%)
Presyncope	0	1 (0.4%)	0
Neuromuscular disorders NEC	0	1 (0.4%)	1 (0.7%)
Muscle contractions involuntary	0	1 (0.4%)	1 (0.7%)

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Table 15.11.2.1.2.2: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Induction Study: Cohort B
Safety Analysis Set

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Number (%) of Subjects with Any Treatment-Emergent Adverse Events	169 (64.5%)	161 (56.5%)	100 (70.4%)
Nervous system disorders (cont)			
Paraesthesias and dysaesthesias	4 (1.5%)	3 (1.1%)	1 (0.7%)
Paraesthesia	3 (1.1%)	2 (0.7%)	1 (0.7%)
Hypoaesthesia	1 (0.4%)	1 (0.4%)	0
Parkinson's disease and parkinsonism	0	0	1 (0.7%)
Parkinson's disease	0	0	1 (0.7%)
Sensory abnormalities NEC	0	1 (0.4%)	0
Sensory loss	0	1 (0.4%)	0
Pregnancy, puerperium and perinatal conditions	0	1 (0.4%)	0
Maternal complications of pregnancy NEC	0	1 (0.4%)	0
Ectopic pregnancy	0	1 (0.4%)	0
Psychiatric disorders	9 (3.4%)	3 (1.1%)	6 (4.2%)
Adjustment disorders	0	1 (0.4%)	0
Adjustment disorder with depressed mood	0	1 (0.4%)	0

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Table 15.11.2.1.2.2: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Induction Study: Cohort B
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Filgotinib 200 mg (N=262)	Filgotinib 100 mg (N=285)	Placebo (N=142)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	169 (64.5%)	161 (56.5%)	100 (70.4%)
Psychiatric disorders (cont)			
Anxiety symptoms	1 (0.4%)	0	1 (0.7%)
Anxiety	1 (0.4%)	0	1 (0.7%)
Attention deficit and disruptive behaviour disorders	1 (0.4%)	0	0
Attention deficit/hyperactivity disorder	1 (0.4%)	0	0
Disturbances in initiating and maintaining sleep	4 (1.5%)	1 (0.4%)	2 (1.4%)
Insomnia	3 (1.1%)	1 (0.4%)	2 (1.4%)
Initial insomnia	1 (0.4%)	0	0
Emotional and mood disturbances NEC	1 (0.4%)	0	0
Emotional disorder	1 (0.4%)	0	0
Fear symptoms and phobic disorders (incl social phobia)	1 (0.4%)	0	0
Social anxiety disorder	1 (0.4%)	0	0
Mood alterations with depressive symptoms	2 (0.8%)	0	0
Depressed mood	2 (0.8%)	0	0
Panic attacks and disorders	1 (0.4%)	0	0
Panic attack	1 (0.4%)	0	0

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Table 15.11.2.1.2.2: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Induction Study: Cohort B
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Filgotinib 200 mg (N=262)	Filgotinib 100 mg (N=285)	Placebo (N=142)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	169 (64.5%)	161 (56.5%)	100 (70.4%)
Psychiatric disorders (cont)			
Parasomnias	0	0	1 (0.7%)
Nightmare	0	0	1 (0.7%)
Sleep disorders NEC	0	1 (0.4%)	1 (0.7%)
Sleep disorder	0	1 (0.4%)	1 (0.7%)
Thinking disturbances	0	0	1 (0.7%)
Thinking abnormal	0	0	1 (0.7%)
Renal and urinary disorders	6 (2.3%)	3 (1.1%)	4 (2.8%)
Bladder and urethral symptoms	1 (0.4%)	0	0
Dysuria	1 (0.4%)	0	0
Renal failure and impairment	1 (0.4%)	0	1 (0.7%)
Chronic kidney disease	0	0	1 (0.7%)
Renal failure	1 (0.4%)	0	0
Renal lithiasis	1 (0.4%)	1 (0.4%)	0
Nephrolithiasis	1 (0.4%)	1 (0.4%)	0

TEAE = treatment-emergent adverse event. NEC = Not Elsewhere Classified. Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Induction first dose date up to one day before the Maintenance first dose date or 30 days after the Induction last dose date whichever is earlier, or led to premature discontinuation of Induction study drug.
System organ classes and high level terms (within each system organ class) were presented alphabetically, and preferred terms were presented by descending order of the total frequencies. Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
Source: Listing 16.2.7.1

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Table 15.11.2.1.2.2: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Induction Study: Cohort B
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Filgotinib 200 mg (N=262)	Filgotinib 100 mg (N=285)	Placebo (N=142)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	169 (64.5%)	161 (56.5%)	100 (70.4%)
Renal and urinary disorders (cont)			
Urinary abnormalities	3 (1.1%)	1 (0.4%)	2 (1.4%)
Proteinuria	1 (0.4%)	0	1 (0.7%)
Chromaturia	0	1 (0.4%)	0
Glycosuria	1 (0.4%)	0	0
Haematuria	0	0	1 (0.7%)
Sterile pyuria	1 (0.4%)	0	0
Urinary tract signs and symptoms NEC	1 (0.4%)	1 (0.4%)	1 (0.7%)
Nocturia	1 (0.4%)	0	0
Polyuria	0	1 (0.4%)	0
Renal colic	0	0	1 (0.7%)
Reproductive system and breast disorders	2 (0.8%)	4 (1.4%)	5 (3.5%)
Breast signs and symptoms	0	0	1 (0.7%)
Breast discomfort	0	0	1 (0.7%)
Erection and ejaculation conditions and disorders	0	0	1 (0.7%)
Erectile dysfunction	0	0	1 (0.7%)

TEAE = treatment-emergent adverse event. NEC = Not Elsewhere Classified. Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Induction first dose date up to one day before the Maintenance first dose date or 30 days after the Induction last dose date whichever is earlier, or led to premature discontinuation of Induction study drug.
System organ classes and high level terms (within each system organ class) were presented alphabetically, and preferred terms were presented by descending order of the total frequencies. Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
Source: Listing 16.2.7.1

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Table 15.11.2.1.2.2: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Induction Study: Cohort B
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Filgotinib 200 mg (N=262)	Filgotinib 100 mg (N=285)	Placebo (N=142)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	169 (64.5%)	161 (56.5%)	100 (70.4%)
Reproductive system and breast disorders (cont)			
Menstruation and uterine bleeding NEC	1 (0.4%)	2 (0.7%)	1 (0.7%)
Dysmenorrhoea	0	1 (0.4%)	1 (0.7%)
Metrorrhagia	1 (0.4%)	1 (0.4%)	0
Ovarian and fallopian tube cysts and neoplasms	0	0	1 (0.7%)
Ovarian cyst	0	0	1 (0.7%)
Pelvic prolapse conditions	0	1 (0.4%)	0
Cystocele	0	1 (0.4%)	0
Rectocele	0	1 (0.4%)	0
Uterine prolapse	0	1 (0.4%)	0
Penile disorders NEC (excl erection and ejaculation)	1 (0.4%)	0	0
Penile erythema	1 (0.4%)	0	0
Prostatic neoplasms and hypertrophy	0	0	1 (0.7%)
Benign prostatic hyperplasia	0	0	1 (0.7%)
Vulvovaginal signs and symptoms	0	1 (0.4%)	0
Vulvovaginal burning sensation	0	1 (0.4%)	0

TEAE = treatment-emergent adverse event. NEC = Not Elsewhere Classified. Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Induction first dose date up to one day before the Maintenance first dose date or 30 days after the Induction last dose date whichever is earlier, or led to premature discontinuation of Induction study drug.
System organ classes and high level terms (within each system organ class) were presented alphabetically, and preferred terms were presented by descending order of the total frequencies. Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
Source: Listing 16.2.7.1

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Table 15.11.2.1.2.2: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Induction Study: Cohort B
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Filgotinib 200 mg (N=262)	Filgotinib 100 mg (N=285)	Placebo (N=142)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	169 (64.5%)	161 (56.5%)	100 (70.4%)
Respiratory, thoracic and mediastinal disorders	17 (6.5%)	11 (3.9%)	7 (4.9%)
Breathing abnormalities	1 (0.4%)	2 (0.7%)	2 (1.4%)
Dyspnoea	0	2 (0.7%)	2 (1.4%)
Hyperventilation	1 (0.4%)	0	0
Bronchial conditions NEC	0	1 (0.4%)	0
Bronchial disorder	0	1 (0.4%)	0
Coughing and associated symptoms	6 (2.3%)	3 (1.1%)	4 (2.8%)
Cough	4 (1.5%)	2 (0.7%)	3 (2.1%)
Productive cough	2 (0.8%)	1 (0.4%)	0
Haemoptysis	0	0	1 (0.7%)
Nasal congestion and inflammations	2 (0.8%)	1 (0.4%)	1 (0.7%)
Nasal congestion	2 (0.8%)	1 (0.4%)	1 (0.7%)
Nasal disorders NEC	2 (0.8%)	1 (0.4%)	0
Epistaxis	1 (0.4%)	1 (0.4%)	0
Nasal dryness	1 (0.4%)	0	0

TEAE = treatment-emergent adverse event. NEC = Not Elsewhere Classified. Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Induction first dose date up to one day before the Maintenance first dose date or 30 days after the Induction last dose date whichever is earlier, or led to premature discontinuation of Induction study drug.
System organ classes and high level terms (within each system organ class) were presented alphabetically, and preferred terms were presented by descending order of the total frequencies. Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
Source: Listing 16.2.7.1

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Table 15.11.2.1.2.2: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Induction Study: Cohort B
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Filgotinib 200 mg (N=262)	Filgotinib 100 mg (N=285)	Placebo (N=142)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	169 (64.5%)	161 (56.5%)	100 (70.4%)
Respiratory, thoracic and mediastinal disorders (cont)			
Paranasal sinus disorders (excl infections and neoplasms)	1 (0.4%)	0	0
Paranasal sinus hypersecretion	1 (0.4%)	0	0
Pulmonary thrombotic and embolic conditions	1 (0.4%)	0	0
Pulmonary embolism	1 (0.4%)	0	0
Upper respiratory tract signs and symptoms	7 (2.7%)	4 (1.4%)	3 (2.1%)
Oropharyngeal pain	6 (2.3%)	2 (0.7%)	3 (2.1%)
Rhinorrhoea	1 (0.4%)	0	1 (0.7%)
Catarrh	0	1 (0.4%)	0
Upper-airway cough syndrome	0	1 (0.4%)	0
Skin and subcutaneous tissue disorders	17 (6.5%)	14 (4.9%)	17 (12.0%)
Acnes	0	2 (0.7%)	2 (1.4%)
Acne	0	2 (0.7%)	1 (0.7%)
Dermatitis acneiform	0	0	1 (0.7%)
Alopecias	4 (1.5%)	0	2 (1.4%)
Alopecia	4 (1.5%)	0	2 (1.4%)

TEAE = treatment-emergent adverse event. NEC = Not Elsewhere Classified. Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Induction first dose date up to one day before the Maintenance first dose date or 30 days after the Induction last dose date whichever is earlier, or led to premature discontinuation of Induction study drug.
System organ classes and high level terms (within each system organ class) were presented alphabetically, and preferred terms were presented by descending order of the total frequencies. Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
Source: Listing 16.2.7.1

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Table 15.11.2.1.2.2: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Induction Study: Cohort B
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Filgotinib 200 mg (N=262)	Filgotinib 100 mg (N=285)	Placebo (N=142)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	169 (64.5%)	161 (56.5%)	100 (70.4%)
Skin and subcutaneous tissue disorders (cont)			
Apocrine and eccrine gland disorders	3 (1.1%)	3 (1.1%)	0
Hyperhidrosis	3 (1.1%)	1 (0.4%)	0
Night sweats	0	2 (0.7%)	0
Dermal and epidermal conditions NEC	1 (0.4%)	2 (0.7%)	2 (1.4%)
Skin lesion	0	0	2 (1.4%)
Papule	0	1 (0.4%)	0
Skin burning sensation	0	1 (0.4%)	0
Skin discolouration	1 (0.4%)	0	0
Dermatitis and eczema	1 (0.4%)	2 (0.7%)	2 (1.4%)
Eczema	1 (0.4%)	0	2 (1.4%)
Dermatitis contact	0	1 (0.4%)	0
Skin irritation	0	1 (0.4%)	0
Dermatitis ascribed to specific agent	0	0	1 (0.7%)
Palmar-plantar erythrodysaesthesia syndrome	0	0	1 (0.7%)
Erythemas	1 (0.4%)	0	1 (0.7%)
Erythema	1 (0.4%)	0	1 (0.7%)

TEAE = treatment-emergent adverse event. NEC = Not Elsewhere Classified. Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Induction first dose date up to one day before the Maintenance first dose date or 30 days after the Induction last dose date whichever is earlier, or led to premature discontinuation of Induction study drug.
System organ classes and high level terms (within each system organ class) were presented alphabetically, and preferred terms were presented by descending order of the total frequencies. Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
Source: Listing 16.2.7.1

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Table 15.11.2.1.2.2: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Induction Study: Cohort B
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Filgotinib 200 mg (N=262)	Filgotinib 100 mg (N=285)	Placebo (N=142)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	169 (64.5%)	161 (56.5%)	100 (70.4%)
Skin and subcutaneous tissue disorders (cont)			
Hyperkeratoses	1 (0.4%)	0	0
Hyperkeratosis	1 (0.4%)	0	0
Hypertrichoses	0	1 (0.4%)	0
Hirsutism	0	1 (0.4%)	0
Hypopigmentation disorders	1 (0.4%)	0	0
Leukoderma	1 (0.4%)	0	0
Panniculitides	0	1 (0.4%)	0
Erythema nodosum	0	1 (0.4%)	0
Pilar disorders NEC	0	0	1 (0.7%)
Hair growth abnormal	0	0	1 (0.7%)
Pruritus NEC	0	1 (0.4%)	2 (1.4%)
Pruritus	0	1 (0.4%)	2 (1.4%)
Purpura and related conditions	2 (0.8%)	0	0
Ecchymosis	1 (0.4%)	0	0
Purpura	1 (0.4%)	0	0

TEAE = treatment-emergent adverse event. NEC = Not Elsewhere Classified. Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Induction first dose date up to one day before the Maintenance first dose date or 30 days after the Induction last dose date whichever is earlier, or led to premature discontinuation of Induction study drug.
System organ classes and high level terms (within each system organ class) were presented alphabetically, and preferred terms were presented by descending order of the total frequencies. Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
Source: Listing 16.2.7.1

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Table 15.11.2.1.2.2: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Induction Study: Cohort B
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Filgotinib 200 mg (N=262)	Filgotinib 100 mg (N=285)	Placebo (N=142)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	169 (64.5%)	161 (56.5%)	100 (70.4%)
Skin and subcutaneous tissue disorders (cont)			
Rashes, eruptions and exanthems NEC	4 (1.5%)	3 (1.1%)	3 (2.1%)
Rash	3 (1.1%)	2 (0.7%)	2 (1.4%)
Rash papular	0	1 (0.4%)	1 (0.7%)
Rash erythematous	1 (0.4%)	0	0
Scaly conditions	1 (0.4%)	0	0
Dandruff	1 (0.4%)	0	0
Sebaceous gland disorders	1 (0.4%)	0	0
Asteatosis	1 (0.4%)	0	0
Skin and subcutaneous conditions NEC	0	0	1 (0.7%)
Skin mass	0	0	1 (0.7%)
Skin preneoplastic conditions NEC	0	0	1 (0.7%)
Actinic keratosis	0	0	1 (0.7%)
Vascular disorders	8 (3.1%)	7 (2.5%)	3 (2.1%)
Non-site specific necrosis and vascular insufficiency NEC	0	0	1 (0.7%)
Peripheral venous disease	0	0	1 (0.7%)

TEAE = treatment-emergent adverse event. NEC = Not Elsewhere Classified. Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Induction first dose date up to one day before the Maintenance first dose date or 30 days after the Induction last dose date whichever is earlier, or led to premature discontinuation of Induction study drug.
System organ classes and high level terms (within each system organ class) were presented alphabetically, and preferred terms were presented by descending order of the total frequencies. Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
Source: Listing 16.2.7.1

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Table 15.11.2.1.2.2: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Induction Study: Cohort B
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Filgotinib 200 mg (N=262)	Filgotinib 100 mg (N=285)	Placebo (N=142)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	169 (64.5%)	161 (56.5%)	100 (70.4%)
Vascular disorders (cont)			
Peripheral embolism and thrombosis	0	1 (0.4%)	0
Thrombophlebitis superficial	0	1 (0.4%)	0
Peripheral vascular disorders NEC	1 (0.4%)	0	0
Hot flush	1 (0.4%)	0	0
Peripheral vasoconstriction, necrosis and vascular insufficiency	0	1 (0.4%)	0
Peripheral coldness	0	1 (0.4%)	0
Phlebitis NEC	1 (0.4%)	1 (0.4%)	0
Phlebitis	1 (0.4%)	1 (0.4%)	0
Varicose veins NEC	0	1 (0.4%)	0
Varicose vein	0	1 (0.4%)	0
Vascular hypertensive disorders NEC	6 (2.3%)	3 (1.1%)	2 (1.4%)
Hypertension	6 (2.3%)	3 (1.1%)	2 (1.4%)

TEAE = treatment-emergent adverse event. NEC = Not Elsewhere Classified. Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Induction first dose date up to one day before the Maintenance first dose date or 30 days after the Induction last dose date whichever is earlier, or led to premature discontinuation of Induction study drug.
System organ classes and high level terms (within each system organ class) were presented alphabetically, and preferred terms were presented by descending order of the total frequencies. Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
Source: Listing 16.2.7.1

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Tabelle 4-3 (Anhang): Ergebnisse für UE nach SOC und PT aus RCT mit dem zu bewertenden Arzneimittel (SELECTION, Erhaltungsphase)

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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
Blood and lymphatic system disorders	8 (4.0%)	4 (4.0%)	12 (6.7%)	2 (2.2%)	3 (3.2%)
Anaemia deficiencies	0	0	2 (1.1%)	1 (1.1%)	1 (1.1%)
Iron deficiency anaemia	0	0	2 (1.1%)	1 (1.1%)	1 (1.1%)
Anaemias NEC	4 (2.0%)	1 (1.0%)	4 (2.2%)	1 (1.1%)	0
Anaemia	4 (2.0%)	0	4 (2.2%)	1 (1.1%)	0
Microcytic anaemia	0	1 (1.0%)	0	0	0
Eosinophilic disorders	0	0	0	1 (1.1%)	0
Eosinophilia	0	0	0	1 (1.1%)	0
Leukopenias NEC	1 (0.5%)	2 (2.0%)	5 (2.8%)	0	3 (3.2%)
Lymphopenia	0	1 (1.0%)	3 (1.7%)	0	2 (2.2%)
Leukopenia	1 (0.5%)	1 (1.0%)	2 (1.1%)	0	1 (1.1%)

TEAE = treatment-emergent adverse event. NEC = Not Elsewhere Classified. Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Maintenance first dose date up to 30 days after Maintenance last dose date, or led to premature discontinuation of Maintenance study drug.
System organ classes and high level terms (within each system organ class) were presented alphabetically, and preferred terms were presented by descending order of the total frequencies. Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
Source: Listing 16.2.7.1

Data Extracted: 05MAY2020
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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
Blood and lymphatic system disorders (cont)					
Neutropenias	4 (2.0%)	2 (2.0%)	2 (1.1%)	0	0
Neutropenia	4 (2.0%)	2 (2.0%)	2 (1.1%)	0	0
Cardiac disorders	4 (2.0%)	0	2 (1.1%)	2 (2.2%)	2 (2.2%)
Cardiac conduction disorders	1 (0.5%)	0	0	0	0
Bundle branch block right	1 (0.5%)	0	0	0	0
Coronary artery disorders NEC	1 (0.5%)	0	2 (1.1%)	1 (1.1%)	0
Arteriosclerosis coronary artery	1 (0.5%)	0	1 (0.6%)	0	0
Coronary artery disease	0	0	1 (0.6%)	0	0
Coronary artery stenosis	0	0	0	1 (1.1%)	0
Ischaemic coronary artery disorders	0	0	0	1 (1.1%)	1 (1.1%)
Angina pectoris	0	0	0	1 (1.1%)	1 (1.1%)

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TEAEs are defined as any AEs that began on or after the Maintenance first dose date up to 30 days after Maintenance last dose date, or led to premature discontinuation of Maintenance study drug.
System organ classes and high level terms (within each system organ class) were presented alphabetically, and preferred terms were presented by descending order of the total frequencies. Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
Source: Listing 16.2.7.1

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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
Cardiac disorders (cont)					
Left ventricular failures	1 (0.5%)	0	0	0	0
Left ventricular failure	1 (0.5%)	0	0	0	0
Rate and rhythm disorders NEC	0	0	0	0	1 (1.1%)
Tachycardia	0	0	0	0	1 (1.1%)
Supraventricular arrhythmias	2 (1.0%)	0	0	1 (1.1%)	0
Arrhythmia supraventricular	1 (0.5%)	0	0	0	0
Atrial fibrillation	0	0	0	1 (1.1%)	0
Sinus arrhythmia	1 (0.5%)	0	0	0	0
Congenital, familial and genetic disorders	1 (0.5%)	0	0	0	0
Skin and subcutaneous tissue disorders congenital NEC	1 (0.5%)	0	0	0	0
Ichthyosis	1 (0.5%)	0	0	0	0

TEAE = treatment-emergent adverse event. NEC = Not Elsewhere Classified. Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Maintenance first dose date up to 30 days after Maintenance last dose date, or led to premature discontinuation of Maintenance study drug.
System organ classes and high level terms (within each system organ class) were presented alphabetically, and preferred terms were presented by descending order of the total frequencies. Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
Source: Listing 16.2.7.1

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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
Ear and labyrinth disorders	3 (1.5%)	0	3 (1.7%)	0	0
Hearing disorders NEC	0	0	1 (0.6%)	0	0
Auditory disorder	0	0	1 (0.6%)	0	0
Inner ear signs and symptoms	3 (1.5%)	0	2 (1.1%)	0	0
Vertigo	3 (1.5%)	0	1 (0.6%)	0	0
Tinnitus	0	0	1 (0.6%)	0	0
Endocrine disorders	2 (1.0%)	1 (1.0%)	0	0	0
Hyperparathyroid disorders	0	1 (1.0%)	0	0	0
Hyperparathyroidism	0	1 (1.0%)	0	0	0
Thyroid hypofunction disorders	2 (1.0%)	0	0	0	0
Hypothyroidism	2 (1.0%)	0	0	0	0

TEAE = treatment-emergent adverse event. NEC = Not Elsewhere Classified. Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Maintenance first dose date up to 30 days after Maintenance last dose date, or led to premature discontinuation of Maintenance study drug.
System organ classes and high level terms (within each system organ class) were presented alphabetically, and preferred terms were presented by descending order of the total frequencies. Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
Eye disorders	1 (0.5%)	2 (2.0%)	1 (0.6%)	1 (1.1%)	3 (3.2%)
Glaucomas (excl congenital)	1 (0.5%)	0	1 (0.6%)	0	0
Glaucoma	1 (0.5%)	0	1 (0.6%)	0	0
Lacrimation disorders	0	0	0	0	1 (1.1%)
Dry eye	0	0	0	0	1 (1.1%)
Lid, lash and lacrimal infections, irritations and inflammations	0	0	0	1 (1.1%)	0
Erythema of eyelid	0	0	0	1 (1.1%)	0
Ocular infections, inflammations and associated manifestations	0	0	0	0	1 (1.1%)
Eye pruritus	0	0	0	0	1 (1.1%)

TEAE = treatment-emergent adverse event. NEC = Not Elsewhere Classified. Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Maintenance first dose date up to 30 days after Maintenance last dose date, or led to premature discontinuation of Maintenance study drug.
System organ classes and high level terms (within each system organ class) were presented alphabetically, and preferred terms were presented by descending order of the total frequencies. Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
Eye disorders (cont)					
Ocular sensation disorders	0	1 (1.0%)	0	0	0
Abnormal sensation in eye	0	1 (1.0%)	0	0	0
Retinal structural change, deposit and degeneration	0	1 (1.0%)	0	0	0
Macular fibrosis	0	1 (1.0%)	0	0	0
Retinal, choroid and vitreous infections and inflammations	0	1 (1.0%)	0	0	0
Cystoid macular oedema	0	1 (1.0%)	0	0	0
Visual disorders NEC	0	0	0	0	1 (1.1%)
Vision blurred	0	0	0	0	1 (1.1%)
Gastrointestinal disorders	58 (28.7%)	33 (33.3%)	49 (27.4%)	31 (34.1%)	25 (26.9%)

TEAE = treatment-emergent adverse event. NEC = Not Elsewhere Classified. Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Maintenance first dose date up to 30 days after Maintenance last dose date, or led to premature discontinuation of Maintenance study drug.
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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
Gastrointestinal disorders (cont)					
Acute and chronic pancreatitis	0	0	1 (0.6%)	0	0
Pancreatitis acute	0	0	1 (0.6%)	0	0
Anal and rectal disorders NEC	1 (0.5%)	0	0	1 (1.1%)	0
Anal fissure	1 (0.5%)	0	0	1 (1.1%)	0
Anal and rectal pains	0	0	1 (0.6%)	0	0
Proctalgia	0	0	1 (0.6%)	0	0
Anal and rectal signs and symptoms	2 (1.0%)	1 (1.0%)	0	0	1 (1.1%)
Anal eczema	0	0	0	0	1 (1.1%)
Anal inflammation	1 (0.5%)	0	0	0	0
Anal pruritus	0	1 (1.0%)	0	0	0
Rectal tenesmus	1 (0.5%)	0	0	0	0

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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
Gastrointestinal disorders (cont)					
Benign neoplasms gastrointestinal (excl oral cavity)	1 (0.5%)	0	0	4 (4.4%)	2 (2.2%)
Large intestine polyp	1 (0.5%)	0	0	4 (4.4%)	2 (2.2%)
Rectal polyp	0	0	0	0	1 (1.1%)
Colitis (excl infective)	23 (11.4%)	20 (20.2%)	20 (11.2%)	16 (17.6%)	11 (11.8%)
Colitis ulcerative	21 (10.4%)	20 (20.2%)	19 (10.6%)	16 (17.6%)	11 (11.8%)
Colitis	1 (0.5%)	0	1 (0.6%)	0	0
Pseudopolyposis	1 (0.5%)	0	0	0	0
Dental and periodontal infections and inflammations	2 (1.0%)	0	1 (0.6%)	0	0
Dental caries	2 (1.0%)	0	1 (0.6%)	0	0
Dental developmental disorders and anomalies	0	0	0	0	1 (1.1%)
Supernumerary teeth	0	0	0	0	1 (1.1%)

TEAE = treatment-emergent adverse event. NEC = Not Elsewhere Classified. Adverse events were coded according to MedDRA Version 22.1.
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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
Gastrointestinal disorders (cont)					
Dental disorders NEC	1 (0.5%)	0	0	0	1 (1.1%)
Dental cyst	0	0	0	0	1 (1.1%)
Periodontal disease	1 (0.5%)	0	0	0	0
Dental pain and sensation disorders	1 (0.5%)	1 (1.0%)	1 (0.6%)	1 (1.1%)	0
Toothache	1 (0.5%)	1 (1.0%)	1 (0.6%)	1 (1.1%)	0
Dental pulp disorders	1 (0.5%)	0	0	0	0
Dental pulp disorder	1 (0.5%)	0	0	0	0
Diarrhoea (excl infective)	4 (2.0%)	1 (1.0%)	3 (1.7%)	2 (2.2%)	3 (3.2%)
Diarrhoea	4 (2.0%)	1 (1.0%)	2 (1.1%)	2 (2.2%)	3 (3.2%)
Diarrhoea haemorrhagic	0	0	1 (0.6%)	0	0
Dyspeptic signs and symptoms	0	0	4 (2.2%)	1 (1.1%)	0
Dyspepsia	0	0	4 (2.2%)	1 (1.1%)	0

TEAE = treatment-emergent adverse event. NEC = Not Elsewhere Classified. Adverse events were coded according to MedDRA Version 22.1.
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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
Gastrointestinal disorders (cont)					
Flatulence, bloating and distension	4 (2.0%)	2 (2.0%)	5 (2.8%)	1 (1.1%)	0
Abdominal distension	1 (0.5%)	2 (2.0%)	3 (1.7%)	1 (1.1%)	0
Flatulence	3 (1.5%)	0	2 (1.1%)	0	0
Gastric ulcers and perforation	0	1 (1.0%)	0	1 (1.1%)	0
Gastric ulcer	0	1 (1.0%)	0	0	0
Gastritis erosive	0	0	0	1 (1.1%)	0
Gastritis (excl infective)	2 (1.0%)	1 (1.0%)	1 (0.6%)	1 (1.1%)	2 (2.2%)
Gastritis	2 (1.0%)	1 (1.0%)	1 (0.6%)	1 (1.1%)	2 (2.2%)
Gastrointestinal and abdominal pains (excl oral and throat)	11 (5.4%)	6 (6.1%)	10 (5.6%)	3 (3.3%)	5 (5.4%)
Abdominal pain	8 (4.0%)	6 (6.1%)	6 (3.4%)	2 (2.2%)	4 (4.3%)
Abdominal pain upper	3 (1.5%)	0	1 (0.6%)	1 (1.1%)	0
Abdominal pain lower	1 (0.5%)	0	2 (1.1%)	0	0
Abdominal tenderness	0	0	0	0	1 (1.1%)

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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
Gastrointestinal disorders (cont)					
Gastrointestinal and abdominal pains (excl oral and throat) (cont)					
Gastrointestinal pain	0	0	1 (0.6%)	0	0
Gastrointestinal atonic and hypomotility disorders NEC	4 (2.0%)	1 (1.0%)	6 (3.4%)	3 (3.3%)	0
Constipation	2 (1.0%)	0	3 (1.7%)	3 (3.3%)	0
Gastrooesophageal reflux disease	2 (1.0%)	1 (1.0%)	3 (1.7%)	0	0
Gastrointestinal disorders NEC	1 (0.5%)	0	0	0	0
Food poisoning	1 (0.5%)	0	0	0	0
Gastrointestinal inflammatory disorders NEC	1 (0.5%)	1 (1.0%)	1 (0.6%)	0	1 (1.1%)
Enteritis	1 (0.5%)	1 (1.0%)	1 (0.6%)	0	1 (1.1%)

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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
Gastrointestinal disorders (cont)					
Gastrointestinal signs and symptoms NEC	4 (2.0%)	0	0	0	0
Abdominal discomfort	3 (1.5%)	0	0	0	0
Breath odour	1 (0.5%)	0	0	0	0
Gastrointestinal spastic and hypermotility disorders	2 (1.0%)	1 (1.0%)	1 (0.6%)	2 (2.2%)	1 (1.1%)
Frequent bowel movements	2 (1.0%)	0	1 (0.6%)	1 (1.1%)	1 (1.1%)
Defaecation urgency	1 (0.5%)	1 (1.0%)	0	1 (1.1%)	0
Gingival haemorrhages	0	0	1 (0.6%)	0	0
Gingival bleeding	0	0	1 (0.6%)	0	0
Haemorrhoids and gastrointestinal varices (excl oesophageal)	3 (1.5%)	0	1 (0.6%)	0	0
Haemorrhoids	3 (1.5%)	0	1 (0.6%)	0	0

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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Maintenance Study
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Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
Gastrointestinal disorders (cont)					
Inguinal hernias	0	1 (1.0%)	0	0	0
Inguinal hernia	0	1 (1.0%)	0	0	0
Intestinal haemorrhages	1 (0.5%)	0	0	0	3 (3.2%)
Rectal haemorrhage	1 (0.5%)	0	0	0	3 (3.2%)
Nausea and vomiting symptoms	8 (4.0%)	1 (1.0%)	4 (2.2%)	0	3 (3.2%)
Nausea	5 (2.5%)	1 (1.0%)	4 (2.2%)	0	2 (2.2%)
Vomiting	4 (2.0%)	0	2 (1.1%)	0	2 (2.2%)
Non-mechanical ileus	0	0	1 (0.6%)	0	0
Ileus paralytic	0	0	1 (0.6%)	0	0
Non-site specific gastrointestinal haemorrhages	0	0	0	1 (1.1%)	0
Haematochezia	0	0	0	1 (1.1%)	0

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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Maintenance Study
Safety Analysis Set

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Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
Gastrointestinal disorders (cont)					
Oral dryness and saliva altered	0	0	1 (0.6%)	0	0
Dry mouth	0	0	1 (0.6%)	0	0
Stomatitis and ulceration	2 (1.0%)	1 (1.0%)	1 (0.6%)	0	0
Stomatitis	1 (0.5%)	1 (1.0%)	1 (0.6%)	0	0
Mouth ulceration	1 (0.5%)	0	0	0	0
General disorders and administration site conditions	15 (7.4%)	4 (4.0%)	14 (7.8%)	7 (7.7%)	3 (3.2%)
Asthenic conditions	4 (2.0%)	1 (1.0%)	2 (1.1%)	2 (2.2%)	0
Asthenia	2 (1.0%)	1 (1.0%)	1 (0.6%)	0	0
Fatigue	1 (0.5%)	0	1 (0.6%)	2 (2.2%)	0
Malaise	1 (0.5%)	0	0	0	0
Febrile disorders	6 (3.0%)	1 (1.0%)	5 (2.8%)	3 (3.3%)	1 (1.1%)
Pyrexia	6 (3.0%)	1 (1.0%)	5 (2.8%)	3 (3.3%)	1 (1.1%)

TEAE = treatment-emergent adverse event. NEC = Not Elsewhere Classified. Adverse events were coded according to MedDRA Version 22.1.
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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
General disorders and administration site conditions (cont)					
General signs and symptoms NEC	0	1 (1.0%)	1 (0.6%)	1 (1.1%)	0
Influenza like illness	0	0	1 (0.6%)	1 (1.1%)	0
Swelling face	0	1 (1.0%)	0	0	0
Hernias NEC	1 (0.5%)	0	0	0	0
Hernia	1 (0.5%)	0	0	0	0
Inflammations	0	0	0	0	2 (2.2%)
Granuloma	0	0	0	0	1 (1.1%)
Inflammation	0	0	0	0	1 (1.1%)
Mass conditions NEC	1 (0.5%)	0	1 (0.6%)	0	0
Cyst	0	0	1 (0.6%)	0	0
Nodule	1 (0.5%)	0	0	0	0

TEAE = treatment-emergent adverse event. NEC = Not Elsewhere Classified. Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Maintenance first dose date up to 30 days after Maintenance last dose date, or led to premature discontinuation of Maintenance study drug.
System organ classes and high level terms (within each system organ class) were presented alphabetically, and preferred terms were presented by descending order of the total frequencies. Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
Source: Listing 16.2.7.1

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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
General disorders and administration site conditions (cont)					
Oedema NEC	3 (1.5%)	0	2 (1.1%)	1 (1.1%)	0
Oedema peripheral	3 (1.5%)	0	2 (1.1%)	1 (1.1%)	0
Face oedema	0	0	1 (0.6%)	0	0
Pain and discomfort NEC	4 (2.0%)	1 (1.0%)	4 (2.2%)	0	0
Chest pain	2 (1.0%)	0	2 (1.1%)	0	0
Chest discomfort	1 (0.5%)	1 (1.0%)	1 (0.6%)	0	0
Non-cardiac chest pain	0	0	1 (0.6%)	0	0
Pain	1 (0.5%)	0	0	0	0
Hepatobiliary disorders	3 (1.5%)	0	1 (0.6%)	1 (1.1%)	0
Cholecystitis and cholelithiasis	0	0	1 (0.6%)	0	0
Cholelithiasis	0	0	1 (0.6%)	0	0

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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
Hepatobiliary disorders (cont)					
Hepatic vascular disorders	0	0	0	1 (1.1%)	0
Portal hypertension	0	0	0	1 (1.1%)	0
Hepatocellular damage and hepatitis NEC	3 (1.5%)	0	0	1 (1.1%)	0
Hepatic steatosis	3 (1.5%)	0	0	0	0
Autoimmune hepatitis	0	0	0	1 (1.1%)	0
Immune system disorders	0	0	2 (1.1%)	1 (1.1%)	0
Allergic conditions NEC	0	0	1 (0.6%)	1 (1.1%)	0
Hypersensitivity	0	0	1 (0.6%)	1 (1.1%)	0
Atopic disorders	0	0	1 (0.6%)	0	0
Seasonal allergy	0	0	1 (0.6%)	0	0

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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
Infections and infestations	71 (35.1%)	25 (25.3%)	46 (25.7%)	27 (29.7%)	21 (22.6%)
Abdominal and gastrointestinal infections	6 (3.0%)	3 (3.0%)	3 (1.7%)	2 (2.2%)	0
Gastroenteritis	1 (0.5%)	3 (3.0%)	1 (0.6%)	1 (1.1%)	0
Appendicitis	1 (0.5%)	0	2 (1.1%)	0	0
Diverticulitis	2 (1.0%)	0	0	0	0
Diarrhoea infectious	1 (0.5%)	0	0	0	0
Douglas' abscess	0	0	1 (0.6%)	0	0
Enteritis infectious	0	0	0	1 (1.1%)	0
Gastrointestinal infection	1 (0.5%)	0	0	0	0
Bacterial infections NEC	3 (1.5%)	1 (1.0%)	1 (0.6%)	0	1 (1.1%)
Bacterial vaginosis	2 (1.0%)	0	0	0	0
Cellulitis	0	0	1 (0.6%)	0	1 (1.1%)
Antibiotic associated colitis	1 (0.5%)	0	0	0	0
Sinusitis bacterial	0	1 (1.0%)	0	0	0

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TEAEs are defined as any AEs that began on or after the Maintenance first dose date up to 30 days after Maintenance last dose date, or led to premature discontinuation of Maintenance study drug.
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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
Infections and infestations (cont)					
Caliciviral infections	1 (0.5%)	0	0	0	0
Gastroenteritis norovirus	1 (0.5%)	0	0	0	0
Candida infections	1 (0.5%)	0	0	0	0
Vulvovaginal candidiasis	1 (0.5%)	0	0	0	0
Chlamydial infections	0	0	0	0	1 (1.1%)
Chlamydial infection	0	0	0	0	1 (1.1%)
Clostridia infections	1 (0.5%)	1 (1.0%)	0	1 (1.1%)	0
Clostridium difficile infection	1 (0.5%)	0	0	1 (1.1%)	0
Clostridial infection	0	1 (1.0%)	0	0	0

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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
Infections and infestations (cont)					
Dental and oral soft tissue infections	4 (2.0%)	0	0	0	0
Gingivitis	1 (0.5%)	0	0	0	0
Periodontitis	1 (0.5%)	0	0	0	0
Pulpitis dental	1 (0.5%)	0	0	0	0
Tooth abscess	1 (0.5%)	0	0	0	0
Ear infections	4 (2.0%)	1 (1.0%)	2 (1.1%)	0	0
Ear infection	1 (0.5%)	1 (1.0%)	0	0	0
Otitis externa	2 (1.0%)	0	0	0	0
Otitis media	1 (0.5%)	0	1 (0.6%)	0	0
Otitis media acute	0	0	1 (0.6%)	0	0
Eye and eyelid infections	1 (0.5%)	2 (2.0%)	2 (1.1%)	2 (2.2%)	0
Hordeolum	0	1 (1.0%)	2 (1.1%)	2 (2.2%)	0
Conjunctivitis	1 (0.5%)	1 (1.0%)	0	0	0

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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
Infections and infestations (cont)					
Female reproductive tract infections	0	0	0	2 (2.2%)	0
Cervicitis	0	0	0	1 (1.1%)	0
Vaginal infection	0	0	0	1 (1.1%)	0
Hepatitis viral infections	0	0	0	1 (1.1%)	0
Acute hepatitis B	0	0	0	1 (1.1%)	0
Herpes viral infections	3 (1.5%)	1 (1.0%)	1 (0.6%)	1 (1.1%)	1 (1.1%)
Oral herpes	2 (1.0%)	1 (1.0%)	1 (0.6%)	0	1 (1.1%)
Herpes zoster	1 (0.5%)	0	0	1 (1.1%)	0
Herpes simplex	1 (0.5%)	0	0	0	0
Nasal herpes	1 (0.5%)	0	0	0	0
Ophthalmic herpes simplex	1 (0.5%)	0	0	0	0

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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
Infections and infestations (cont)					
Infections NEC	1 (0.5%)	1 (1.0%)	0	3 (3.3%)	2 (2.2%)
Respiratory tract infection	1 (0.5%)	1 (1.0%)	0	2 (2.2%)	2 (2.2%)
Post procedural infection	0	0	0	1 (1.1%)	0
Influenza viral infections	6 (3.0%)	1 (1.0%)	3 (1.7%)	2 (2.2%)	4 (4.3%)
Influenza	6 (3.0%)	1 (1.0%)	3 (1.7%)	2 (2.2%)	4 (4.3%)
Lower respiratory tract and lung infections	3 (1.5%)	3 (3.0%)	6 (3.4%)	4 (4.4%)	3 (3.2%)
Bronchitis	3 (1.5%)	2 (2.0%)	5 (2.8%)	3 (3.3%)	1 (1.1%)
Pneumonia	0	0	1 (0.6%)	0	2 (2.2%)
Lower respiratory tract infection	0	1 (1.0%)	0	0	0
Tracheobronchitis	0	0	0	1 (1.1%)	0
Papilloma viral infections	1 (0.5%)	1 (1.0%)	0	0	0
Papilloma viral infection	1 (0.5%)	1 (1.0%)	0	0	0

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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
Infections and infestations (cont)					
Skin structures and soft tissue infections	3 (1.5%)	0	2 (1.1%)	0	1 (1.1%)
Paronychia	2 (1.0%)	0	1 (0.6%)	0	0
Folliculitis	0	0	1 (0.6%)	0	1 (1.1%)
Impetigo	1 (0.5%)	0	0	0	0
Staphylococcal infections	0	0	0	1 (1.1%)	0
Vulvovaginitis staphylococcal	0	0	0	1 (1.1%)	0
Streptococcal infections	0	0	2 (1.1%)	0	0
Pharyngitis streptococcal	0	0	2 (1.1%)	0	0
Tinea infections	0	1 (1.0%)	0	0	1 (1.1%)
Body tinea	0	1 (1.0%)	0	0	0
Tinea pedis	0	0	0	0	1 (1.1%)

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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
Infections and infestations (cont)					
Upper respiratory tract infections	43 (21.3%)	11 (11.1%)	25 (14.0%)	10 (11.0%)	12 (12.9%)
Nasopharyngitis	22 (10.9%)	6 (6.1%)	12 (6.7%)	6 (6.6%)	5 (5.4%)
Upper respiratory tract infection	11 (5.4%)	3 (3.0%)	6 (3.4%)	3 (3.3%)	3 (3.2%)
Pharyngitis	6 (3.0%)	1 (1.0%)	4 (2.2%)	1 (1.1%)	4 (4.3%)
Sinusitis	4 (2.0%)	1 (1.0%)	0	1 (1.1%)	0
Tonsillitis	1 (0.5%)	0	1 (0.6%)	0	1 (1.1%)
Laryngitis	2 (1.0%)	0	0	0	0
Pharyngotonsillitis	0	0	2 (1.1%)	0	0
Rhinitis	1 (0.5%)	1 (1.0%)	0	0	0
Urinary tract infections	5 (2.5%)	0	2 (1.1%)	3 (3.3%)	1 (1.1%)
Urinary tract infection	4 (2.0%)	0	2 (1.1%)	2 (2.2%)	0
Cystitis	1 (0.5%)	0	0	1 (1.1%)	0
Urethritis	0	0	0	0	1 (1.1%)

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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
Infections and infestations (cont)					
Viral infections NEC	8 (4.0%)	5 (5.1%)	6 (3.4%)	6 (6.6%)	2 (2.2%)
Respiratory tract infection viral	4 (2.0%)	2 (2.0%)	3 (1.7%)	4 (4.4%)	0
Viral infection	2 (1.0%)	3 (3.0%)	1 (0.6%)	0	1 (1.1%)
Viral upper respiratory tract infection	1 (0.5%)	0	0	1 (1.1%)	1 (1.1%)
Gastroenteritis viral	0	0	1 (0.6%)	1 (1.1%)	0
Bronchitis viral	1 (0.5%)	0	0	0	0
Viral pharyngitis	0	0	1 (0.6%)	0	0
Injury, poisoning and procedural complications	7 (3.5%)	2 (2.0%)	12 (6.7%)	2 (2.2%)	4 (4.3%)
Bone and joint injuries NEC	0	1 (1.0%)	3 (1.7%)	1 (1.1%)	0
Meniscus injury	0	1 (1.0%)	1 (0.6%)	1 (1.1%)	0
Cartilage injury	0	0	1 (0.6%)	0	0
Joint injury	0	0	1 (0.6%)	0	0

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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
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Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
Injury, poisoning and procedural complications (cont)					
Chest and respiratory tract injuries NEC	1 (0.5%)	0	0	0	0
Foreign body in respiratory tract	1 (0.5%)	0	0	0	0
Conditions caused by cold	1 (0.5%)	0	0	0	0
Chillblains	1 (0.5%)	0	0	0	0
Eye injuries NEC	0	0	1 (0.6%)	0	0
Foreign body in eye	0	0	1 (0.6%)	0	0
Fractures and dislocations NEC	0	0	1 (0.6%)	0	0
Joint dislocation	0	0	1 (0.6%)	0	0
Limb fractures and dislocations	0	0	3 (1.7%)	0	0
Bankart lesion	0	0	1 (0.6%)	0	0
Foot fracture	0	0	1 (0.6%)	0	0
Humerus fracture	0	0	1 (0.6%)	0	0
Wrist fracture	0	0	1 (0.6%)	0	0

TEAE = treatment-emergent adverse event. NEC = Not Elsewhere Classified. Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Maintenance first dose date up to 30 days after Maintenance last dose date, or led to premature discontinuation of Maintenance study drug.
System organ classes and high level terms (within each system organ class) were presented alphabetically, and preferred terms were presented by descending order of the total frequencies. Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
Source: Listing 16.2.7.1

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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
Injury, poisoning and procedural complications (cont)					
Muscle, tendon and ligament injuries	4 (2.0%)	1 (1.0%)	2 (1.1%)	0	0
Ligament sprain	2 (1.0%)	0	0	0	0
Epicondylitis	0	0	1 (0.6%)	0	0
Ligament injury	0	0	1 (0.6%)	0	0
Muscle contusion	0	1 (1.0%)	0	0	0
Muscle rupture	0	0	1 (0.6%)	0	0
Muscle strain	1 (0.5%)	0	0	0	0
Tendon rupture	1 (0.5%)	0	0	0	0
Non-site specific injuries NEC	1 (0.5%)	0	4 (2.2%)	0	1 (1.1%)
Fall	0	0	1 (0.6%)	0	1 (1.1%)
Arthropod bite	1 (0.5%)	0	0	0	0
Arthropod sting	0	0	1 (0.6%)	0	0
Road traffic accident	0	0	1 (0.6%)	0	0
Traumatic haematoma	0	0	1 (0.6%)	0	0
Wound complication	0	0	1 (0.6%)	0	0

TEAE = treatment-emergent adverse event. NEC = Not Elsewhere Classified. Adverse events were coded according to MedDRA Version 22.1.
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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
Injury, poisoning and procedural complications (cont)					
Site specific injuries NEC	0	0	1 (0.6%)	1 (1.1%)	2 (2.2%)
Limb injury	0	0	0	0	2 (2.2%)
Spinal column injury	0	0	1 (0.6%)	0	0
Tooth fracture	0	0	0	1 (1.1%)	0
Skin injuries NEC	0	0	1 (0.6%)	0	0
Contusion	0	0	1 (0.6%)	0	0
Thoracic cage fractures and dislocations	0	0	1 (0.6%)	0	1 (1.1%)
Rib fracture	0	0	1 (0.6%)	0	1 (1.1%)
Investigations	19 (9.4%)	5 (5.1%)	11 (6.1%)	6 (6.6%)	8 (8.6%)

TEAE = treatment-emergent adverse event. NEC = Not Elsewhere Classified. Adverse events were coded according to MedDRA Version 22.1.
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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
Investigations (cont)					
Bacteria identification and serology (excl mycobacteria)	1 (0.5%)	0	1 (0.6%)	0	0
Clostridium test positive	1 (0.5%)	0	1 (0.6%)	0	0
Carbohydrate tolerance analyses (incl diabetes)	0	0	0	1 (1.1%)	0
Blood glucose increased	0	0	0	1 (1.1%)	0
Cholesterol analyses	3 (1.5%)	0	1 (0.6%)	0	0
Blood cholesterol increased	3 (1.5%)	0	0	0	0
Low density lipoprotein increased	0	0	1 (0.6%)	0	0
ECG investigations	1 (0.5%)	0	0	0	0
Electrocardiogram T wave abnormal	1 (0.5%)	0	0	0	0
Faecal analyses NEC	0	0	1 (0.6%)	0	0
Faecal calprotectin increased	0	0	1 (0.6%)	0	0

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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
Investigations (cont)					
Liver function analyses	2 (1.0%)	2 (2.0%)	2 (1.1%)	2 (2.2%)	1 (1.1%)
Alanine aminotransferase increased	2 (1.0%)	1 (1.0%)	2 (1.1%)	2 (2.2%)	0
Aspartate aminotransferase increased	1 (0.5%)	1 (1.0%)	1 (0.6%)	1 (1.1%)	0
Liver function test increased	0	1 (1.0%)	0	0	0
Transaminases increased	0	0	0	0	1 (1.1%)
Mineral and electrolyte analyses	1 (0.5%)	0	1 (0.6%)	1 (1.1%)	1 (1.1%)
Blood phosphorus decreased	0	0	1 (0.6%)	1 (1.1%)	0
Blood iron decreased	1 (0.5%)	0	0	0	0
Serum ferritin decreased	0	0	0	0	1 (1.1%)
Mycobacteria identification and serology	1 (0.5%)	1 (1.0%)	3 (1.7%)	0	3 (3.2%)
Mycobacterium tuberculosis complex test positive	1 (0.5%)	1 (1.0%)	3 (1.7%)	0	3 (3.2%)

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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
Investigations (cont)					
Physical examination procedures and organ system status	2 (1.0%)	1 (1.0%)	2 (1.1%)	2 (2.2%)	1 (1.1%)
Weight increased	2 (1.0%)	1 (1.0%)	1 (0.6%)	2 (2.2%)	1 (1.1%)
Body temperature decreased	0	0	1 (0.6%)	0	0
Platelet analyses	0	0	0	0	1 (1.1%)
Platelet count decreased	0	0	0	0	1 (1.1%)
Red blood cell analyses	2 (1.0%)	0	0	0	0
Haemoglobin decreased	2 (1.0%)	0	0	0	0
Renal function analyses	1 (0.5%)	0	0	0	0
Blood creatinine increased	1 (0.5%)	0	0	0	0

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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
Investigations (cont)					
Skeletal and cardiac muscle analyses	3 (1.5%)	0	0	0	0
Blood creatine phosphokinase increased	2 (1.0%)	0	0	0	0
Blood creatine phosphokinase abnormal	1 (0.5%)	0	0	0	0
Tissue enzyme analyses NEC	0	0	0	1 (1.1%)	0
Blood alkaline phosphatase increased	0	0	0	1 (1.1%)	0
Vascular tests NEC (incl blood pressure)	0	1 (1.0%)	0	0	0
Blood pressure systolic increased	0	1 (1.0%)	0	0	0
White blood cell analyses	2 (1.0%)	0	0	0	2 (2.2%)
Neutrophil count decreased	2 (1.0%)	0	0	0	1 (1.1%)
Lymphocyte count decreased	1 (0.5%)	0	0	0	1 (1.1%)
White blood cell count decreased	1 (0.5%)	0	0	0	1 (1.1%)
Lymphocyte count increased	1 (0.5%)	0	0	0	0

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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
Metabolism and nutrition disorders	14 (6.9%)	8 (8.1%)	3 (1.7%)	5 (5.5%)	7 (7.5%)
Appetite disorders	2 (1.0%)	0	1 (0.6%)	0	1 (1.1%)
Decreased appetite	2 (1.0%)	0	1 (0.6%)	0	1 (1.1%)
Diabetes mellitus (incl subtypes)	1 (0.5%)	1 (1.0%)	0	0	0
Diabetes mellitus	0	1 (1.0%)	0	0	0
Type 2 diabetes mellitus	1 (0.5%)	0	0	0	0
Disorders of purine metabolism	1 (0.5%)	0	0	0	0
Hyperuricaemia	1 (0.5%)	0	0	0	0
Elevated cholesterol	1 (0.5%)	0	0	0	0
Hypercholesterolaemia	1 (0.5%)	0	0	0	0
Elevated triglycerides	0	3 (3.0%)	0	0	0
Hypertriglyceridaemia	0	3 (3.0%)	0	0	0

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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
Metabolism and nutrition disorders (cont)					
Fat soluble vitamin deficiencies and disorders	2 (1.0%)	1 (1.0%)	0	0	0
Vitamin D deficiency	2 (1.0%)	1 (1.0%)	0	0	0
General nutritional disorders NEC	1 (0.5%)	0	0	0	0
Obesity	1 (0.5%)	0	0	0	0
Hyperglycaemic conditions NEC	1 (0.5%)	1 (1.0%)	1 (0.6%)	0	3 (3.2%)
Hyperglycaemia	1 (0.5%)	1 (1.0%)	1 (0.6%)	0	1 (1.1%)
Glucose tolerance impaired	0	0	0	0	1 (1.1%)
Insulin resistance	0	0	0	0	1 (1.1%)
Hyperlipidaemias NEC	1 (0.5%)	1 (1.0%)	1 (0.6%)	1 (1.1%)	0
Hyperlipidaemia	1 (0.5%)	1 (1.0%)	1 (0.6%)	1 (1.1%)	0
Hypoglycaemic conditions NEC	0	0	0	1 (1.1%)	0
Hypoglycaemia	0	0	0	1 (1.1%)	0

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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
Metabolism and nutrition disorders (cont)					
Iron deficiencies	0	1 (1.0%)	0	2 (2.2%)	1 (1.1%)
Iron deficiency	0	1 (1.0%)	0	2 (2.2%)	1 (1.1%)
Lipid metabolism and deposit disorders NEC	1 (0.5%)	0	0	0	0
Dyslipidaemia	1 (0.5%)	0	0	0	0
Phosphorus metabolism disorders	2 (1.0%)	0	0	0	0
Hyperphosphataemia	1 (0.5%)	0	0	0	0
Hypophosphataemia	1 (0.5%)	0	0	0	0
Potassium imbalance	1 (0.5%)	0	0	1 (1.1%)	2 (2.2%)
Hypokalaemia	0	0	0	1 (1.1%)	2 (2.2%)
Hyperkalaemia	1 (0.5%)	0	0	0	0
Total fluid volume decreased	0	1 (1.0%)	0	0	0
Dehydration	0	1 (1.0%)	0	0	0

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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Placebo Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Placebo Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
Metabolism and nutrition disorders (cont)					
Water soluble vitamin deficiencies	0	0	1 (0.6%)	0	0
Vitamin B12 deficiency	0	0	1 (0.6%)	0	0
Musculoskeletal and connective tissue disorders	29 (14.4%)	11 (11.1%)	19 (10.6%)	7 (7.7%)	13 (14.0%)
Arthropathies NEC	2 (1.0%)	0	1 (0.6%)	0	1 (1.1%)
Arthritis	1 (0.5%)	0	0	0	0
Arthritis enteropathic	0	0	0	0	1 (1.1%)
Arthropathy	0	0	0	0	1 (1.1%)
Polyarthritis	1 (0.5%)	0	0	0	0
Sacroiliitis	0	0	1 (0.6%)	0	0
Bone disorders NEC	0	0	1 (0.6%)	0	1 (1.1%)
Osteonecrosis	0	0	1 (0.6%)	0	0
Periostitis	0	0	0	0	1 (1.1%)

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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Maintenance Study
Safety Analysis Set

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Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
Musculoskeletal and connective tissue disorders (cont)					
Bone related signs and symptoms	1 (0.5%)	1 (1.0%)	0	0	0
Coccydynia	0	1 (1.0%)	0	0	0
Spinal pain	1 (0.5%)	0	0	0	0
Bursal disorders	0	0	1 (0.6%)	0	0
Bursitis	0	0	1 (0.6%)	0	0
Joint related disorders NEC	1 (0.5%)	0	0	0	0
Periarthritis	1 (0.5%)	0	0	0	0
Joint related signs and symptoms	10 (5.0%)	7 (7.1%)	8 (4.5%)	3 (3.3%)	4 (4.3%)
Arthralgia	8 (4.0%)	7 (7.1%)	6 (3.4%)	3 (3.3%)	4 (4.3%)
Joint swelling	1 (0.5%)	0	1 (0.6%)	0	0
Joint effusion	0	0	1 (0.6%)	0	0
Joint stiffness	1 (0.5%)	0	0	0	0

TEAE = treatment-emergent adverse event. NEC = Not Elsewhere Classified. Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Maintenance first dose date up to 30 days after Maintenance last dose date, or led to premature discontinuation of Maintenance study drug.
System organ classes and high level terms (within each system organ class) were presented alphabetically, and preferred terms were presented by descending order of the total frequencies. Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
Source: Listing 16.2.7.1

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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
Musculoskeletal and connective tissue disorders (cont)					
Metabolic bone disorders	1 (0.5%)	1 (1.0%)	0	0	0
Osteopenia	0	1 (1.0%)	0	0	0
Osteoporosis	1 (0.5%)	0	0	0	0
Muscle pains	1 (0.5%)	0	1 (0.6%)	2 (2.2%)	0
Myalgia	1 (0.5%)	0	1 (0.6%)	2 (2.2%)	0
Muscle related signs and symptoms NEC	2 (1.0%)	1 (1.0%)	1 (0.6%)	0	3 (3.2%)
Muscle spasms	2 (1.0%)	1 (1.0%)	1 (0.6%)	0	3 (3.2%)
Muscle tone abnormalities	0	0	0	0	1 (1.1%)
Trismus	0	0	0	0	1 (1.1%)
Muscle weakness conditions	1 (0.5%)	0	0	0	0
Muscular weakness	1 (0.5%)	0	0	0	0

TEAE = treatment-emergent adverse event. NEC = Not Elsewhere Classified. Adverse events were coded according to MedDRA Version 22.1.
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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
Musculoskeletal and connective tissue disorders (cont)					
Musculoskeletal and connective tissue infections and inflammations NEC	1 (0.5%)	0	1 (0.6%)	0	0
Plantar fasciitis	1 (0.5%)	0	1 (0.6%)	0	0
Musculoskeletal and connective tissue pain and discomfort	12 (5.9%)	5 (5.1%)	6 (3.4%)	1 (1.1%)	5 (5.4%)
Back pain	8 (4.0%)	4 (4.0%)	2 (1.1%)	1 (1.1%)	1 (1.1%)
Pain in extremity	2 (1.0%)	0	2 (1.1%)	0	2 (2.2%)
Musculoskeletal pain	2 (1.0%)	0	0	0	1 (1.1%)
Neck pain	1 (0.5%)	0	2 (1.1%)	0	0
Musculoskeletal chest pain	0	1 (1.0%)	0	0	1 (1.1%)
Flank pain	1 (0.5%)	0	0	0	0
Myopathies	0	0	0	0	1 (1.1%)
Rhabdomyolysis	0	0	0	0	1 (1.1%)

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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
Musculoskeletal and connective tissue disorders (cont)					
Osteoarthropathies	1 (0.5%)	0	0	1 (1.1%)	1 (1.1%)
Osteoarthritis	1 (0.5%)	0	0	1 (1.1%)	1 (1.1%)
Rheumatoid arthropathies	0	0	0	0	1 (1.1%)
Rheumatoid arthritis	0	0	0	0	1 (1.1%)
Soft tissue disorders NEC	1 (0.5%)	0	1 (0.6%)	0	0
Axillary mass	0	0	1 (0.6%)	0	0
Groin pain	1 (0.5%)	0	0	0	0
Synovial disorders	0	0	1 (0.6%)	0	1 (1.1%)
Synovial cyst	0	0	1 (0.6%)	0	1 (1.1%)
Tendon disorders	1 (0.5%)	0	1 (0.6%)	0	0
Tendon pain	0	0	1 (0.6%)	0	0
Tenosynovitis	1 (0.5%)	0	0	0	0

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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4 (2.0%)	1 (1.0%)	3 (1.7%)	1 (1.1%)	3 (3.2%)
Breast and nipple neoplasms benign	1 (0.5%)	0	0	0	0
Fibroadenoma of breast	1 (0.5%)	0	0	0	0
Cardiovascular neoplasms benign	1 (0.5%)	0	0	0	0
Haemangioma	1 (0.5%)	0	0	0	0
Colorectal neoplasms malignant	0	0	1 (0.6%)	0	0
Colon cancer	0	0	1 (0.6%)	0	0
Lower gastrointestinal neoplasms benign	0	1 (1.0%)	0	1 (1.1%)	0
Colon adenoma	0	1 (1.0%)	0	1 (1.1%)	0
Skin melanomas (excl ocular)	1 (0.5%)	0	0	0	0
Malignant melanoma	1 (0.5%)	0	0	0	0

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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont)					
Skin neoplasms benign	1 (0.5%)	0	1 (0.6%)	0	3 (3.2%)
Skin papilloma	0	0	1 (0.6%)	0	2 (2.2%)
Acrochordon	0	0	0	0	1 (1.1%)
Anogenital warts	1 (0.5%)	0	0	0	0
Skin neoplasms malignant and unspecified (excl melanoma)	0	0	1 (0.6%)	0	0
Basal cell carcinoma	0	0	1 (0.6%)	0	0
Nervous system disorders	16 (7.9%)	4 (4.0%)	15 (8.4%)	5 (5.5%)	11 (11.8%)
Cerebrovascular venous and sinus thrombosis	0	0	0	0	1 (1.1%)
Cerebral venous sinus thrombosis	0	0	0	0	1 (1.1%)

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TEAEs are defined as any AEs that began on or after the Maintenance first dose date up to 30 days after Maintenance last dose date, or led to premature discontinuation of Maintenance study drug.
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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
Nervous system disorders (cont)					
Disturbances in consciousness NEC	3 (1.5%)	1 (1.0%)	1 (0.6%)	0	0
Lethargy	2 (1.0%)	1 (1.0%)	1 (0.6%)	0	0
Syncope	1 (0.5%)	0	0	0	0
Headaches NEC	7 (3.5%)	0	11 (6.1%)	5 (5.5%)	6 (6.5%)
Headache	7 (3.5%)	0	11 (6.1%)	5 (5.5%)	5 (5.4%)
Tension headache	0	0	0	0	1 (1.1%)
Lumbar spinal cord and nerve root disorders	1 (0.5%)	1 (1.0%)	1 (0.6%)	0	2 (2.2%)
Sciatica	1 (0.5%)	1 (1.0%)	1 (0.6%)	0	2 (2.2%)
Migraine headaches	1 (0.5%)	1 (1.0%)	0	0	0
Migraine	1 (0.5%)	1 (1.0%)	0	0	0
Mononeuropathies	0	0	1 (0.6%)	0	0
Carpal tunnel syndrome	0	0	1 (0.6%)	0	0

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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
Nervous system disorders (cont)					
Neurological signs and symptoms NEC	2 (1.0%)	1 (1.0%)	0	0	1 (1.1%)
Dizziness	2 (1.0%)	1 (1.0%)	0	0	1 (1.1%)
Paraesthesias and dysaesthesias	1 (0.5%)	0	0	0	0
Dysaesthesia	1 (0.5%)	0	0	0	0
Peripheral neuropathies NEC	1 (0.5%)	0	0	0	0
Polyneuropathy	1 (0.5%)	0	0	0	0
Sensory abnormalities NEC	1 (0.5%)	0	0	0	1 (1.1%)
Dysgeusia	1 (0.5%)	0	0	0	1 (1.1%)
Neuralgia	1 (0.5%)	0	0	0	0
Transient cerebrovascular events	0	0	1 (0.6%)	0	0
Transient ischaemic attack	0	0	1 (0.6%)	0	0

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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
Nervous system disorders (cont)					
Vagus nerve disorders	1 (0.5%)	0	0	0	0
Vagus nerve disorder	1 (0.5%)	0	0	0	0
Psychiatric disorders	4 (2.0%)	1 (1.0%)	3 (1.7%)	1 (1.1%)	3 (3.2%)
Anxiety symptoms	0	0	0	0	2 (2.2%)
Anxiety	0	0	0	0	2 (2.2%)
Depressive disorders	2 (1.0%)	1 (1.0%)	1 (0.6%)	0	0
Depression	2 (1.0%)	1 (1.0%)	1 (0.6%)	0	0
Disturbances in initiating and maintaining sleep	0	0	2 (1.1%)	1 (1.1%)	1 (1.1%)
Insomnia	0	0	2 (1.1%)	1 (1.1%)	1 (1.1%)

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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
Psychiatric disorders (cont)					
Emotional and mood disturbances NEC	1 (0.5%)	0	0	0	0
Anger	1 (0.5%)	0	0	0	0
Emotional disorder	1 (0.5%)	0	0	0	0
Sleep disorders NEC	1 (0.5%)	0	0	0	0
Sleep disorder	1 (0.5%)	0	0	0	0
Renal and urinary disorders	3 (1.5%)	1 (1.0%)	4 (2.2%)	2 (2.2%)	1 (1.1%)
Bladder and urethral symptoms	0	0	0	1 (1.1%)	0
Micturition urgency	0	0	0	1 (1.1%)	0
Renal failure and impairment	0	0	1 (0.6%)	0	1 (1.1%)
Acute kidney injury	0	0	0	0	1 (1.1%)
Renal impairment	0	0	1 (0.6%)	0	0

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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Maintenance Study
Safety Analysis Set

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Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
Renal and urinary disorders (cont)					
Renal lithiasis	1 (0.5%)	0	1 (0.6%)	1 (1.1%)	0
Nephrolithiasis	1 (0.5%)	0	1 (0.6%)	1 (1.1%)	0
Urinary abnormalities	1 (0.5%)	1 (1.0%)	1 (0.6%)	0	0
Haematuria	1 (0.5%)	0	0	0	0
Proteinuria	0	1 (1.0%)	0	0	0
Urine odour abnormal	0	0	1 (0.6%)	0	0
Urinary tract lithiasis (excl renal)	1 (0.5%)	0	0	0	0
Calculus urinary	1 (0.5%)	0	0	0	0
Urinary tract signs and symptoms NEC	0	0	1 (0.6%)	0	0
Renal colic	0	0	1 (0.6%)	0	0
Reproductive system and breast disorders	6 (3.0%)	0	4 (2.2%)	2 (2.2%)	1 (1.1%)

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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
Reproductive system and breast disorders (cont)					
Benign and malignant breast neoplasms	1 (0.5%)	0	0	0	0
Breast cyst	1 (0.5%)	0	0	0	0
Breast signs and symptoms	1 (0.5%)	0	0	0	0
Nipple pain	1 (0.5%)	0	0	0	0
Cervix neoplasms	0	0	1 (0.6%)	0	0
Cervical polyp	0	0	1 (0.6%)	0	0
Erection and ejaculation conditions and disorders	1 (0.5%)	0	0	1 (1.1%)	1 (1.1%)
Erectile dysfunction	1 (0.5%)	0	0	1 (1.1%)	1 (1.1%)
Menstruation and uterine bleeding NEC	0	0	2 (1.1%)	0	0
Menstrual disorder	0	0	1 (0.6%)	0	0
Menstruation irregular	0	0	1 (0.6%)	0	0

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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
Reproductive system and breast disorders (cont)					
Menstruation with increased bleeding	1 (0.5%)	0	0	0	0
Menorrhagia	1 (0.5%)	0	0	0	0
Ovarian and fallopian tube cysts and neoplasms	0	0	0	1 (1.1%)	0
Ovarian cyst	0	0	0	1 (1.1%)	0
Prostate and seminal vesicles infections and inflammations	0	0	1 (0.6%)	0	0
Prostatitis	0	0	1 (0.6%)	0	0
Prostatic signs, symptoms and disorders NEC	1 (0.5%)	0	0	0	0
Prostatomegaly	1 (0.5%)	0	0	0	0
Uterine neoplasms	0	0	0	1 (1.1%)	0
Uterine polyp	0	0	0	1 (1.1%)	0

TEAE = treatment-emergent adverse event. NEC = Not Elsewhere Classified. Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Maintenance first dose date up to 30 days after Maintenance last dose date, or led to premature discontinuation of Maintenance study drug.
System organ classes and high level terms (within each system organ class) were presented alphabetically, and preferred terms were presented by descending order of the total frequencies. Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
Reproductive system and breast disorders (cont)					
Vulvovaginal disorders NEC	1 (0.5%)	0	0	1 (1.1%)	0
Vaginal disorder	1 (0.5%)	0	0	0	0
Vaginal haemorrhage	0	0	0	1 (1.1%)	0
Vulvovaginal signs and symptoms	0	0	1 (0.6%)	1 (1.1%)	0
Vaginal discharge	0	0	1 (0.6%)	1 (1.1%)	0
Respiratory, thoracic and mediastinal disorders	16 (7.9%)	5 (5.1%)	5 (2.8%)	6 (6.6%)	3 (3.2%)
Breathing abnormalities	0	0	2 (1.1%)	0	0
Dyspnoea	0	0	2 (1.1%)	0	0
Bronchospasm and obstruction	1 (0.5%)	2 (2.0%)	0	0	1 (1.1%)
Asthma	1 (0.5%)	0	0	0	1 (1.1%)
Bronchospasm	0	1 (1.0%)	0	0	0
Chronic obstructive pulmonary disease	0	0	0	0	1 (1.1%)
Wheezing	0	1 (1.0%)	0	0	0

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TEAEs are defined as any AEs that began on or after the Maintenance first dose date up to 30 days after Maintenance last dose date, or led to premature discontinuation of Maintenance study drug.
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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
Respiratory, thoracic and mediastinal disorders (cont)					
Coughing and associated symptoms	8 (4.0%)	3 (3.0%)	0	2 (2.2%)	1 (1.1%)
Cough	7 (3.5%)	2 (2.0%)	0	2 (2.2%)	1 (1.1%)
Productive cough	1 (0.5%)	1 (1.0%)	0	0	0
Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)	1 (0.5%)	0	0	0	0
Vocal cord polyp	1 (0.5%)	0	0	0	0
Nasal congestion and inflammations	3 (1.5%)	0	0	0	0
Rhinitis allergic	2 (1.0%)	0	0	0	0
Nasal congestion	1 (0.5%)	0	0	0	0
Nasal disorders NEC	0	0	0	1 (1.1%)	0
Epistaxis	0	0	0	1 (1.1%)	0

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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
Respiratory, thoracic and mediastinal disorders (cont)					
Paranasal sinus disorders (excl infections and neoplasms)	0	0	0	1 (1.1%)	0
Sinus congestion	0	0	0	1 (1.1%)	0
Parenchymal lung disorders NEC	0	0	1 (0.6%)	0	0
Atelectasis	0	0	1 (0.6%)	0	0
Respiratory tract disorders NEC	1 (0.5%)	0	1 (0.6%)	0	0
Pulmonary mass	0	0	1 (0.6%)	0	0
Respiratory disorder	1 (0.5%)	0	0	0	0
Upper respiratory tract signs and symptoms	4 (2.0%)	0	3 (1.7%)	2 (2.2%)	1 (1.1%)
Oropharyngeal pain	3 (1.5%)	0	2 (1.1%)	1 (1.1%)	1 (1.1%)
Rhinorrhoea	1 (0.5%)	0	0	0	0
Upper respiratory tract inflammation	0	0	0	1 (1.1%)	0
Upper-airway cough syndrome	0	0	1 (0.6%)	0	0

TEAE = treatment-emergent adverse event. NEC = Not Elsewhere Classified. Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Maintenance first dose date up to 30 days after Maintenance last dose date, or led to premature discontinuation of Maintenance study drug.
System organ classes and high level terms (within each system organ class) were presented alphabetically, and preferred terms were presented by descending order of the total frequencies. Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
Skin and subcutaneous tissue disorders	14 (6.9%)	5 (5.1%)	10 (5.6%)	6 (6.6%)	7 (7.5%)
Acnes	2 (1.0%)	0	1 (0.6%)	0	0
Acne	1 (0.5%)	0	1 (0.6%)	0	0
Dermatitis acneiform	1 (0.5%)	0	0	0	0
Alopecias	1 (0.5%)	0	1 (0.6%)	0	0
Alopecia	1 (0.5%)	0	1 (0.6%)	0	0
Apocrine and eccrine gland disorders	1 (0.5%)	0	0	0	0
Cold sweat	1 (0.5%)	0	0	0	0
Dermal and epidermal conditions NEC	0	1 (1.0%)	1 (0.6%)	1 (1.1%)	0
Dry skin	0	0	1 (0.6%)	1 (1.1%)	0
Macule	0	1 (1.0%)	0	0	0

TEAE = treatment-emergent adverse event. NEC = Not Elsewhere Classified. Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Maintenance first dose date up to 30 days after Maintenance last dose date, or led to premature discontinuation of Maintenance study drug.
System organ classes and high level terms (within each system organ class) were presented alphabetically, and preferred terms were presented by descending order of the total frequencies. Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
Skin and subcutaneous tissue disorders (cont)					
Dermatitis and eczema	3 (1.5%)	2 (2.0%)	1 (0.6%)	0	1 (1.1%)
Dermatitis contact	1 (0.5%)	2 (2.0%)	0	0	0
Eczema	1 (0.5%)	0	0	0	1 (1.1%)
Dermatitis	1 (0.5%)	0	0	0	0
Skin irritation	0	0	1 (0.6%)	0	0
Erythemas	1 (0.5%)	0	1 (0.6%)	1 (1.1%)	0
Erythema	1 (0.5%)	0	1 (0.6%)	1 (1.1%)	0
Exfoliative conditions	0	0	0	1 (1.1%)	0
Skin exfoliation	0	0	0	1 (1.1%)	0
Hyperkeratoses	1 (0.5%)	0	0	0	1 (1.1%)
Hyperkeratosis	1 (0.5%)	0	0	0	1 (1.1%)

TEAE = treatment-emergent adverse event. NEC = Not Elsewhere Classified. Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Maintenance first dose date up to 30 days after Maintenance last dose date, or led to premature discontinuation of Maintenance study drug.
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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
Skin and subcutaneous tissue disorders (cont)					
Hyperpigmentation disorders	0	0	0	1 (1.1%)	0
Solar lentigo	0	0	0	1 (1.1%)	0
Nail and nail bed conditions (excl infections and infestations)	0	1 (1.0%)	0	0	2 (2.2%)
Onychoclasis	0	0	0	0	2 (2.2%)
Nail disorder	0	1 (1.0%)	0	0	0
Papulosquamous conditions	0	0	0	1 (1.1%)	0
Pityriasis rosea	0	0	0	1 (1.1%)	0
Photosensitivity and photodermatosis conditions	1 (0.5%)	0	0	0	0
Photosensitivity reaction	1 (0.5%)	0	0	0	0
Pruritus NEC	1 (0.5%)	0	1 (0.6%)	1 (1.1%)	1 (1.1%)
Pruritus	1 (0.5%)	0	1 (0.6%)	1 (1.1%)	1 (1.1%)

TEAE = treatment-emergent adverse event. NEC = Not Elsewhere Classified. Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Maintenance first dose date up to 30 days after Maintenance last dose date, or led to premature discontinuation of Maintenance study drug.
System organ classes and high level terms (within each system organ class) were presented alphabetically, and preferred terms were presented by descending order of the total frequencies. Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
Skin and subcutaneous tissue disorders (cont)					
Psoriatic conditions	0	0	1 (0.6%)	0	1 (1.1%)
Psoriasis	0	0	1 (0.6%)	0	1 (1.1%)
Rashes, eruptions and exanthems NEC	2 (1.0%)	1 (1.0%)	3 (1.7%)	1 (1.1%)	2 (2.2%)
Rash	1 (0.5%)	1 (1.0%)	2 (1.1%)	1 (1.1%)	0
Rash erythematous	0	0	0	0	1 (1.1%)
Rash macular	0	0	0	0	1 (1.1%)
Rash maculo-papular	1 (0.5%)	0	0	0	0
Rash papular	0	0	1 (0.6%)	0	0
Rosaceas	2 (1.0%)	0	0	0	0
Rosacea	2 (1.0%)	0	0	0	0
Skin and subcutaneous tissue ulcerations	0	0	0	0	1 (1.1%)
Skin ulcer	0	0	0	0	1 (1.1%)

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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
Skin and subcutaneous tissue disorders (cont)					
Skin cysts and polyps	1 (0.5%)	0	0	0	0
Dermal cyst	1 (0.5%)	0	0	0	0
Skin preneoplastic conditions NEC	0	0	0	0	1 (1.1%)
Actinic keratosis	0	0	0	0	1 (1.1%)
Urticarias	1 (0.5%)	0	0	0	0
Urticaria	1 (0.5%)	0	0	0	0
Vascular disorders	9 (4.5%)	2 (2.0%)	1 (0.6%)	4 (4.4%)	5 (5.4%)
Haemorrhages NEC	1 (0.5%)	0	0	0	0
Haematoma	1 (0.5%)	0	0	0	0
Non-site specific embolism and thrombosis	0	0	0	0	1 (1.1%)
Venous thrombosis	0	0	0	0	1 (1.1%)

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System organ classes and high level terms (within each system organ class) were presented alphabetically, and preferred terms were presented by descending order of the total frequencies. Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
Vascular disorders (cont)					
Non-site specific necrosis and vascular insufficiency NEC	0	0	0	0	1 (1.1%)
Haemorrhagic infarction	0	0	0	0	1 (1.1%)
Non-site specific vascular disorders NEC	0	0	0	1 (1.1%)	0
Hyperaemia	0	0	0	1 (1.1%)	0
Peripheral embolism and thrombosis	0	0	0	0	1 (1.1%)
Deep vein thrombosis	0	0	0	0	1 (1.1%)
Peripheral vascular disorders NEC	1 (0.5%)	0	0	0	0
Hot flush	1 (0.5%)	0	0	0	0
Varicose veins NEC	1 (0.5%)	0	0	0	0
Varicose vein	1 (0.5%)	0	0	0	0

TEAE = treatment-emergent adverse event. NEC = Not Elsewhere Classified. Adverse events were coded according to MedDRA Version 22.1.
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Table 15.11.2.1.2.4: Treatment-Emergent Adverse Events by System Organ Class, High-Level Term and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class High-Level Term Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events	135 (66.8%)	59 (59.6%)	108 (60.3%)	60 (65.9%)	57 (61.3%)
Vascular disorders (cont)					
Vascular hypertensive disorders NEC	6 (3.0%)	2 (2.0%)	1 (0.6%)	3 (3.3%)	2 (2.2%)
Hypertension	6 (3.0%)	2 (2.0%)	1 (0.6%)	3 (3.3%)	2 (2.2%)
Vascular hypotensive disorders	0	0	0	0	1 (1.1%)
Orthostatic hypotension	0	0	0	0	1 (1.1%)

TEAE = treatment-emergent adverse event. NEC = Not Elsewhere Classified. Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Maintenance first dose date up to 30 days after Maintenance last dose date, or led to premature discontinuation of Maintenance study drug.
System organ classes and high level terms (within each system organ class) were presented alphabetically, and preferred terms were presented by descending order of the total frequencies. Multiple AEs were counted only once per subject for each SOC, HLT, and PT.
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Anhang 4-G2: SUE nach SOC und PT - Safety Analyse Set

Tabelle 4-4 (Anhang): Ergebnisse für SUE nach SOC und PT aus RCT mit dem zu bewertenden Arzneimittel (SELECTION, Induktionsphase: Kohorte A)

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Table 15.11.4.1.1: Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term
Induction Study: Cohort A
Safety Analysis Set

System Organ Class Preferred Term	Filgotinib 200 mg (N=245)	Filgotinib 100 mg (N=277)	Placebo (N=137)
Number (%) of Subjects with Any Treatment-Emergent Serious Adverse Events	3 (1.2%)	13 (4.7%)	4 (2.9%)
Blood and lymphatic system disorders	0	3 (1.1%)	1 (0.7%)
Anaemia	0	1 (0.4%)	1 (0.7%)
Iron deficiency anaemia	0	1 (0.4%)	0
Pancytopenia	0	1 (0.4%)	0
Cardiac disorders	1 (0.4%)	0	0
Pericarditis	1 (0.4%)	0	0
Gastrointestinal disorders	1 (0.4%)	4 (1.4%)	3 (2.2%)
Colitis ulcerative	0	3 (1.1%)	3 (2.2%)
Gastrointestinal haemorrhage	1 (0.4%)	0	0
Vomiting	0	1 (0.4%)	0
Immune system disorders	0	1 (0.4%)	0
Type I hypersensitivity	0	1 (0.4%)	0
Infections and infestations	1 (0.4%)	2 (0.7%)	1 (0.7%)
Appendicitis	0	1 (0.4%)	0
Cellulitis	0	0	1 (0.7%)
Dengue fever	1 (0.4%)	0	0
Gastroenteritis	0	1 (0.4%)	0
Osteomyelitis	0	0	1 (0.7%)

TEAE = treatment-emergent adverse event. Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Induction first dose date up to one day before the Maintenance first dose date or 30 days after the Induction last dose date whichever is earlier, or led to premature discontinuation of Induction study drug.
Multiple AEs were counted only once per subject for each system organ class and preferred term.
System organ classes were presented alphabetically, and preferred terms were presented by descending order of the total frequencies.
Source: Listing 16.2.7.3

Data Extracted: 05MAY2020
Source: .../final/version1/prog/t-teae-sub.sas v9.4 Output file: t-teae-sub-ser-a.pdf 28MAY2020:14:28 Page 1 of 2

Gilead Sciences, Inc.
Study GS-US-418-3898

Table 15.11.4.1.1: Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term
Induction Study: Cohort A
Safety Analysis Set

System Organ Class Preferred Term	Filgotinib 200 mg (N=245)	Filgotinib 100 mg (N=277)	Placebo (N=137)
Number (%) of Subjects with Any Treatment-Emergent Serious Adverse Events	3 (1.2%)	13 (4.7%)	4 (2.9%)
Injury, poisoning and procedural complications	0	1 (0.4%)	1 (0.7%)
Procedural intestinal perforation	0	0	1 (0.7%)
Road traffic accident	0	1 (0.4%)	0
Reproductive system and breast disorders	0	1 (0.4%)	0
Ovarian cyst ruptured	0	1 (0.4%)	0
Vascular disorders	0	1 (0.4%)	0
Hypertension	0	1 (0.4%)	0

TEAE = treatment-emergent adverse event. Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Induction first dose date up to one day before the Maintenance first dose date or 30 days after the Induction last dose date whichever is earlier, or led to premature discontinuation of Induction study drug.
Multiple AEs were counted only once per subject for each system organ class and preferred term.
System organ classes were presented alphabetically, and preferred terms were presented by descending order of the total frequencies.
Source: Listing 16.2.7.3

Data Extracted: 05MAY2020
Source: .../final/version1/prog/t-teae-sub.sas v9.4 Output file: t-teae-sub-ser-a.pdf 28MAY2020:14:28 Page 2 of 2

Tabelle 4-5 (Anhang): Ergebnisse für SUE nach SOC und PT aus RCT mit dem zu bewertenden Arzneimittel (SELECTION, Induktionsphase: Kohorte B)

Gilead Sciences, Inc.
Study GS-US-418-3898

Table 15.11.4.1.2: Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term
Induction Study: Cohort B
Safety Analysis Set

System Organ Class Preferred Term	Filgotinib 200 mg (N=262)	Filgotinib 100 mg (N=285)	Placebo (N=142)
Number (%) of Subjects with Any Treatment-Emergent Serious Adverse Events	19 (7.3%)	15 (5.3%)	9 (6.3%)
Blood and lymphatic system disorders	2 (0.8%)	1 (0.4%)	0
Anaemia	1 (0.4%)	1 (0.4%)	0
Iron deficiency anaemia	1 (0.4%)	0	0
Gastrointestinal disorders	11 (4.2%)	7 (2.5%)	6 (4.2%)
Colitis ulcerative	7 (2.7%)	5 (1.8%)	5 (3.5%)
Abdominal pain	1 (0.4%)	0	0
Anal fissure	1 (0.4%)	0	0
Appendiceal mucocoele	1 (0.4%)	0	0
Duodenal ulcer haemorrhage	1 (0.4%)	0	0
Gastritis	0	1 (0.4%)	0
Large intestinal haemorrhage	1 (0.4%)	0	0
Nausea	0	1 (0.4%)	0
Pancreatitis acute	0	0	1 (0.7%)
Vomiting	0	1 (0.4%)	0
General disorders and administration site conditions	0	1 (0.4%)	0
Chest pain	0	1 (0.4%)	0

TEAE = treatment-emergent adverse event. Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Induction first dose date up to one day before the Maintenance first dose date or 30 days after the Induction last dose date whichever is earlier, or led to premature discontinuation of Induction study drug.
Multiple AEs were counted only once per subject for each system organ class and preferred term.
System organ classes were presented alphabetically, and preferred terms were presented by descending order of the total frequencies.
Source: Listing 16.2.7.3

Data Extracted: 05MAY2020
Source: .../final/version1/prog/t-teae-sub.sas v9.4 Output file: t-teae-sub-ser-b.pdf 28MAY2020:14:28 Page 1 of 3

Gilead Sciences, Inc.
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Table 15.11.4.1.2: Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term
Induction Study: Cohort B
Safety Analysis Set

System Organ Class Preferred Term	Filgotinib 200 mg (N=262)	Filgotinib 100 mg (N=285)	Placebo (N=142)
Number (%) of Subjects with Any Treatment-Emergent Serious Adverse Events	19 (7.3%)	15 (5.3%)	9 (6.3%)
Infections and infestations	2 (0.8%)	4 (1.4%)	2 (1.4%)
Gastroenteritis viral	1 (0.4%)	0	1 (0.7%)
Sepsis	0	2 (0.7%)	0
Anal abscess	0	1 (0.4%)	0
Campylobacter gastroenteritis	0	0	1 (0.7%)
Clostridium difficile infection	1 (0.4%)	0	0
Staphylococcal infection	0	1 (0.4%)	0
Injury, poisoning and procedural complications	0	1 (0.4%)	0
Femur fracture	0	1 (0.4%)	0
Musculoskeletal and connective tissue disorders	2 (0.8%)	1 (0.4%)	0
Intervertebral disc protrusion	2 (0.8%)	0	0
Myalgia	0	1 (0.4%)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.4%)	0	0
Breast cancer	1 (0.4%)	0	0
Nervous system disorders	0	1 (0.4%)	1 (0.7%)
Cerebrovascular accident	0	0	1 (0.7%)
Headache	0	1 (0.4%)	0

TEAE = treatment-emergent adverse event. Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Induction first dose date up to one day before the Maintenance first dose date or 30 days after the Induction last dose date whichever is earlier, or led to premature discontinuation of Induction study drug.
Multiple AEs were counted only once per subject for each system organ class and preferred term.
System organ classes were presented alphabetically, and preferred terms were presented by descending order of the total frequencies.
Source: Listing 16.2.7.3

Data Extracted: 05MAY2020
Source: .../final/version1/prog/t-teae-sub.sas v9.4 Output file: t-teae-sub-ser-b.pdf 28MAY2020:14:28 Page 2 of 3

Gilead Sciences, Inc.
Study GS-US-418-3898

Table 15.11.4.1.2: Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term
Induction Study: Cohort B
Safety Analysis Set

System Organ Class Preferred Term	Filgotinib 200 mg (N=262)	Filgotinib 100 mg (N=285)	Placebo (N=142)
Number (%) of Subjects with Any Treatment-Emergent Serious Adverse Events	19 (7.3%)	15 (5.3%)	9 (6.3%)
Pregnancy, puerperium and perinatal conditions	0	1 (0.4%)	0
Ectopic pregnancy	0	1 (0.4%)	0
Renal and urinary disorders	1 (0.4%)	0	1 (0.7%)
Nephrolithiasis	1 (0.4%)	0	0
Renal colic	0	0	1 (0.7%)
Respiratory, thoracic and mediastinal disorders	1 (0.4%)	0	1 (0.7%)
Haemoptysis	0	0	1 (0.7%)
Pulmonary embolism	1 (0.4%)	0	0

TEAE = treatment-emergent adverse event. Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Induction first dose date up to one day before the Maintenance first dose date or 30 days after the Induction last dose date whichever is earlier, or led to premature discontinuation of Induction study drug.
Multiple AEs were counted only once per subject for each system organ class and preferred term.
System organ classes were presented alphabetically, and preferred terms were presented by descending order of the total frequencies.
Source: Listing 16.2.7.3

Data Extracted: 05MAY2020
Source: .../final/version1/prog/t-teae-sub.sas v9.4 Output file: t-teae-sub-ser-b.pdf 28MAY2020:14:28 Page 3 of 3

Tabelle 4-6 (Anhang): Ergebnisse für SUE nach SOC und PT aus RCT mit dem zu bewertenden Arzneimittel (SELECTION, Erhaltungsphase)

Gilead Sciences, Inc.
Study GS-US-418-3898

Table 15.11.4.1.4: Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Serious Adverse Events	9 (4.5%)	0	8 (4.5%)	7 (7.7%)	4 (4.3%)
Blood and lymphatic system disorders	0	0	0	1 (1.1%)	0
Iron deficiency anaemia	0	0	0	1 (1.1%)	0
Cardiac disorders	1 (0.5%)	0	0	1 (1.1%)	0
Coronary artery stenosis	0	0	0	1 (1.1%)	0
Left ventricular failure	1 (0.5%)	0	0	0	0
Gastrointestinal disorders	0	0	2 (1.1%)	1 (1.1%)	1 (1.1%)
Colitis ulcerative	0	0	1 (0.6%)	1 (1.1%)	0
Abdominal pain	0	0	1 (0.6%)	0	0
Dental cyst	0	0	0	0	1 (1.1%)
Pancreatitis acute	0	0	1 (0.6%)	0	0
Supernumerary teeth	0	0	0	0	1 (1.1%)

TEAE = treatment-emergent adverse event. Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Maintenance first dose date up to 30 days after Maintenance last dose date, or led to premature discontinuation of Maintenance study drug.
Multiple AEs were counted only once per subject for each system organ class and preferred term.
System organ classes were presented alphabetically, and preferred terms were presented by descending order of the total frequencies.
Source: Listing 16.2.7.3

Data Extracted: 05MAY2020
Source: .../final/version1/prog/t-teae-m-sub.sas v9.4 Output file: t-teae-m-sub-ser-m.pdf 28MAY2020:14:29 Page 1 of 4

Gilead Sciences, Inc.
Study GS-US-418-3898

Table 15.11.4.1.4: Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Serious Adverse Events	9 (4.5%)	0	8 (4.5%)	7 (7.7%)	4 (4.3%)
General disorders and administration site conditions	2 (1.0%)	0	2 (1.1%)	0	0
Pyrexia	1 (0.5%)	0	1 (0.6%)	0	0
Chest pain	1 (0.5%)	0	0	0	0
Non-cardiac chest pain	0	0	1 (0.6%)	0	0
Hepatobiliary disorders	0	0	1 (0.6%)	1 (1.1%)	0
Autoimmune hepatitis	0	0	0	1 (1.1%)	0
Cholelithiasis	0	0	1 (0.6%)	0	0
Infections and infestations	2 (1.0%)	0	3 (1.7%)	2 (2.2%)	1 (1.1%)
Appendicitis	1 (0.5%)	0	2 (1.1%)	0	0
Acute hepatitis B	0	0	0	1 (1.1%)	0
Cellulitis	0	0	1 (0.6%)	0	0
Diverticulitis	1 (0.5%)	0	0	0	0
Gastroenteritis viral	0	0	0	1 (1.1%)	0
Paronychia	0	0	1 (0.6%)	0	0
Pneumonia	0	0	0	0	1 (1.1%)

TEAE = treatment-emergent adverse event. Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Maintenance first dose date up to 30 days after Maintenance last dose date, or led to premature discontinuation of Maintenance study drug.
Multiple AEs were counted only once per subject for each system organ class and preferred term.
System organ classes were presented alphabetically, and preferred terms were presented by descending order of the total frequencies.
Source: Listing 16.2.7.3

Data Extracted: 05MAY2020
Source: .../final/version1/prog/t-teae-m-sub.sas v9.4 Output file: t-teae-m-sub-ser-m.pdf 28MAY2020:14:29 Page 2 of 4

Gilead Sciences, Inc.
Study GS-US-418-3898

Table 15.11.4.1.4: Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Serious Adverse Events	9 (4.5%)	0	8 (4.5%)	7 (7.7%)	4 (4.3%)
Injury, poisoning and procedural complications	1 (0.5%)	0	0	1 (1.1%)	0
Meniscus injury	0	0	0	1 (1.1%)	0
Tendon rupture	1 (0.5%)	0	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.5%)	0	1 (0.6%)	0	0
Colon cancer	0	0	1 (0.6%)	0	0
Malignant melanoma	1 (0.5%)	0	0	0	0
Nervous system disorders	0	0	1 (0.6%)	0	0
Transient ischaemic attack	0	0	1 (0.6%)	0	0
Renal and urinary disorders	1 (0.5%)	0	0	0	1 (1.1%)
Acute kidney injury	0	0	0	0	1 (1.1%)
Calculus urinary	1 (0.5%)	0	0	0	0

TEAE = treatment-emergent adverse event. Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Maintenance first dose date up to 30 days after Maintenance last dose date, or led to premature discontinuation of Maintenance study drug.
Multiple AEs were counted only once per subject for each system organ class and preferred term.
System organ classes were presented alphabetically, and preferred terms were presented by descending order of the total frequencies.
Source: Listing 16.2.7.3

Data Extracted: 05MAY2020
Source: .../final/version1/prog/t-teae-m-sub.sas v9.4 Output file: t-teae-m-sub-ser-m.pdf 28MAY2020:14:29 Page 3 of 4

Gilead Sciences, Inc.
Study GS-US-418-3898

Table 15.11.4.1.4: Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Serious Adverse Events	9 (4.5%)	0	8 (4.5%)	7 (7.7%)	4 (4.3%)
Respiratory, thoracic and mediastinal disorders	1 (0.5%)	0	1 (0.6%)	0	0
Asthma	1 (0.5%)	0	0	0	0
Atelectasis	0	0	1 (0.6%)	0	0
Dyspnoea	0	0	1 (0.6%)	0	0
Pulmonary mass	0	0	1 (0.6%)	0	0
Vascular disorders	0	0	0	0	2 (2.2%)
Deep vein thrombosis	0	0	0	0	1 (1.1%)
Haemorrhagic infarction	0	0	0	0	1 (1.1%)

TEAE = treatment-emergent adverse event. Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Maintenance first dose date up to 30 days after Maintenance last dose date, or led to premature discontinuation of Maintenance study drug.
Multiple AEs were counted only once per subject for each system organ class and preferred term.
System organ classes were presented alphabetically, and preferred terms were presented by descending order of the total frequencies.
Source: Listing 16.2.7.3

Data Extracted: 05MAY2020
Source: .../final/version1/prog/t-teae-m-sub.sas v9.4 Output file: t-teae-m-sub-ser-m.pdf 28MAY2020:14:29 Page 4 of 4

Anhang 4-G3: Schwere UE (CTCAE Grad ≥3) nach SOC und PT - Safety Analyse Set

Tabelle 4-7 (Anhang): Ergebnisse für schwere UE nach SOC und PT aus RCT mit dem zu bewertenden Arzneimittel (SELECTION, Induktionsphase: Kohorte A)

Gilead Sciences, Inc.
Study GS-US-418-3898

Table 15.11.2.2.1.1.1: Grade 3 or Higher Treatment-Emergent Adverse Events by System Organ Class, Preferred Term, and Severity
Induction Study: Cohort A
Safety Analysis Set

System Organ Class Preferred Term Severity	Filgotinib 200 mg (N=245)	Filgotinib 100 mg (N=277)	Placebo (N=137)
Number(%) of Subjects with Any Grade 3 or Higher Treatment-Emergent Adverse Events	5 (2.0%)	22 (7.9%)	11 (8.0%)
Grade 3	5 (2.0%)	19 (6.9%)	11 (8.0%)
Grade 4	0	3 (1.1%)	0
Grade 5	0	0	0
Blood and lymphatic system disorders	2 (0.8%)	3 (1.1%)	3 (2.2%)
Grade 3	2 (0.8%)	2 (0.7%)	3 (2.2%)
Grade 4	0	1 (0.4%)	0
Anaemia	2 (0.8%)	1 (0.4%)	1 (0.7%)
Grade 3	2 (0.8%)	1 (0.4%)	1 (0.7%)
Lymphopenia	0	0	2 (1.5%)
Grade 3	0	0	2 (1.5%)
Neutropenia	0	1 (0.4%)	0
Grade 3	0	1 (0.4%)	0
Pancytopenia	0	1 (0.4%)	0
Grade 4	0	1 (0.4%)	0

Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Induction first dose date up to one day before the Maintenance first dose date or 30 days after the Induction last dose date whichever is earlier, or led to premature discontinuation of Induction study drug.
Severity grades were defined by the CTCAE Version 4.03. 1 = Mild; 2 = Moderate; 3 = Severe; 4 = Life-Threatening; 5 = Death. Multiple AEs were counted only once per subject for the highest severity grade for each SOC and PT.
System organ classes were presented alphabetically, and preferred terms were presented by descending order of the total frequencies.
Source: Listing 16.2.7.4.1

Data Extracted: 05MAY2020
Source: .../final/version1/prog/t-teae-g.sas v9.4 Output file: t-teae-g-g34-a.pdf 28MAY2020:14:28 Page 1 of 9

Gilead Sciences, Inc.
Study GS-US-418-3898

Table 15.11.2.2.1.1.1: Grade 3 or Higher Treatment-Emergent Adverse Events by System Organ Class, Preferred Term, and Severity
Induction Study: Cohort A
Safety Analysis Set

System Organ Class Preferred Term Severity	Filgotinib 200 mg (N=245)	Filgotinib 100 mg (N=277)	Placebo (N=137)
Number(%) of Subjects with Any Grade 3 or Higher Treatment-Emergent Adverse Events	5 (2.0%)	22 (7.9%)	11 (8.0%)
Cardiac disorders	1 (0.4%)	0	0
Grade 3	1 (0.4%)	0	0
Pericarditis	1 (0.4%)	0	0
Grade 3	1 (0.4%)	0	0
Congenital, familial and genetic disorders	0	1 (0.4%)	0
Grade 3	0	1 (0.4%)	0
Thalassaemia	0	1 (0.4%)	0
Grade 3	0	1 (0.4%)	0
Gastrointestinal disorders	3 (1.2%)	6 (2.2%)	4 (2.9%)
Grade 3	3 (1.2%)	5 (1.8%)	4 (2.9%)
Grade 4	0	1 (0.4%)	0
Colitis ulcerative	1 (0.4%)	4 (1.4%)	4 (2.9%)
Grade 3	1 (0.4%)	3 (1.1%)	4 (2.9%)
Grade 4	0	1 (0.4%)	0

Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Induction first dose date up to one day before the Maintenance first dose date or 30 days after the Induction last dose date whichever is earlier, or led to premature discontinuation of Induction study drug.
Severity grades were defined by the CTCAE Version 4.03. 1 = Mild; 2 = Moderate; 3 = Severe; 4 = Life-Threatening; 5 = Death. Multiple AEs were counted only once per subject for the highest severity grade for each SOC and PT.
System organ classes were presented alphabetically, and preferred terms were presented by descending order of the total frequencies.
Source: Listing 16.2.7.4.1

Data Extracted: 05MAY2020
Source: .../final/version1/prog/t-teae-g.sas v9.4 Output file: t-teae-g-g34-a.pdf 28MAY2020:14:28 Page 2 of 9

Gilead Sciences, Inc.
Study GS-US-418-3898

Table 15.11.2.2.1.1.1: Grade 3 or Higher Treatment-Emergent Adverse Events by System Organ Class, Preferred Term, and Severity
Induction Study: Cohort A
Safety Analysis Set

System Organ Class Preferred Term Severity	Filgotinib 200 mg (N=245)	Filgotinib 100 mg (N=277)	Placebo (N=137)
Number(%) of Subjects with Any Grade 3 or Higher Treatment-Emergent Adverse Events	5 (2.0%)	22 (7.9%)	11 (8.0%)
Gastrointestinal disorders (cont)			
Abdominal pain	0	1 (0.4%)	0
Grade 3	0	1 (0.4%)	0
Colon dysplasia	1 (0.4%)	0	0
Grade 3	1 (0.4%)	0	0
Gastrointestinal haemorrhage	1 (0.4%)	0	0
Grade 3	1 (0.4%)	0	0
Large intestine polyp	0	1 (0.4%)	0
Grade 3	0	1 (0.4%)	0
Rectal polyp	0	1 (0.4%)	0
Grade 3	0	1 (0.4%)	0
Vomiting	0	1 (0.4%)	0
Grade 3	0	1 (0.4%)	0

Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Induction first dose date up to one day before the Maintenance first dose date or 30 days after the Induction last dose date whichever is earlier, or led to premature discontinuation of Induction study drug.
Severity grades were defined by the CTCAE Version 4.03. 1 = Mild; 2 = Moderate; 3 = Severe; 4 = Life-Threatening; 5 = Death. Multiple AEs were counted only once per subject for the highest severity grade for each SOC and PT.
System organ classes were presented alphabetically, and preferred terms were presented by descending order of the total frequencies.
Source: Listing 16.2.7.4.1

Data Extracted: 05MAY2020
Source: .../final/version1/prog/t-teae-g.sas v9.4 Output file: t-teae-g-g34-a.pdf 28MAY2020:14:28 Page 3 of 9

Gilead Sciences, Inc.
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Table 15.11.2.2.1.1.1: Grade 3 or Higher Treatment-Emergent Adverse Events by System Organ Class, Preferred Term, and Severity
Induction Study: Cohort A
Safety Analysis Set

System Organ Class Preferred Term Severity	Filgotinib 200 mg (N=245)	Filgotinib 100 mg (N=277)	Placebo (N=137)
Number(%) of Subjects with Any Grade 3 or Higher Treatment-Emergent Adverse Events	5 (2.0%)	22 (7.9%)	11 (8.0%)
General disorders and administration site conditions	0	0	1 (0.7%)
Grade 3	0	0	1 (0.7%)
Pyrexia	0	0	1 (0.7%)
Grade 3	0	0	1 (0.7%)
Hepatobiliary disorders	0	1 (0.4%)	0
Grade 3	0	1 (0.4%)	0
Hyperbilirubinaemia	0	1 (0.4%)	0
Grade 3	0	1 (0.4%)	0
Immune system disorders	0	1 (0.4%)	0
Grade 3	0	1 (0.4%)	0
Type I hypersensitivity	0	1 (0.4%)	0
Grade 3	0	1 (0.4%)	0

Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Induction first dose date up to one day before the Maintenance first dose date or 30 days after the Induction last dose date whichever is earlier, or led to premature discontinuation of Induction study drug.
Severity grades were defined by the CTCAE Version 4.03. 1 = Mild; 2 = Moderate; 3 = Severe; 4 = Life-Threatening; 5 = Death. Multiple AEs were counted only once per subject for the highest severity grade for each SOC and PT.
System organ classes were presented alphabetically, and preferred terms were presented by descending order of the total frequencies.
Source: Listing 16.2.7.4.1

Data Extracted: 05MAY2020
Source: .../final/version1/prog/t-teae-g.sas v9.4 Output file: t-teae-g-g34-a.pdf 28MAY2020:14:28 Page 4 of 9

Gilead Sciences, Inc.
Study GS-US-418-3898

Table 15.11.2.2.1.1.1: Grade 3 or Higher Treatment-Emergent Adverse Events by System Organ Class, Preferred Term, and Severity
Induction Study: Cohort A
Safety Analysis Set

System Organ Class Preferred Term Severity	Filgotinib 200 mg (N=245)	Filgotinib 100 mg (N=277)	Placebo (N=137)
Number(%) of Subjects with Any Grade 3 or Higher Treatment-Emergent Adverse Events	5 (2.0%)	22 (7.9%)	11 (8.0%)
Infections and infestations	0	2 (0.7%)	1 (0.7%)
Grade 3	0	1 (0.4%)	1 (0.7%)
Grade 4	0	1 (0.4%)	0
Appendicitis	0	1 (0.4%)	0
Grade 3	0	1 (0.4%)	0
Cellulitis	0	0	1 (0.7%)
Grade 3	0	0	1 (0.7%)
Gastroenteritis	0	1 (0.4%)	0
Grade 4	0	1 (0.4%)	0
Osteomyelitis	0	0	1 (0.7%)
Grade 3	0	0	1 (0.7%)
Injury, poisoning and procedural complications	0	1 (0.4%)	1 (0.7%)
Grade 3	0	1 (0.4%)	1 (0.7%)

Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Induction first dose date up to one day before the Maintenance first dose date or 30 days after the Induction last dose date whichever is earlier, or led to premature discontinuation of Induction study drug.
Severity grades were defined by the CTCAE Version 4.03. 1 = Mild; 2 = Moderate; 3 = Severe; 4 = Life-Threatening; 5 = Death. Multiple AEs were counted only once per subject for the highest severity grade for each SOC and PT.
System organ classes were presented alphabetically, and preferred terms were presented by descending order of the total frequencies.
Source: Listing 16.2.7.4.1

Data Extracted: 05MAY2020
Source: .../final/version1/prog/t-teae-g.sas v9.4 Output file: t-teae-g-g34-a.pdf 28MAY2020:14:28 Page 5 of 9

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Table 15.11.2.2.1.1.1: Grade 3 or Higher Treatment-Emergent Adverse Events by System Organ Class, Preferred Term, and Severity
Induction Study: Cohort A
Safety Analysis Set

System Organ Class Preferred Term Severity	Filgotinib 200 mg (N=245)	Filgotinib 100 mg (N=277)	Placebo (N=137)
Number(%) of Subjects with Any Grade 3 or Higher Treatment-Emergent Adverse Events	5 (2.0%)	22 (7.9%)	11 (8.0%)
Injury, poisoning and procedural complications (cont)			
Procedural intestinal perforation	0	0	1 (0.7%)
Grade 3	0	0	1 (0.7%)
Road traffic accident	0	1 (0.4%)	0
Grade 3	0	1 (0.4%)	0
Investigations	0	3 (1.1%)	4 (2.9%)
Grade 3	0	3 (1.1%)	4 (2.9%)
Blood phosphorus decreased	0	2 (0.7%)	0
Grade 3	0	2 (0.7%)	0
Neutrophil count decreased	0	0	2 (1.5%)
Grade 3	0	0	2 (1.5%)
Blood pressure increased	0	0	1 (0.7%)
Grade 3	0	0	1 (0.7%)

Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Induction first dose date up to one day before the Maintenance first dose date or 30 days after the Induction last dose date whichever is earlier, or led to premature discontinuation of Induction study drug.
Severity grades were defined by the CTCAE Version 4.03. 1 = Mild; 2 = Moderate; 3 = Severe; 4 = Life-Threatening; 5 = Death. Multiple AEs were counted only once per subject for the highest severity grade for each SOC and PT.
System organ classes were presented alphabetically, and preferred terms were presented by descending order of the total frequencies.
Source: Listing 16.2.7.4.1

Data Extracted: 05MAY2020
Source: .../final/version1/prog/t-teae-g.sas v9.4 Output file: t-teae-g-g34-a.pdf 28MAY2020:14:28 Page 6 of 9

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Table 15.11.2.2.1.1.1: Grade 3 or Higher Treatment-Emergent Adverse Events by System Organ Class, Preferred Term, and Severity
Induction Study: Cohort A
Safety Analysis Set

System Organ Class Preferred Term Severity	Filgotinib 200 mg (N=245)	Filgotinib 100 mg (N=277)	Placebo (N=137)
Number(%) of Subjects with Any Grade 3 or Higher Treatment-Emergent Adverse Events	5 (2.0%)	22 (7.9%)	11 (8.0%)
Investigations (cont)			
Haemoglobin abnormal	0	0	1 (0.7%)
Grade 3	0	0	1 (0.7%)
Haemoglobin decreased	0	1 (0.4%)	0
Grade 3	0	1 (0.4%)	0
Metabolism and nutrition disorders	0	1 (0.4%)	1 (0.7%)
Grade 3	0	1 (0.4%)	1 (0.7%)
Hyperglycaemia	0	0	1 (0.7%)
Grade 3	0	0	1 (0.7%)
Hypertriglyceridaemia	0	1 (0.4%)	0
Grade 3	0	1 (0.4%)	0
Renal and urinary disorders	0	1 (0.4%)	0
Grade 3	0	1 (0.4%)	0

Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Induction first dose date up to one day before the Maintenance first dose date or 30 days after the Induction last dose date whichever is earlier, or led to premature discontinuation of Induction study drug.
Severity grades were defined by the CTCAE Version 4.03. 1 = Mild; 2 = Moderate; 3 = Severe; 4 = Life-Threatening; 5 = Death. Multiple AEs were counted only once per subject for the highest severity grade for each SOC and PT.
System organ classes were presented alphabetically, and preferred terms were presented by descending order of the total frequencies.
Source: Listing 16.2.7.4.1

Data Extracted: 05MAY2020
Source: .../final/version1/prog/t-teae-g.sas v9.4 Output file: t-teae-g-g34-a.pdf 28MAY2020:14:28 Page 7 of 9

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Table 15.11.2.2.1.1.1: Grade 3 or Higher Treatment-Emergent Adverse Events by System Organ Class, Preferred Term, and Severity
Induction Study: Cohort A
Safety Analysis Set

System Organ Class Preferred Term Severity	Filgotinib 200 mg (N=245)	Filgotinib 100 mg (N=277)	Placebo (N=137)
Number(%) of Subjects with Any Grade 3 or Higher Treatment-Emergent Adverse Events	5 (2.0%)	22 (7.9%)	11 (8.0%)
Renal and urinary disorders (cont)			
Proteinuria	0	1 (0.4%)	0
Grade 3	0	1 (0.4%)	0
Reproductive system and breast disorders	0	1 (0.4%)	0
Grade 3	0	1 (0.4%)	0
Ovarian cyst ruptured	0	1 (0.4%)	0
Grade 3	0	1 (0.4%)	0
Skin and subcutaneous tissue disorders	0	0	1 (0.7%)
Grade 3	0	0	1 (0.7%)
Purpura	0	0	1 (0.7%)
Grade 3	0	0	1 (0.7%)
Vascular disorders	0	1 (0.4%)	0
Grade 3	0	1 (0.4%)	0

Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Induction first dose date up to one day before the Maintenance first dose date or 30 days after the Induction last dose date whichever is earlier, or led to premature discontinuation of Induction study drug.
Severity grades were defined by the CTCAE Version 4.03. 1 = Mild; 2 = Moderate; 3 = Severe; 4 = Life-Threatening; 5 = Death. Multiple AEs were counted only once per subject for the highest severity grade for each SOC and PT.
System organ classes were presented alphabetically, and preferred terms were presented by descending order of the total frequencies.
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Data Extracted: 05MAY2020
Source: .../final/version1/prog/t-teae-g.sas v9.4 Output file: t-teae-g-g34-a.pdf 28MAY2020:14:28 Page 8 of 9

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Table 15.11.2.2.1.1.1: Grade 3 or Higher Treatment-Emergent Adverse Events by System Organ Class, Preferred Term, and Severity
Induction Study: Cohort A
Safety Analysis Set

System Organ Class Preferred Term Severity	Filgotinib 200 mg (N=245)	Filgotinib 100 mg (N=277)	Placebo (N=137)
Number(%) of Subjects with Any Grade 3 or Higher Treatment-Emergent Adverse Events	5 (2.0%)	22 (7.9%)	11 (8.0%)
Vascular disorders (cont)			
Hypertension	0	1 (0.4%)	0
Grade 3	0	1 (0.4%)	0

Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Induction first dose date up to one day before the Maintenance first dose date or 30 days after the Induction last dose date whichever is earlier, or led to premature discontinuation of Induction study drug.
Severity grades were defined by the CTCAE Version 4.03. 1 = Mild; 2 = Moderate; 3 = Severe; 4 = Life-Threatening; 5 = Death. Multiple AEs were counted only once per subject for the highest severity grade for each SOC and PT.
System organ classes were presented alphabetically, and preferred terms were presented by descending order of the total frequencies.
Source: Listing 16.2.7.4.1

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Tabelle 4-8 (Anhang): Ergebnisse für schwere UE nach SOC und PT aus RCT mit dem zu bewertenden Arzneimittel (SELECTION, Induktionsphase: Kohorte B)

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Table 15.11.2.2.1.1.2: Grade 3 or Higher Treatment-Emergent Adverse Events by System Organ Class, Preferred Term, and Severity
Induction Study: Cohort B
Safety Analysis Set

System Organ Class Preferred Term Severity	Filgotinib 200 mg (N=262)	Filgotinib 100 mg (N=285)	Placebo (N=142)
Number(%) of Subjects with Any Grade 3 or Higher Treatment-Emergent Adverse Events	30 (11.5%)	26 (9.1%)	20 (14.1%)
Grade 3	29 (11.1%)	22 (7.7%)	19 (13.4%)
Grade 4	1 (0.4%)	4 (1.4%)	1 (0.7%)
Grade 5	0	0	0
Blood and lymphatic system disorders	4 (1.5%)	2 (0.7%)	4 (2.8%)
Grade 3	4 (1.5%)	2 (0.7%)	4 (2.8%)
Anaemia	1 (0.4%)	1 (0.4%)	2 (1.4%)
Grade 3	1 (0.4%)	1 (0.4%)	2 (1.4%)
Iron deficiency anaemia	2 (0.8%)	0	1 (0.7%)
Grade 3	2 (0.8%)	0	1 (0.7%)
Lymphopenia	1 (0.4%)	0	1 (0.7%)
Grade 3	1 (0.4%)	0	1 (0.7%)
Neutropenia	0	1 (0.4%)	0
Grade 3	0	1 (0.4%)	0

Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Induction first dose date up to one day before the Maintenance first dose date or 30 days after the Induction last dose date whichever is earlier, or led to premature discontinuation of Induction study drug.
Severity grades were defined by the CTCAE Version 4.03. 1 = Mild; 2 = Moderate; 3 = Severe; 4 = Life-Threatening; 5 = Death. Multiple AEs were counted only once per subject for the highest severity grade for each SOC and PT.
System organ classes were presented alphabetically, and preferred terms were presented by descending order of the total frequencies.
Source: Listing 16.2.7.4.1

Data Extracted: 05MAY2020
Source: .../final/version1/prog/t-teae-g.sas v9.4 Output file: t-teae-g-g34-b.pdf 28MAY2020:14:28 Page 1 of 10

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Table 15.11.2.2.1.1.2: Grade 3 or Higher Treatment-Emergent Adverse Events by System Organ Class, Preferred Term, and Severity
Induction Study: Cohort B
Safety Analysis Set

System Organ Class Preferred Term Severity	Filgotinib 200 mg (N=262)	Filgotinib 100 mg (N=285)	Placebo (N=142)
Number(%) of Subjects with Any Grade 3 or Higher Treatment-Emergent Adverse Events	30 (11.5%)	26 (9.1%)	20 (14.1%)
Gastrointestinal disorders	12 (4.6%)	8 (2.8%)	8 (5.6%)
Grade 3	12 (4.6%)	8 (2.8%)	8 (5.6%)
Colitis ulcerative	8 (3.1%)	7 (2.5%)	6 (4.2%)
Grade 3	8 (3.1%)	7 (2.5%)	6 (4.2%)
Abdominal pain	1 (0.4%)	0	0
Grade 3	1 (0.4%)	0	0
Anal fissure	1 (0.4%)	0	0
Grade 3	1 (0.4%)	0	0
Appendiceal mucocoele	1 (0.4%)	0	0
Grade 3	1 (0.4%)	0	0
Colitis	0	0	1 (0.7%)
Grade 3	0	0	1 (0.7%)
Duodenal ulcer	1 (0.4%)	0	0
Grade 3	1 (0.4%)	0	0

Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Induction first dose date up to one day before the Maintenance first dose date or 30 days after the Induction last dose date whichever is earlier, or led to premature discontinuation of Induction study drug.
Severity grades were defined by the CTCAE Version 4.03. 1 = Mild; 2 = Moderate; 3 = Severe; 4 = Life-Threatening; 5 = Death. Multiple AEs were counted only once per subject for the highest severity grade for each SOC and PT.
System organ classes were presented alphabetically, and preferred terms were presented by descending order of the total frequencies.
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Table 15.11.2.2.1.1.2: Grade 3 or Higher Treatment-Emergent Adverse Events by System Organ Class, Preferred Term, and Severity
Induction Study: Cohort B
Safety Analysis Set

System Organ Class Preferred Term Severity	Filgotinib 200 mg (N=262)	Filgotinib 100 mg (N=285)	Placebo (N=142)
Number(%) of Subjects with Any Grade 3 or Higher Treatment-Emergent Adverse Events	30 (11.5%)	26 (9.1%)	20 (14.1%)
Gastrointestinal disorders (cont)			
Duodenal ulcer haemorrhage	1 (0.4%)	0	0
Grade 3	1 (0.4%)	0	0
Large intestinal haemorrhage	1 (0.4%)	0	0
Grade 3	1 (0.4%)	0	0
Nausea	0	1 (0.4%)	0
Grade 3	0	1 (0.4%)	0
Pancreatitis acute	0	0	1 (0.7%)
Grade 3	0	0	1 (0.7%)
Vomiting	0	1 (0.4%)	0
Grade 3	0	1 (0.4%)	0
Infections and infestations	2 (0.8%)	4 (1.4%)	2 (1.4%)
Grade 3	2 (0.8%)	1 (0.4%)	2 (1.4%)
Grade 4	0	3 (1.1%)	0

Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Induction first dose date up to one day before the Maintenance first dose date or 30 days after the Induction last dose date whichever is earlier, or led to premature discontinuation of Induction study drug.
Severity grades were defined by the CTCAE Version 4.03. 1 = Mild; 2 = Moderate; 3 = Severe; 4 = Life-Threatening; 5 = Death. Multiple AEs were counted only once per subject for the highest severity grade for each SOC and PT.
System organ classes were presented alphabetically, and preferred terms were presented by descending order of the total frequencies.
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Table 15.11.2.2.1.1.2: Grade 3 or Higher Treatment-Emergent Adverse Events by System Organ Class, Preferred Term, and Severity
Induction Study: Cohort B
Safety Analysis Set

System Organ Class Preferred Term Severity	Filgotinib 200 mg (N=262)	Filgotinib 100 mg (N=285)	Placebo (N=142)
Number(%) of Subjects with Any Grade 3 or Higher Treatment-Emergent Adverse Events	30 (11.5%)	26 (9.1%)	20 (14.1%)
Infections and infestations (cont)			
Gastroenteritis viral	1 (0.4%)	0	1 (0.7%)
Grade 3	1 (0.4%)	0	1 (0.7%)
Sepsis	0	2 (0.7%)	0
Grade 4	0	2 (0.7%)	0
Anal abscess	0	1 (0.4%)	0
Grade 3	0	1 (0.4%)	0
Campylobacter gastroenteritis	0	0	1 (0.7%)
Grade 3	0	0	1 (0.7%)
Clostridium difficile infection	1 (0.4%)	0	0
Grade 3	1 (0.4%)	0	0
Staphylococcal infection	0	1 (0.4%)	0
Grade 4	0	1 (0.4%)	0

Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Induction first dose date up to one day before the Maintenance first dose date or 30 days after the Induction last dose date whichever is earlier, or led to premature discontinuation of Induction study drug.
Severity grades were defined by the CTCAE Version 4.03. 1 = Mild; 2 = Moderate; 3 = Severe; 4 = Life-Threatening; 5 = Death. Multiple AEs were counted only once per subject for the highest severity grade for each SOC and PT.
System organ classes were presented alphabetically, and preferred terms were presented by descending order of the total frequencies.
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Table 15.11.2.2.1.1.2: Grade 3 or Higher Treatment-Emergent Adverse Events by System Organ Class, Preferred Term, and Severity
Induction Study: Cohort B
Safety Analysis Set

System Organ Class Preferred Term Severity	Filgotinib 200 mg (N=262)	Filgotinib 100 mg (N=285)	Placebo (N=142)
Number(%) of Subjects with Any Grade 3 or Higher Treatment-Emergent Adverse Events	30 (11.5%)	26 (9.1%)	20 (14.1%)
Injury, poisoning and procedural complications	0	1 (0.4%)	0
Grade 3	0	1 (0.4%)	0
Femur fracture	0	1 (0.4%)	0
Grade 3	0	1 (0.4%)	0
Investigations	8 (3.1%)	3 (1.1%)	0
Grade 3	7 (2.7%)	3 (1.1%)	0
Grade 4	1 (0.4%)	0	0
Blood phosphorus decreased	3 (1.1%)	2 (0.7%)	0
Grade 3	3 (1.1%)	2 (0.7%)	0
Haemoglobin decreased	2 (0.8%)	0	0
Grade 3	2 (0.8%)	0	0
Blood creatine phosphokinase increased	1 (0.4%)	0	0
Grade 4	1 (0.4%)	0	0

Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Induction first dose date up to one day before the Maintenance first dose date or 30 days after the Induction last dose date whichever is earlier, or led to premature discontinuation of Induction study drug.
Severity grades were defined by the CTCAE Version 4.03. 1 = Mild; 2 = Moderate; 3 = Severe; 4 = Life-Threatening; 5 = Death. Multiple AEs were counted only once per subject for the highest severity grade for each SOC and PT.
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Table 15.11.2.2.1.1.2: Grade 3 or Higher Treatment-Emergent Adverse Events by System Organ Class, Preferred Term, and Severity
Induction Study: Cohort B
Safety Analysis Set

System Organ Class Preferred Term Severity	Filgotinib 200 mg (N=262)	Filgotinib 100 mg (N=285)	Placebo (N=142)
Number(%) of Subjects with Any Grade 3 or Higher Treatment-Emergent Adverse Events	30 (11.5%)	26 (9.1%)	20 (14.1%)
Investigations (cont)			
Blood glucose increased	0	1 (0.4%)	0
Grade 3	0	1 (0.4%)	0
Platelet count increased	1 (0.4%)	0	0
Grade 3	1 (0.4%)	0	0
Transaminases increased	1 (0.4%)	0	0
Grade 3	1 (0.4%)	0	0
Metabolism and nutrition disorders	4 (1.5%)	6 (2.1%)	5 (3.5%)
Grade 3	4 (1.5%)	6 (2.1%)	5 (3.5%)
Hypophosphataemia	3 (1.1%)	6 (2.1%)	4 (2.8%)
Grade 3	3 (1.1%)	6 (2.1%)	4 (2.8%)
Diabetes mellitus	1 (0.4%)	0	0
Grade 3	1 (0.4%)	0	0

Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Induction first dose date up to one day before the Maintenance first dose date or 30 days after the Induction last dose date whichever is earlier, or led to premature discontinuation of Induction study drug.
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Table 15.11.2.2.1.1.2: Grade 3 or Higher Treatment-Emergent Adverse Events by System Organ Class, Preferred Term, and Severity
Induction Study: Cohort B
Safety Analysis Set

System Organ Class Preferred Term Severity	Filgotinib 200 mg (N=262)	Filgotinib 100 mg (N=285)	Placebo (N=142)
Number(%) of Subjects with Any Grade 3 or Higher Treatment-Emergent Adverse Events	30 (11.5%)	26 (9.1%)	20 (14.1%)
Metabolism and nutrition disorders (cont)			
Hyperglycaemia	0	0	1 (0.7%)
Grade 3	0	0	1 (0.7%)
Musculoskeletal and connective tissue disorders	2 (0.8%)	1 (0.4%)	0
Grade 3	2 (0.8%)	1 (0.4%)	0
Intervertebral disc protrusion	2 (0.8%)	0	0
Grade 3	2 (0.8%)	0	0
Back pain	1 (0.4%)	0	0
Grade 3	1 (0.4%)	0	0
Myalgia	0	1 (0.4%)	0
Grade 3	0	1 (0.4%)	0
Nervous system disorders	0	1 (0.4%)	1 (0.7%)
Grade 3	0	1 (0.4%)	0
Grade 4	0	0	1 (0.7%)

Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Induction first dose date up to one day before the Maintenance first dose date or 30 days after the Induction last dose date whichever is earlier, or led to premature discontinuation of Induction study drug.
Severity grades were defined by the CTCAE Version 4.03. 1 = Mild; 2 = Moderate; 3 = Severe; 4 = Life-Threatening; 5 = Death. Multiple AEs were counted only once per subject for the highest severity grade for each SOC and PT.
System organ classes were presented alphabetically, and preferred terms were presented by descending order of the total frequencies.
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Table 15.11.2.2.1.1.2: Grade 3 or Higher Treatment-Emergent Adverse Events by System Organ Class, Preferred Term, and Severity
Induction Study: Cohort B
Safety Analysis Set

System Organ Class Preferred Term Severity	Filgotinib 200 mg (N=262)	Filgotinib 100 mg (N=285)	Placebo (N=142)
Number(%) of Subjects with Any Grade 3 or Higher Treatment-Emergent Adverse Events	30 (11.5%)	26 (9.1%)	20 (14.1%)
Nervous system disorders (cont)			
Cerebrovascular accident	0	0	1 (0.7%)
Grade 4	0	0	1 (0.7%)
Headache	0	1 (0.4%)	0
Grade 3	0	1 (0.4%)	0
Pregnancy, puerperium and perinatal conditions	0	1 (0.4%)	0
Grade 4	0	1 (0.4%)	0
Ectopic pregnancy	0	1 (0.4%)	0
Grade 4	0	1 (0.4%)	0
Psychiatric disorders	1 (0.4%)	0	0
Grade 3	1 (0.4%)	0	0
Insomnia	1 (0.4%)	0	0
Grade 3	1 (0.4%)	0	0

Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Induction first dose date up to one day before the Maintenance first dose date or 30 days after the Induction last dose date whichever is earlier, or led to premature discontinuation of Induction study drug.
Severity grades were defined by the CTCAE Version 4.03. 1 = Mild; 2 = Moderate; 3 = Severe; 4 = Life-Threatening; 5 = Death. Multiple AEs were counted only once per subject for the highest severity grade for each SOC and PT.
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Induction Study: Cohort B
Safety Analysis Set

System Organ Class Preferred Term Severity	Filgotinib 200 mg (N=262)	Filgotinib 100 mg (N=285)	Placebo (N=142)
Number(%) of Subjects with Any Grade 3 or Higher Treatment-Emergent Adverse Events	30 (11.5%)	26 (9.1%)	20 (14.1%)
Renal and urinary disorders	0	0	1 (0.7%)
Grade 3	0	0	1 (0.7%)
Renal colic	0	0	1 (0.7%)
Grade 3	0	0	1 (0.7%)
Reproductive system and breast disorders	0	1 (0.4%)	0
Grade 3	0	1 (0.4%)	0
Rectocele	0	1 (0.4%)	0
Grade 3	0	1 (0.4%)	0
Respiratory, thoracic and mediastinal disorders	1 (0.4%)	0	1 (0.7%)
Grade 3	1 (0.4%)	0	1 (0.7%)
Haemoptysis	0	0	1 (0.7%)
Grade 3	0	0	1 (0.7%)
Pulmonary embolism	1 (0.4%)	0	0
Grade 3	1 (0.4%)	0	0

Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Induction first dose date up to one day before the Maintenance first dose date or 30 days after the Induction last dose date whichever is earlier, or led to premature discontinuation of Induction study drug.
Severity grades were defined by the CTCAE Version 4.03. 1 = Mild; 2 = Moderate; 3 = Severe; 4 = Life-Threatening; 5 = Death. Multiple AEs were counted only once per subject for the highest severity grade for each SOC and PT.
System organ classes were presented alphabetically, and preferred terms were presented by descending order of the total frequencies.
Source: Listing 16.2.7.4.1

Data Extracted: 05MAY2020
Source: .../final/version1/prog/t-teae-g.sas v9.4 Output file: t-teae-g-g34-b.pdf 28MAY2020:14:28 Page 9 of 10

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Table 15.11.2.2.1.1.2: Grade 3 or Higher Treatment-Emergent Adverse Events by System Organ Class, Preferred Term, and Severity
Induction Study: Cohort B
Safety Analysis Set

System Organ Class Preferred Term Severity	Filgotinib 200 mg (N=262)	Filgotinib 100 mg (N=285)	Placebo (N=142)
Number(%) of Subjects with Any Grade 3 or Higher Treatment-Emergent Adverse Events	30 (11.5%)	26 (9.1%)	20 (14.1%)
Vascular disorders	1 (0.4%)	0	0
Grade 3	1 (0.4%)	0	0
Hypertension	1 (0.4%)	0	0
Grade 3	1 (0.4%)	0	0

Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Induction first dose date up to one day before the Maintenance first dose date or 30 days after the Induction last dose date whichever is earlier, or led to premature discontinuation of Induction study drug.
Severity grades were defined by the CTCAE Version 4.03. 1 = Mild; 2 = Moderate; 3 = Severe; 4 = Life-Threatening; 5 = Death. Multiple AEs were counted only once per subject for the highest severity grade for each SOC and PT.
System organ classes were presented alphabetically, and preferred terms were presented by descending order of the total frequencies.
Source: Listing 16.2.7.4.1

Data Extracted: 05MAY2020
Source: .../final/version1/prog/t-teae-g.sas v9.4 Output file: t-teae-g-g34-b.pdf 28MAY2020:14:28 Page 10 of 10

Tabelle 4-9 (Anhang): Ergebnisse für schwere UE nach SOC und PT aus RCT mit dem zu bewertenden Arzneimittel (SELECTION, Erhaltungsphase)

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Table 15.11.2.2.1.1.4: Grade 3 or Higher Treatment-Emergent Adverse Events by System Organ Class, Preferred Term, and Severity
Maintenance Study
Safety Analysis Set

System Organ Class Preferred Term Severity	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number(%) of Subjects with Any Grade 3 or Higher Treatment-Emergent Adverse Events	16 (7.9%)	7 (7.1%)	11 (6.1%)	10 (11.0%)	9 (9.7%)
Grade 3	14 (6.9%)	7 (7.1%)	10 (5.6%)	7 (7.7%)	7 (7.5%)
Grade 4	0	0	1 (0.6%)	3 (3.3%)	2 (2.2%)
Grade 5	2 (1.0%)	0	0	0	0
Blood and lymphatic system disorders	0	2 (2.0%)	2 (1.1%)	1 (1.1%)	0
Grade 3	0	2 (2.0%)	2 (1.1%)	1 (1.1%)	0
Anaemia	0	0	1 (0.6%)	0	0
Grade 3	0	0	1 (0.6%)	0	0
Iron deficiency anaemia	0	0	0	1 (1.1%)	0
Grade 3	0	0	0	1 (1.1%)	0
Lymphopenia	0	1 (1.0%)	0	0	0
Grade 3	0	1 (1.0%)	0	0	0

Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Maintenance first dose date up to 30 days after Maintenance last dose date, or led to premature discontinuation of Maintenance study drug.
Severity grades were defined by the CTCAE Version 4.03. 1 = Mild; 2 = Moderate; 3 = Severe; 4 = Life-Threatening; 5 = Death. Multiple AEs were counted only once per subject for the highest severity grade for each SOC and PT.
System organ classes were presented alphabetically, and preferred terms were presented by descending order of the total frequencies.
Source: Listing 16.2.7.4.1

Data Extracted: 05MAY2020
Source: .../final/version1/prog/t-teae-g-m.sas v9.4 Output file: t-teae-g-m-g34-m.pdf 28MAY2020:14:28 Page 1 of 14

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Table 15.11.2.2.1.1.4: Grade 3 or Higher Treatment-Emergent Adverse Events by System Organ Class, Preferred Term, and Severity
Maintenance Study
Safety Analysis Set

System Organ Class Preferred Term Severity	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number(%) of Subjects with Any Grade 3 or Higher Treatment-Emergent Adverse Events	16 (7.9%)	7 (7.1%)	11 (6.1%)	10 (11.0%)	9 (9.7%)
Blood and lymphatic system disorders (cont)					
Microcytic anaemia	0	1 (1.0%)	0	0	0
Grade 3	0	1 (1.0%)	0	0	0
Neutropenia	0	0	1 (0.6%)	0	0
Grade 3	0	0	1 (0.6%)	0	0
Cardiac disorders	1 (0.5%)	0	0	1 (1.1%)	0
Grade 4	0	0	0	1 (1.1%)	0
Grade 5	1 (0.5%)	0	0	0	0
Arteriosclerosis coronary artery	1 (0.5%)	0	0	0	0
Grade 4	1 (0.5%)	0	0	0	0
Coronary artery stenosis	0	0	0	1 (1.1%)	0
Grade 4	0	0	0	1 (1.1%)	0

Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Maintenance first dose date up to 30 days after Maintenance last dose date, or led to premature discontinuation of Maintenance study drug.
Severity grades were defined by the CTCAE Version 4.03. 1 = Mild; 2 = Moderate; 3 = Severe; 4 = Life-Threatening; 5 = Death. Multiple AEs were counted only once per subject for the highest severity grade for each SOC and PT.
System organ classes were presented alphabetically, and preferred terms were presented by descending order of the total frequencies.
Source: Listing 16.2.7.4.1

Data Extracted: 05MAY2020
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Table 15.11.2.2.1.1.4: Grade 3 or Higher Treatment-Emergent Adverse Events by System Organ Class, Preferred Term, and Severity
Maintenance Study
Safety Analysis Set

System Organ Class Preferred Term Severity	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number(%) of Subjects with Any Grade 3 or Higher Treatment-Emergent Adverse Events	16 (7.9%)	7 (7.1%)	11 (6.1%)	10 (11.0%)	9 (9.7%)
Cardiac disorders (cont)					
Left ventricular failure	1 (0.5%)	0	0	0	0
Grade 5	1 (0.5%)	0	0	0	0
Eye disorders	1 (0.5%)	0	0	0	0
Grade 3	1 (0.5%)	0	0	0	0
Glaucoma	1 (0.5%)	0	0	0	0
Grade 3	1 (0.5%)	0	0	0	0
Gastrointestinal disorders	2 (1.0%)	2 (2.0%)	4 (2.2%)	3 (3.3%)	5 (5.4%)
Grade 3	2 (1.0%)	2 (2.0%)	3 (1.7%)	2 (2.2%)	4 (4.3%)
Grade 4	0	0	1 (0.6%)	1 (1.1%)	1 (1.1%)

Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Maintenance first dose date up to 30 days after Maintenance last dose date, or led to premature discontinuation of Maintenance study drug.
Severity grades were defined by the CTCAE Version 4.03. 1 = Mild; 2 = Moderate; 3 = Severe; 4 = Life-Threatening; 5 = Death. Multiple AEs were counted only once per subject for the highest severity grade for each SOC and PT.
System organ classes were presented alphabetically, and preferred terms were presented by descending order of the total frequencies.
Source: Listing 16.2.7.4.1

Data Extracted: 05MAY2020
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Table 15.11.2.2.1.1.4: Grade 3 or Higher Treatment-Emergent Adverse Events by System Organ Class, Preferred Term, and Severity
Maintenance Study
Safety Analysis Set

System Organ Class Preferred Term Severity	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number(%) of Subjects with Any Grade 3 or Higher Treatment-Emergent Adverse Events	16 (7.9%)	7 (7.1%)	11 (6.1%)	10 (11.0%)	9 (9.7%)
Gastrointestinal disorders (cont)					
Colitis ulcerative	2 (1.0%)	1 (1.0%)	3 (1.7%)	3 (3.3%)	3 (3.2%)
Grade 3	2 (1.0%)	1 (1.0%)	3 (1.7%)	2 (2.2%)	3 (3.2%)
Grade 4	0	0	0	1 (1.1%)	0
Dental cyst	0	0	0	0	1 (1.1%)
Grade 4	0	0	0	0	1 (1.1%)
Inguinal hernia	0	1 (1.0%)	0	0	0
Grade 3	0	1 (1.0%)	0	0	0
Nausea	0	0	0	0	1 (1.1%)
Grade 3	0	0	0	0	1 (1.1%)
Pancreatitis acute	0	0	1 (0.6%)	0	0
Grade 4	0	0	1 (0.6%)	0	0

Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Maintenance first dose date up to 30 days after Maintenance last dose date, or led to premature discontinuation of Maintenance study drug.
Severity grades were defined by the CTCAE Version 4.03. 1 = Mild; 2 = Moderate; 3 = Severe; 4 = Life-Threatening; 5 = Death. Multiple AEs were counted only once per subject for the highest severity grade for each SOC and PT.
System organ classes were presented alphabetically, and preferred terms were presented by descending order of the total frequencies.
Source: Listing 16.2.7.4.1

Data Extracted: 05MAY2020
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Table 15.11.2.2.1.1.4: Grade 3 or Higher Treatment-Emergent Adverse Events by System Organ Class, Preferred Term, and Severity
Maintenance Study
Safety Analysis Set

System Organ Class Preferred Term Severity	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number(%) of Subjects with Any Grade 3 or Higher Treatment-Emergent Adverse Events	16 (7.9%)	7 (7.1%)	11 (6.1%)	10 (11.0%)	9 (9.7%)
Gastrointestinal disorders (cont)					
Supernumerary teeth	0	0	0	0	1 (1.1%)
Grade 4	0	0	0	0	1 (1.1%)
General disorders and administration site conditions	1 (0.5%)	0	1 (0.6%)	0	0
Grade 3	1 (0.5%)	0	1 (0.6%)	0	0
Non-cardiac chest pain	0	0	1 (0.6%)	0	0
Grade 3	0	0	1 (0.6%)	0	0
Pyrexia	1 (0.5%)	0	0	0	0
Grade 3	1 (0.5%)	0	0	0	0
Hepatobiliary disorders	0	0	1 (0.6%)	1 (1.1%)	0
Grade 3	0	0	1 (0.6%)	1 (1.1%)	0

Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Maintenance first dose date up to 30 days after Maintenance last dose date, or led to premature discontinuation of Maintenance study drug.
Severity grades were defined by the CTCAE Version 4.03. 1 = Mild; 2 = Moderate; 3 = Severe; 4 = Life-Threatening; 5 = Death. Multiple AEs were counted only once per subject for the highest severity grade for each SOC and PT.
System organ classes were presented alphabetically, and preferred terms were presented by descending order of the total frequencies.
Source: Listing 16.2.7.4.1

Data Extracted: 05MAY2020
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Table 15.11.2.2.1.1.4: Grade 3 or Higher Treatment-Emergent Adverse Events by System Organ Class, Preferred Term, and Severity
Maintenance Study
Safety Analysis Set

System Organ Class Preferred Term Severity	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number(%) of Subjects with Any Grade 3 or Higher Treatment-Emergent Adverse Events	16 (7.9%)	7 (7.1%)	11 (6.1%)	10 (11.0%)	9 (9.7%)
Hepatobiliary disorders (cont)					
Autoimmune hepatitis	0	0	0	1 (1.1%)	0
Grade 3	0	0	0	1 (1.1%)	0
Cholelithiasis	0	0	1 (0.6%)	0	0
Grade 3	0	0	1 (0.6%)	0	0
Infections and infestations	1 (0.5%)	1 (1.0%)	3 (1.7%)	3 (3.3%)	1 (1.1%)
Grade 3	1 (0.5%)	1 (1.0%)	3 (1.7%)	2 (2.2%)	0
Grade 4	0	0	0	1 (1.1%)	1 (1.1%)
Appendicitis	0	0	2 (1.1%)	0	0
Grade 3	0	0	2 (1.1%)	0	0
Acute hepatitis B	0	0	0	1 (1.1%)	0
Grade 4	0	0	0	1 (1.1%)	0

Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Maintenance first dose date up to 30 days after Maintenance last dose date, or led to premature discontinuation of Maintenance study drug.
Severity grades were defined by the CTCAE Version 4.03. 1 = Mild; 2 = Moderate; 3 = Severe; 4 = Life-Threatening; 5 = Death. Multiple AEs were counted only once per subject for the highest severity grade for each SOC and PT.
System organ classes were presented alphabetically, and preferred terms were presented by descending order of the total frequencies.
Source: Listing 16.2.7.4.1

Data Extracted: 05MAY2020
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Table 15.11.2.2.1.1.4: Grade 3 or Higher Treatment-Emergent Adverse Events by System Organ Class, Preferred Term, and Severity
Maintenance Study
Safety Analysis Set

System Organ Class Preferred Term Severity	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number(%) of Subjects with Any Grade 3 or Higher Treatment-Emergent Adverse Events	16 (7.9%)	7 (7.1%)	11 (6.1%)	10 (11.0%)	9 (9.7%)
Infections and infestations (cont)					
Cellulitis	0	0	1 (0.6%)	0	0
Grade 3	0	0	1 (0.6%)	0	0
Clostridium difficile infection	1 (0.5%)	0	0	0	0
Grade 3	1 (0.5%)	0	0	0	0
Gastroenteritis	0	1 (1.0%)	0	0	0
Grade 3	0	1 (1.0%)	0	0	0
Gastroenteritis viral	0	0	0	1 (1.1%)	0
Grade 3	0	0	0	1 (1.1%)	0
Paronychia	0	0	1 (0.6%)	0	0
Grade 3	0	0	1 (0.6%)	0	0

Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Maintenance first dose date up to 30 days after Maintenance last dose date, or led to premature discontinuation of Maintenance study drug.
Severity grades were defined by the CTCAE Version 4.03. 1 = Mild; 2 = Moderate; 3 = Severe; 4 = Life-Threatening; 5 = Death. Multiple AEs were counted only once per subject for the highest severity grade for each SOC and PT.
System organ classes were presented alphabetically, and preferred terms were presented by descending order of the total frequencies.
Source: Listing 16.2.7.4.1

Data Extracted: 05MAY2020
Source: .../final/version1/prog/t-teae-g-m.sas v9.4 Output file: t-teae-g-m-g34-m.pdf 28MAY2020:14:28 Page 7 of 14

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Table 15.11.2.2.1.1.4: Grade 3 or Higher Treatment-Emergent Adverse Events by System Organ Class, Preferred Term, and Severity
Maintenance Study
Safety Analysis Set

System Organ Class Preferred Term Severity	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number(%) of Subjects with Any Grade 3 or Higher Treatment-Emergent Adverse Events	16 (7.9%)	7 (7.1%)	11 (6.1%)	10 (11.0%)	9 (9.7%)
Infections and infestations (cont)					
Pneumonia	0	0	0	0	1 (1.1%)
Grade 4	0	0	0	0	1 (1.1%)
Respiratory tract infection viral	0	0	0	1 (1.1%)	0
Grade 3	0	0	0	1 (1.1%)	0
Injury, poisoning and procedural complications	1 (0.5%)	0	0	1 (1.1%)	1 (1.1%)
Grade 3	1 (0.5%)	0	0	1 (1.1%)	1 (1.1%)
Limb injury	0	0	0	0	1 (1.1%)
Grade 3	0	0	0	0	1 (1.1%)
Meniscus injury	0	0	0	1 (1.1%)	0
Grade 3	0	0	0	1 (1.1%)	0

Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Maintenance first dose date up to 30 days after Maintenance last dose date, or led to premature discontinuation of Maintenance study drug.
Severity grades were defined by the CTCAE Version 4.03. 1 = Mild; 2 = Moderate; 3 = Severe; 4 = Life-Threatening; 5 = Death. Multiple AEs were counted only once per subject for the highest severity grade for each SOC and PT.
System organ classes were presented alphabetically, and preferred terms were presented by descending order of the total frequencies.
Source: Listing 16.2.7.4.1

Data Extracted: 05MAY2020
Source: .../final/version1/prog/t-teae-g-m.sas v9.4 Output file: t-teae-g-m-g34-m.pdf 28MAY2020:14:28 Page 8 of 14

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Table 15.11.2.2.1.1.4: Grade 3 or Higher Treatment-Emergent Adverse Events by System Organ Class, Preferred Term, and Severity
Maintenance Study
Safety Analysis Set

System Organ Class Preferred Term Severity	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number(%) of Subjects with Any Grade 3 or Higher Treatment-Emergent Adverse Events	16 (7.9%)	7 (7.1%)	11 (6.1%)	10 (11.0%)	9 (9.7%)
Injury, poisoning and procedural complications (cont)					
Tendon rupture	1 (0.5%)	0	0	0	0
Grade 3	1 (0.5%)	0	0	0	0
Investigations	5 (2.5%)	0	2 (1.1%)	0	0
Grade 3	5 (2.5%)	0	2 (1.1%)	0	0
Alanine aminotransferase increased	1 (0.5%)	0	1 (0.6%)	0	0
Grade 3	1 (0.5%)	0	1 (0.6%)	0	0
Aspartate aminotransferase increased	1 (0.5%)	0	0	0	0
Grade 3	1 (0.5%)	0	0	0	0
Blood cholesterol increased	1 (0.5%)	0	0	0	0
Grade 3	1 (0.5%)	0	0	0	0

Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Maintenance first dose date up to 30 days after Maintenance last dose date, or led to premature discontinuation of Maintenance study drug.
Severity grades were defined by the CTCAE Version 4.03. 1 = Mild; 2 = Moderate; 3 = Severe; 4 = Life-Threatening; 5 = Death. Multiple AEs were counted only once per subject for the highest severity grade for each SOC and PT.
System organ classes were presented alphabetically, and preferred terms were presented by descending order of the total frequencies.
Source: Listing 16.2.7.4.1

Data Extracted: 05MAY2020
Source: .../final/version1/prog/t-teae-g-m.sas v9.4 Output file: t-teae-g-m-g34-m.pdf 28MAY2020:14:28 Page 9 of 14

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Table 15.11.2.2.1.1.4: Grade 3 or Higher Treatment-Emergent Adverse Events by System Organ Class, Preferred Term, and Severity
Maintenance Study
Safety Analysis Set

System Organ Class Preferred Term Severity	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number(%) of Subjects with Any Grade 3 or Higher Treatment-Emergent Adverse Events	16 (7.9%)	7 (7.1%)	11 (6.1%)	10 (11.0%)	9 (9.7%)
Investigations (cont)					
Blood creatine phosphokinase increased	1 (0.5%)	0	0	0	0
Grade 3	1 (0.5%)	0	0	0	0
Blood phosphorus decreased	0	0	1 (0.6%)	0	0
Grade 3	0	0	1 (0.6%)	0	0
Haemoglobin decreased	1 (0.5%)	0	0	0	0
Grade 3	1 (0.5%)	0	0	0	0
Lymphocyte count decreased	1 (0.5%)	0	0	0	0
Grade 3	1 (0.5%)	0	0	0	0
White blood cell count decreased	1 (0.5%)	0	0	0	0
Grade 3	1 (0.5%)	0	0	0	0

Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Maintenance first dose date up to 30 days after Maintenance last dose date, or led to premature discontinuation of Maintenance study drug.
Severity grades were defined by the CTCAE Version 4.03. 1 = Mild; 2 = Moderate; 3 = Severe; 4 = Life-Threatening; 5 = Death. Multiple AEs were counted only once per subject for the highest severity grade for each SOC and PT.
System organ classes were presented alphabetically, and preferred terms were presented by descending order of the total frequencies.
Source: Listing 16.2.7.4.1

Data Extracted: 05MAY2020
Source: .../final/version1/prog/t-teae-g-m.sas v9.4 Output file: t-teae-g-m-g34-m.pdf 28MAY2020:14:28 Page 10 of 14

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Table 15.11.2.2.1.1.4: Grade 3 or Higher Treatment-Emergent Adverse Events by System Organ Class, Preferred Term, and Severity
Maintenance Study
Safety Analysis Set

System Organ Class Preferred Term Severity	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number(%) of Subjects with Any Grade 3 or Higher Treatment-Emergent Adverse Events	16 (7.9%)	7 (7.1%)	11 (6.1%)	10 (11.0%)	9 (9.7%)
Metabolism and nutrition disorders	0	2 (2.0%)	0	0	0
Grade 3	0	2 (2.0%)	0	0	0
Diabetes mellitus	0	1 (1.0%)	0	0	0
Grade 3	0	1 (1.0%)	0	0	0
Hypertriglyceridaemia	0	1 (1.0%)	0	0	0
Grade 3	0	1 (1.0%)	0	0	0
Musculoskeletal and connective tissue disorders	1 (0.5%)	0	0	0	0
Grade 3	1 (0.5%)	0	0	0	0
Pain in extremity	1 (0.5%)	0	0	0	0
Grade 3	1 (0.5%)	0	0	0	0

Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Maintenance first dose date up to 30 days after Maintenance last dose date, or led to premature discontinuation of Maintenance study drug.
Severity grades were defined by the CTCAE Version 4.03. 1 = Mild; 2 = Moderate; 3 = Severe; 4 = Life-Threatening; 5 = Death. Multiple AEs were counted only once per subject for the highest severity grade for each SOC and PT.
System organ classes were presented alphabetically, and preferred terms were presented by descending order of the total frequencies.
Source: Listing 16.2.7.4.1

Data Extracted: 05MAY2020
Source: .../final/version1/prog/t-teae-g-m.sas v9.4 Output file: t-teae-g-m-g34-m.pdf 28MAY2020:14:28 Page 11 of 14

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Table 15.11.2.2.1.1.4: Grade 3 or Higher Treatment-Emergent Adverse Events by System Organ Class, Preferred Term, and Severity
Maintenance Study
Safety Analysis Set

System Organ Class Preferred Term Severity	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number(%) of Subjects with Any Grade 3 or Higher Treatment-Emergent Adverse Events	16 (7.9%)	7 (7.1%)	11 (6.1%)	10 (11.0%)	9 (9.7%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.5%)	0	1 (0.6%)	0	0
Grade 3	1 (0.5%)	0	1 (0.6%)	0	0
Colon cancer	0	0	1 (0.6%)	0	0
Grade 3	0	0	1 (0.6%)	0	0
Malignant melanoma	1 (0.5%)	0	0	0	0
Grade 3	1 (0.5%)	0	0	0	0
Renal and urinary disorders	1 (0.5%)	0	0	0	1 (1.1%)
Grade 3	1 (0.5%)	0	0	0	1 (1.1%)
Acute kidney injury	0	0	0	0	1 (1.1%)
Grade 3	0	0	0	0	1 (1.1%)

Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Maintenance first dose date up to 30 days after Maintenance last dose date, or led to premature discontinuation of Maintenance study drug.
Severity grades were defined by the CTCAE Version 4.03. 1 = Mild; 2 = Moderate; 3 = Severe; 4 = Life-Threatening; 5 = Death. Multiple AEs were counted only once per subject for the highest severity grade for each SOC and PT.
System organ classes were presented alphabetically, and preferred terms were presented by descending order of the total frequencies.
Source: Listing 16.2.7.4.1

Data Extracted: 05MAY2020
Source: .../final/version1/prog/t-teae-g-m.sas v9.4 Output file: t-teae-g-m-g34-m.pdf 28MAY2020:14:28 Page 12 of 14

Gilead Sciences, Inc.
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Table 15.11.2.2.1.1.4: Grade 3 or Higher Treatment-Emergent Adverse Events by System Organ Class, Preferred Term, and Severity
Maintenance Study
Safety Analysis Set

System Organ Class Preferred Term Severity	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number(%) of Subjects with Any Grade 3 or Higher Treatment-Emergent Adverse Events	16 (7.9%)	7 (7.1%)	11 (6.1%)	10 (11.0%)	9 (9.7%)
Renal and urinary disorders (cont)					
Calculus urinary	1 (0.5%)	0	0	0	0
Grade 3	1 (0.5%)	0	0	0	0
Respiratory, thoracic and mediastinal disorders	1 (0.5%)	0	1 (0.6%)	0	0
Grade 3	0	0	1 (0.6%)	0	0
Grade 5	1 (0.5%)	0	0	0	0
Asthma	1 (0.5%)	0	0	0	0
Grade 5	1 (0.5%)	0	0	0	0
Atelectasis	0	0	1 (0.6%)	0	0
Grade 3	0	0	1 (0.6%)	0	0
Dyspnoea	0	0	1 (0.6%)	0	0
Grade 3	0	0	1 (0.6%)	0	0

Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Maintenance first dose date up to 30 days after Maintenance last dose date, or led to premature discontinuation of Maintenance study drug.
Severity grades were defined by the CTCAE Version 4.03. 1 = Mild; 2 = Moderate; 3 = Severe; 4 = Life-Threatening; 5 = Death. Multiple AEs were counted only once per subject for the highest severity grade for each SOC and PT.
System organ classes were presented alphabetically, and preferred terms were presented by descending order of the total frequencies.
Source: Listing 16.2.7.4.1

Data Extracted: 05MAY2020
Source: .../final/version1/prog/t-teae-g-m.sas v9.4 Output file: t-teae-g-m-g34-m.pdf 28MAY2020:14:28 Page 13 of 14

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Table 15.11.2.2.1.1.4: Grade 3 or Higher Treatment-Emergent Adverse Events by System Organ Class, Preferred Term, and Severity
Maintenance Study
Safety Analysis Set

System Organ Class Preferred Term Severity	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number(%) of Subjects with Any Grade 3 or Higher Treatment-Emergent Adverse Events	16 (7.9%)	7 (7.1%)	11 (6.1%)	10 (11.0%)	9 (9.7%)
Vascular disorders	1 (0.5%)	0	0	0	2 (2.2%)
Grade 3	1 (0.5%)	0	0	0	1 (1.1%)
Grade 4	0	0	0	0	1 (1.1%)
Deep vein thrombosis	0	0	0	0	1 (1.1%)
Grade 3	0	0	0	0	1 (1.1%)
Haemorrhagic infarction	0	0	0	0	1 (1.1%)
Grade 4	0	0	0	0	1 (1.1%)
Hypertension	1 (0.5%)	0	0	0	0
Grade 3	1 (0.5%)	0	0	0	0

Adverse events were coded according to MedDRA Version 22.1.
TEAEs are defined as any AEs that began on or after the Maintenance first dose date up to 30 days after Maintenance last dose date, or led to premature discontinuation of Maintenance study drug.
Severity grades were defined by the CTCAE Version 4.03. 1 = Mild; 2 = Moderate; 3 = Severe; 4 = Life-Threatening; 5 = Death. Multiple AEs were counted only once per subject for the highest severity grade for each SOC and PT.
System organ classes were presented alphabetically, and preferred terms were presented by descending order of the total frequencies.
Source: Listing 16.2.7.4.1

Data Extracted: 05MAY2020
Source: .../final/version1/prog/t-teae-g-m.sas v9.4 Output file: t-teae-g-m-g34-m.pdf 28MAY2020:14:28 Page 14 of 14

Anhang 4-G4: UE, die zum Therapieabbruch führten nach SOC und PT - Safety Analyse Set

Tabelle 4-10 (Anhang): Ergebnisse für UE, die zum Therapieabbruch führten nach SOC und PT aus RCT mit dem zu bewertenden Arzneimittel (SELECTION, Induktionsphase: Kohorte A)

Gilead Sciences, Inc.
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Table 15.11.5.1.1: Treatment-Emergent Adverse Events Leading to Premature Discontinuation of Study Drug by System Organ Class and Preferred Term
Induction Study: Cohort A
Safety Analysis Set

System Organ Class Preferred Term	Filgotinib 200 mg (N=245)	Filgotinib 100 mg (N=277)	Placebo (N=137)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events Leading to Premature Discontinuation of Study Drug	5 (2.0%)	6 (2.2%)	4 (2.9%)
Blood and lymphatic system disorders	0	1 (0.4%)	1 (0.7%)
Anaemia	0	0	1 (0.7%)
Pancytopenia	0	1 (0.4%)	0
Gastrointestinal disorders	3 (1.2%)	2 (0.7%)	2 (1.5%)
Colitis ulcerative	1 (0.4%)	2 (0.7%)	2 (1.5%)
Colon dysplasia	1 (0.4%)	0	0
Gastrointestinal haemorrhage	1 (0.4%)	0	0
Infections and infestations	1 (0.4%)	2 (0.7%)	1 (0.7%)
Appendicitis	0	1 (0.4%)	0
Cellulitis	0	0	1 (0.7%)
Dengue fever	1 (0.4%)	0	0
Gastroenteritis	0	1 (0.4%)	0
Tinea versicolour	1 (0.4%)	0	0
Injury, poisoning and procedural complications	0	0	1 (0.7%)
Procedural intestinal perforation	0	0	1 (0.7%)
Investigations	0	1 (0.4%)	0
Hepatitis B DNA assay positive	0	1 (0.4%)	0

TEAE = treatment-emergent adverse event.
TEAEs are defined as any AEs that began on or after the Induction first dose date up to one day before the Maintenance first dose date or 30 days after the Induction last dose date whichever is earlier, or led to premature discontinuation of Induction study drug.
Multiple AEs were counted only once per subject for each system organ class and preferred term.
System organ classes were presented alphabetically, and preferred terms were presented by descending order of the total frequencies.
Source: Listing 16.2.7.5.1

Data Extracted: 05MAY2020
Source: .../final/version1/prog/t-teae-sub.sas v9.4 Output file: t-teae-sub-drug-disc-a.pdf 28MAY2020:14:29 Page 1 of 2

Gilead Sciences, Inc.
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Table 15.11.5.1.1: Treatment-Emergent Adverse Events Leading to Premature Discontinuation of Study Drug by System Organ Class and Preferred Term
Induction Study: Cohort A
Safety Analysis Set

System Organ Class Preferred Term	Filgotinib 200 mg (N=245)	Filgotinib 100 mg (N=277)	Placebo (N=137)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events Leading to Premature Discontinuation of Study Drug	5 (2.0%)	6 (2.2%)	4 (2.9%)
Skin and subcutaneous tissue disorders	1 (0.4%)	0	0
Rash vesicular	1 (0.4%)	0	0

TEAE = treatment-emergent adverse event.
TEAEs are defined as any AEs that began on or after the Induction first dose date up to one day before the Maintenance first dose date or 30 days after the Induction last dose date whichever is earlier, or led to premature discontinuation of Induction study drug.
Multiple AEs were counted only once per subject for each system organ class and preferred term.
System organ classes were presented alphabetically, and preferred terms were presented by descending order of the total frequencies.
Source: Listing 16.2.7.5.1

Data Extracted: 05MAY2020
Source: .../final/version1/prog/t-teae-sub.sas v9.4 Output file: t-teae-sub-drug-disc-a.pdf 28MAY2020:14:29 Page 2 of 2

Tabelle 4-11 (Anhang): Ergebnisse für UE, die zum Therapieabbruch führten nach SOC und PT aus RCT mit dem zu bewertenden Arzneimittel (SELECTION, Induktionsphase: Kohorte B)

Gilead Sciences, Inc.
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Table 15.11.5.1.2: Treatment-Emergent Adverse Events Leading to Premature Discontinuation of Study Drug by System Organ Class and Preferred Term
Induction Study: Cohort B
Safety Analysis Set

System Organ Class Preferred Term	Filgotinib 200 mg (N=262)	Filgotinib 100 mg (N=285)	Placebo (N=142)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events Leading to Premature Discontinuation of Study Drug	18 (6.9%)	14 (4.9%)	10 (7.0%)
Blood and lymphatic system disorders	1 (0.4%)	0	1 (0.7%)
Anaemia	1 (0.4%)	0	0
Neutropenia	0	0	1 (0.7%)
Gastrointestinal disorders	11 (4.2%)	8 (2.8%)	6 (4.2%)
Colitis ulcerative	9 (3.4%)	7 (2.5%)	5 (3.5%)
Abdominal pain	1 (0.4%)	0	1 (0.7%)
Colon dysplasia	0	1 (0.4%)	0
Large intestinal haemorrhage	1 (0.4%)	0	0
Pancreatitis acute	0	0	1 (0.7%)
General disorders and administration site conditions	0	0	1 (0.7%)
Pyrexia	0	0	1 (0.7%)
Infections and infestations	2 (0.8%)	5 (1.8%)	2 (1.4%)
Gastroenteritis viral	1 (0.4%)	0	1 (0.7%)
Sepsis	0	2 (0.7%)	0
Anal abscess	0	1 (0.4%)	0
Campylobacter gastroenteritis	0	0	1 (0.7%)
Clostridium difficile infection	1 (0.4%)	0	0
Giardiasis	0	1 (0.4%)	0
Staphylococcal infection	0	1 (0.4%)	0

TEAE = treatment-emergent adverse event.
TEAEs are defined as any AEs that began on or after the Induction first dose date up to one day before the Maintenance first dose date or 30 days after the Induction last dose date whichever is earlier, or led to premature discontinuation of Induction study drug.
Multiple AEs were counted only once per subject for each system organ class and preferred term.
System organ classes were presented alphabetically, and preferred terms were presented by descending order of the total frequencies.
Source: Listing 16.2.7.5.1

Data Extracted: 05MAY2020
Source: .../final/version1/prog/t-teae-sub.sas v9.4 Output file: t-teae-sub-drug-disc-b.pdf 28MAY2020:14:29 Page 1 of 2

Gilead Sciences, Inc.
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Table 15.11.5.1.2: Treatment-Emergent Adverse Events Leading to Premature Discontinuation of Study Drug by System Organ Class and Preferred Term
Induction Study: Cohort B
Safety Analysis Set

System Organ Class Preferred Term	Filgotinib 200 mg (N=262)	Filgotinib 100 mg (N=285)	Placebo (N=142)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events Leading to Premature Discontinuation of Study Drug	18 (6.9%)	14 (4.9%)	10 (7.0%)
Investigations	2 (0.8%)	1 (0.4%)	1 (0.7%)
Haemoglobin decreased	1 (0.4%)	0	0
Liver function test increased	0	1 (0.4%)	0
Transaminases increased	1 (0.4%)	0	0
Weight decreased	0	0	1 (0.7%)
White blood cell count increased	0	1 (0.4%)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.4%)	0	0
Breast cancer	1 (0.4%)	0	0
Nervous system disorders	0	0	1 (0.7%)
Cerebrovascular accident	0	0	1 (0.7%)
Respiratory, thoracic and mediastinal disorders	1 (0.4%)	0	0
Pulmonary embolism	1 (0.4%)	0	0

TEAE = treatment-emergent adverse event.
TEAEs are defined as any AEs that began on or after the Induction first dose date up to one day before the Maintenance first dose date or 30 days after the Induction last dose date whichever is earlier, or led to premature discontinuation of Induction study drug.
Multiple AEs were counted only once per subject for each system organ class and preferred term.
System organ classes were presented alphabetically, and preferred terms were presented by descending order of the total frequencies.
Source: Listing 16.2.7.5.1

Data Extracted: 05MAY2020
Source: .../final/version1/prog/t-teae-sub.sas v9.4 Output file: t-teae-sub-drug-disc-b.pdf 28MAY2020:14:29 Page 2 of 2

Tabelle 4-12 (Anhang): Ergebnisse für UE, die zum Therapieabbruch führten nach SOC und PT aus RCT mit dem zu bewertenden Arzneimittel (SELECTION, Erhaltungsphase)

Gilead Sciences, Inc.
Study GS-US-418-3898

Table 15.11.5.1.4: Treatment-Emergent Adverse Events Leading to Premature Discontinuation of Study Drug by System Organ Class and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events Leading to Premature Discontinuation of Study Drug	7 (3.5%)	2 (2.0%)	10 (5.6%)	4 (4.4%)	3 (3.2%)
Blood and lymphatic system disorders	0	1 (1.0%)	0	0	0
Microcytic anaemia	0	1 (1.0%)	0	0	0
Gastrointestinal disorders	2 (1.0%)	1 (1.0%)	4 (2.2%)	1 (1.1%)	0
Colitis ulcerative	2 (1.0%)	1 (1.0%)	4 (2.2%)	1 (1.1%)	0
General disorders and administration site conditions	0	0	2 (1.1%)	0	0
Chest pain	0	0	1 (0.6%)	0	0
Pyrexia	0	0	1 (0.6%)	0	0
Hepatobiliary disorders	0	0	1 (0.6%)	1 (1.1%)	0
Autoimmune hepatitis	0	0	0	1 (1.1%)	0
Cholelithiasis	0	0	1 (0.6%)	0	0

TEAE = treatment-emergent adverse event.
TEAEs are defined as any AEs that began on or after the Maintenance first dose date up to 30 days after Maintenance last dose date, or led to premature discontinuation of Maintenance study drug.
Multiple AEs were counted only once per subject for each system organ class and preferred term.
System organ classes were presented alphabetically, and preferred terms were presented by descending order of the total frequencies.
Source: Listing 16.2.7.5.1

Data Extracted: 05MAY2020
Source: .../final/version1/prog/t-teae-m-sub.sas v9.4 Output file: t-teae-m-sub-drug-disc-m.pdf 28MAY2020:14:29 Page 1 of 4

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Table 15.11.5.1.4: Treatment-Emergent Adverse Events Leading to Premature Discontinuation of Study Drug by System Organ Class and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events Leading to Premature Discontinuation of Study Drug	7 (3.5%)	2 (2.0%)	10 (5.6%)	4 (4.4%)	3 (3.2%)
Infections and infestations	2 (1.0%)	0	2 (1.1%)	2 (2.2%)	1 (1.1%)
Appendicitis	1 (0.5%)	0	1 (0.6%)	0	0
Acute hepatitis B	0	0	0	1 (1.1%)	0
Cellulitis	0	0	1 (0.6%)	0	0
Diverticulitis	1 (0.5%)	0	0	0	0
Gastroenteritis viral	0	0	0	1 (1.1%)	0
Paronychia	0	0	1 (0.6%)	0	0
Pneumonia	0	0	0	0	1 (1.1%)
Investigations	2 (1.0%)	0	0	0	0
Alanine aminotransferase increased	1 (0.5%)	0	0	0	0
Aspartate aminotransferase increased	1 (0.5%)	0	0	0	0
Haemoglobin decreased	1 (0.5%)	0	0	0	0

TEAE = treatment-emergent adverse event.
TEAEs are defined as any AEs that began on or after the Maintenance first dose date up to 30 days after Maintenance last dose date, or led to premature discontinuation of Maintenance study drug.
Multiple AEs were counted only once per subject for each system organ class and preferred term.
System organ classes were presented alphabetically, and preferred terms were presented by descending order of the total frequencies.
Source: Listing 16.2.7.5.1

Data Extracted: 05MAY2020
Source: .../final/version1/prog/t-teae-m-sub.sas v9.4 Output file: t-teae-m-sub-drug-disc-m.pdf 28MAY2020:14:29 Page 2 of 4

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Table 15.11.5.1.4: Treatment-Emergent Adverse Events Leading to Premature Discontinuation of Study Drug by System Organ Class and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events Leading to Premature Discontinuation of Study Drug	7 (3.5%)	2 (2.0%)	10 (5.6%)	4 (4.4%)	3 (3.2%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.5%)	0	1 (0.6%)	0	0
Colon cancer	0	0	1 (0.6%)	0	0
Malignant melanoma	1 (0.5%)	0	0	0	0
Nervous system disorders	0	0	0	0	1 (1.1%)
Cerebral venous sinus thrombosis	0	0	0	0	1 (1.1%)
Renal and urinary disorders	0	0	0	0	1 (1.1%)
Acute kidney injury	0	0	0	0	1 (1.1%)
Respiratory, thoracic and mediastinal disorders	0	0	1 (0.6%)	0	0
Dyspnoea	0	0	1 (0.6%)	0	0

TEAE = treatment-emergent adverse event.
TEAEs are defined as any AEs that began on or after the Maintenance first dose date up to 30 days after Maintenance last dose date, or led to premature discontinuation of Maintenance study drug.
Multiple AEs were counted only once per subject for each system organ class and preferred term.
System organ classes were presented alphabetically, and preferred terms were presented by descending order of the total frequencies.
Source: Listing 16.2.7.5.1

Data Extracted: 05MAY2020
Source: .../final/version1/prog/t-teae-m-sub.sas v9.4 Output file: t-teae-m-sub-drug-disc-m.pdf 28MAY2020:14:29 Page 3 of 4

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Table 15.11.5.1.4: Treatment-Emergent Adverse Events Leading to Premature Discontinuation of Study Drug by System Organ Class and Preferred Term
Maintenance Study
Safety Analysis Set

System Organ Class Preferred Term	Induction Filgotinib 200 mg Maintenance Filgotinib 200 mg (N=202)	Induction Filgotinib 200 mg Maintenance Placebo (N=99)	Induction Filgotinib 100 mg Maintenance Filgotinib 100 mg (N=179)	Induction Filgotinib 100 mg Maintenance Placebo (N=91)	Induction Placebo Maintenance Placebo (N=93)
Number (%) of Subjects with Any Treatment-Emergent Adverse Events Leading to Premature Discontinuation of Study Drug	7 (3.5%)	2 (2.0%)	10 (5.6%)	4 (4.4%)	3 (3.2%)
Vascular disorders	0	0	0	0	1 (1.1%)
Haemorrhagic infarction	0	0	0	0	1 (1.1%)
Venous thrombosis	0	0	0	0	1 (1.1%)

TEAE = treatment-emergent adverse event.
TEAEs are defined as any AEs that began on or after the Maintenance first dose date up to 30 days after Maintenance last dose date, or led to premature discontinuation of Maintenance study drug.
Multiple AEs were counted only once per subject for each system organ class and preferred term.
System organ classes were presented alphabetically, and preferred terms were presented by descending order of the total frequencies.
Source: Listing 16.2.7.5.1

Data Extracted: 05MAY2020
Source: .../final/version1/prog/t-teae-m-sub.sas v9.4 Output file: t-teae-m-sub-drug-disc-m.pdf 28MAY2020:14:29 Page 4 of 4