All Adverse Events		
Preferred Term	Action taken with Filgotinib 100mg Open Label	Action - Other
Abdominal distension	not applicable	none
Haemorrhoids	not applicable	medication required
Gastroenteritis viral	not applicable	medication required
Abdominal pain upper	not applicable	medication required
Colitis ulcerative	not applicable	medication required
Anaemia	not applicable	medication required + other treatment required + permanent study discontinuation

Hematology						
Study Day	Hemoglobin (g/dL)	Hematocrit (%)	Erythrocytes (x10^6/uL)	Platelets (x10^3/uL)	Reticulocytes (x10^6/uL)	Ery. Mean Corpuscular Volume (fL)
1	12.9 (N)	40 (N)	4.5 (N)	294 (N)	0.097 (N)	88 (N)
14	12.4 (L)	38 (L)	4.5 (N)	340 (N)	0.081 (N)	85 (N)
30	13.2 (N)	42 (N)	4.9 (N)	274 (N)	0.069 (N)	85 (N)
91	13.9 (N)	42 (N)	5.3 (N)	316 (N)	0.082 (N)	79 (N)
165	12.4 (L)	36 (L)	4.5 (N)	286 (N)	0.074 (N)	80 (N)
252	13.5 (N)	43 (N)	5.3 (N)	325 (N)	0.05 (N)	81 (N)
338	11.9 (L)	38 (L)	4.5 (N)	384 (N)	0.077 (N)	84 (N)
427	11.5 (L)	37 (L)	4.8 (N)	402 (H)	0.07 (N)	78 (L)
458	11.7 (L)	37 (L)	5 (N)	407 (H)	0.073 (N)	75 (L)
H = High; L = Low; N = Normal.						

Hematology						
Study Day	Leukocytes (x10^3/uL)	Neutrophils, Segmented (x10^3/uL)	Lymphocytes (x10^3/uL)	Monocytes (x10^3/uL)	Basophils (x10^3/uL)	Eosinophils (x10^3/uL)
1	6.72 (N)	3.39 (N)	2.73 (N)	0.49 (N)	0.03 (N)	0.07 (N)
14	8.05 (N)	4.15 (N)	3.25 (N)	0.55 (N)	0.04 (N)	0.07 (N)
30	5.52 (N)	3.68 (N)	1.27 (N)	0.4 (N)	0.04 (N)	0.12 (N)
91	5.24 (N)	3.29 (N)	1.5 (N)	0.32 (N)	0.02 (N)	0.12 (N)
165	5.37 (N)	3.64 (N)	1.19 (N)	0.4 (N)	0.01 (N)	0.13 (N)
252	5.65 (N)	3.96 (N)	1.33 (N)	0.27 (N)	0.03 (N)	0.06 (N)
338	8.17 (N)	6.05 (N)	1.12 (N)	0.81 (N)	0.03 (N)	0.17 (N)
427	4.94 (N)	3.05 (N)	1.42 (N)	0.36 (N)	0.03 (N)	0.08 (N)
458	8.03 (N)	5.66 (N)	1.45 (N)	0.66 (N)	0.08 (N)	0.19 (N)
H = High; L = Low; N = Normal.						

Chemistry						
Study Day	Fasting	Alanine Aminotransferase (U/L)	Aspartate Aminotransferase (U/L)	Alkaline Phosphatase (U/L)	Bilirubin (mg/dL)	Creatinine (mg/dL)
1	No	13 (N)	14 (N)	55 (N)	0.3 (N)	0.88 (N)
14	Yes	20 (N)	18 (N)	47 (N)	0.3 (N)	1.01 (N)
30	Yes	21 (N)	25 (N)	53 (N)	0.5 (N)	0.88 (N)
91	Yes	20 (N)	19 (N)	56 (N)	0.6 (N)	1.01 (N)
165	Yes	20 (N)	20 (N)	61 (N)	0.5 (N)	1.1 (N)
252	Yes	21 (N)	18 (N)	59 (N)	0.4 (N)	0.9 (N)
338	Yes	14 (N)	13 (N)	87 (N)	0.2 (N)	1.05 (N)
427	Yes	17 (N)	16 (N)	87 (N)	<0.2 (L)	1.13 (N)
458	Yes	19 (N)	17 (N)	91 (N)	0.4 (N)	1.18 (N)
H = High; L = Low; N = Normal.						

Chemistry					
Study Day	Fasting	Creatinine Clearance (mL/min)	Creatine Kinase (U/L)	Glucose (mg/dL)	C-Reactive Protein (hs-CRP) (mg/L)
1	No	154.2 (H)	104 (N)	81 (N)	0.68 (N)
14	Yes	136.8 (H)	218 (N)	80 (N)	
30	Yes	154.2 (H)	243 (N)	74 (N)	
91	Yes	138 (H)	251 (N)	82 (N)	
165	Yes	123.6 (N)	270 (N)	78 (N)	1.28 (N)
252	Yes	147 (H)	202 (N)	87 (N)	
338	Yes	126 (H)	194 (N)	77 (N)	29 (H)
427	Yes	115.2 (N)	182 (N)	99 (N)	
458	Yes	110.4 (N)	137 (N)	62 (L)	
H = High; L = Low; N = Normal.					

Lipid Panel					
Study Day	Fasting	Total Cholesterol (mg/dL)	HDL Cholesterol (mg/dL)	LDL Cholesterol (mg/dL)	Triglycerides (mg/dL)
-7	Yes	171 (N)	50 (N)	102 (N)	132 (N)
165	Yes	150 (N)	51 (N)	93 (N)	56 (N)
338	Yes	117 (L)	43 (N)	68 (N)	66 (N)
H = High; L = Low; N = Normal.					

被験者識別番号：[redacted]

投与群：フィルゴチニブ 200 mg 群（非盲検）

治験薬の投与状況：継続

ベースライン特性：本被験者は 6[redacted]歳の白人女性であった。その他の特性として、民族は非ヒスパニック／ラテン系、ニュージーランドからの参加であった。

上気道感染（Day 52～56）（試験治療下の注目すべき有害事象）：
Day 52、Grade 1 の非重篤な上気道感染が発現した。フィルゴチニブ 200 mg/プラセボに対する処置は非該当であった。フィルゴチニブ 100 mg/プラセボに対する処置は非該当であった。フィルゴチニブ 200 mg（非盲検）に対する処置は変更なし。フィルゴチニブ 100 mg（非盲検）に対する処置は非該当であった。本事象は治験薬と関連なしと判断された。Day 56、Grade 1 の本事象は回復した。

副甲状腺過形成（Day 498～499）（試験治療下の重篤な有害事象）：
Day 498、Grade 3 の重篤な副甲状腺過形成が発現した。フィルゴチニブ 200 mg/プラセボに対する処置は非該当であった。フィルゴチニブ 100 mg/プラセボに対する処置は非該当であった。フィルゴチニブ 200 mg（非盲検）に対する処置は投与中断であった。フィルゴチニブ 100 mg（非盲検）に対する処置は非該当であった。本事象は治験薬と関連なしと判断された。Day 499、Grade 3 の本事象は回復した。

その他の関連情報：特になし。

Medical History	
Medical History	**Resolution**
osteoporosis	Ongoing

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
bendroflumethiazide	PROXIMAL ATRIAL FIBRILLATION	ORAL	-3568 days	Ongoing
sotalol	PROXIMAL ATRIAL FIBRILLATION	ORAL	-3479 days	Ongoing
salbutamol	ASTHMA	RESPIRATORY (INHALATION)	-2834 days	Ongoing
paracetamol	INTERMITTENT MUSCULAR ACHES	ORAL	About -1484 days	Ongoing
paroxetine	DEPRESSION	ORAL	-1274 days	Ongoing
candesartan	PROXIMAL ATRIAL FIBRILLATION	ORAL	-453 days	Ongoing
simvastatin	HYPERLIPIDAEMIA	ORAL	608 days	Ongoing
loperamide	ULCERATIVE COLITIS	ORAL	15 days	22 days
colecalciferol	OSTEOPOROSIS	ORAL	-83 days	106 days
influenza vaccine	FLU PROPHYLAXIS	INTRAMUSCULAR	107 days	107 days
zoledronic acid	OSTEPOROSIS	INTRAVENOUS DRIP	427 days	427 days
influenza vaccine	FLU PROPHYLAXIS	INTRAMUSCULAR	483 days	483 days
dexamethasone	PREVENTION OF POST OPERATIVE NAUSEA AND VOMITING	INTRAVENOUS	498 days	498 days
fentanyl	ANAESTHESIA	INTRAVENOUS BOLUS	498 days	498 days

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
ketamine	ANAESTHESIA	INTRAVENOUS BOLUS	498 days	498 days
ondansetron	ANAESTHESIA	INTRAVENOUS BOLUS	498 days	498 days
propofol	ANAESTHESIA	INTRAVENOUS BOLUS	498 days	498 days
rocuronium	ANAETHESIA	INTRAVENOUS BOLUS	498 days	498 days
paracetamol	POST SURGICAL NECK PAIN	ORAL	498 days	504 days
atorvastatin	HYPERLIPIDAEMIA	ORAL	-2565 days	607 days
lidocaine	LOCAL ANAETHETIC PRE FINE NEEDLE ASPIRATION RIGHT NECK	CUTANEOUS	679 days	679 days
paracetamol	POST BIOPSY PROCEDURE TO RIGHT NECK	ORAL	679 days	682 days

All Adverse Events					
Preferred Term	Onset Day	Resolution Day	Toxicity Grade	Causality	Action taken with Filgotinib 200mg/Placebo
Upper respiratory tract infection	52	56	1	not related	not applicable
Hyperparathyroidism	84	Ongoing	1	not related	not applicable
Parathyroid hyperplasia	352	497	1	not related	not applicable
Parathyroid hyperplasia	498	499	3	not related	not applicable
Parathyroid hyperplasia	500	Ongoing	1	not related	not applicable
Mandibular mass	647	790	1	not related	not applicable

All Adverse Events				
Preferred Term	Action taken with Filgotinib 100mg/Placebo	Action taken with Filgotinib 200mg Open Label	Action taken with Filgotinib 100mg Open Label	Action - Other
Upper respiratory tract infection	not applicable	dose not changed	not applicable	none
Hyperparathyroidism	not applicable	dose not changed	not applicable	other treatment required
Parathyroid hyperplasia	not applicable	dose not changed	not applicable	other treatment required
Parathyroid hyperplasia	not applicable	drug interrupted	not applicable	medication required
Parathyroid hyperplasia	not applicable	drug interrupted	not applicable	none
Mandibular mass	not applicable	dose not changed	not applicable	medication required + other treatment required

Hematology						
Study Day	Hemoglobin (g/dL)	Hematocrit (%)	Erythrocytes (x10^6/uL)	Platelets (x10^3/uL)	Reticulocytes (x10^6/uL)	Ery. Mean Corpuscular Volume (fL)
1	12.5 (N)	39 (N)	4.5 (N)	354 (N)	0.05 (N)	86 (N)
15	12.9 (N)	38 (N)	4.7 (N)	379 (N)	0.083 (N)	83 (N)
29	12.7 (N)	38 (N)	4.5 (N)	350 (N)	0.061 (N)	85 (N)
84	13.2 (N)	41 (N)	4.6 (N)	348 (N)	0.056 (N)	88 (N)
170	13 (N)	38 (N)	4.4 (N)	346 (N)	0.089 (N)	87 (N)
253	13.7 (N)	41 (N)	4.5 (N)	386 (N)	0.095 (N)	91 (N)
330	13 (N)	38 (N)	4.2 (N)	359 (N)	0.075 (N)	91 (N)
415	12.7 (N)	38 (N)	4.1 (N)	339 (N)	0.055 (N)	92 (N)
504	13.7 (N)	41 (N)	4.5 (N)	389 (N)	0.096 (N)	91 (N)
589	13.5 (N)	41 (N)	4.5 (N)	357 (N)	0.06 (N)	91 (N)
673	13.7 (N)	42 (N)	4.5 (N)	321 (N)	0.069 (N)	92 (N)
757	13.2 (N)	40 (N)	4.3 (N)	319 (N)	0.067 (N)	94 (N)
H = High; L = Low; N = Normal.						

Hematology						
Study Day	Leukocytes (x10^3/uL)	Neutrophils, Segmented (x10^3/uL)	Lymphocytes (x10^3/uL)	Monocytes (x10^3/uL)	Basophils (x10^3/uL)	Eosinophils (x10^3/uL)
1	6.53 (N)	4.41 (N)	1.57 (N)	0.41 (N)	0.03 (N)	0.11 (N)
15	6.48 (N)	4.39 (N)	1.4 (N)	0.51 (N)	0.03 (N)	0.15 (N)
29	6.65 (N)	4.61 (N)	1.44 (N)	0.42 (N)	0.03 (N)	0.14 (N)
84	7.18 (N)	4.75 (N)	1.66 (N)	0.4 (N)	0.04 (N)	0.32 (N)
170	6.92 (N)	4.57 (N)	1.66 (N)	0.35 (N)	0.03 (N)	0.31 (N)
253	6.57 (N)	4.15 (N)	1.84 (N)	0.39 (N)	0.03 (N)	0.15 (N)
330	6.03 (N)	3.71 (N)	1.79 (N)	0.36 (N)	0.03 (N)	0.15 (N)
415	6.44 (N)	3.89 (N)	1.89 (N)	0.48 (N)	0.04 (N)	0.15 (N)
504	6.43 (N)	4.27 (N)	1.47 (N)	0.4 (N)	0.04 (N)	0.25 (N)
589	5.27 (N)	3.35 (N)	1.46 (N)	0.33 (N)	0.04 (N)	0.09 (N)
673	5.36 (N)	3.43 (N)	1.43 (N)	0.36 (N)	0.05 (N)	0.09 (N)
757	5.9 (N)	4.14 (N)	1.38 (N)	0.32 (N)	0.02 (N)	0.04 (N)
H = High; L = Low; N = Normal.						

Chemistry						
Study Day	Fasting	Alanine Aminotransferase (U/L)	Aspartate Aminotransferase (U/L)	Alkaline Phosphatase (U/L)	Bilirubin (mg/dL)	Creatinine (mg/dL)
1	Yes	14 (N)	20 (N)	54 (N)	0.4 (N)	0.58 (N)
15	No	13 (N)	19 (N)	59 (N)	0.4 (N)	0.59 (N)
29	No	13 (N)	19 (N)	58 (N)	0.4 (N)	0.64 (N)
84	No	16 (N)	21 (N)	63 (N)	0.4 (N)	0.69 (N)
170	Yes	21 (N)	25 (N)	64 (N)	0.4 (N)	0.6 (N)
253	No	55 (H)	45 (H)	72 (N)	0.5 (N)	0.64 (N)
330	No	35 (H)	32 (N)	66 (N)	0.4 (N)	0.66 (N)
415	No	34 (N)	31 (N)	64 (N)	0.5 (N)	0.7 (N)
504	Yes	80 (H)	48 (H)	65 (N)	0.4 (N)	0.68 (N)
589	No	26 (N)	24 (N)	49 (N)	0.3 (N)	0.68 (N)
673	Yes	31 (N)	32 (N)	49 (N)	0.5 (N)	0.67 (N)
757	No	25 (N)	28 (N)	49 (N)	0.4 (N)	0.63 (N)
H = High; L = Low; N = Normal.						

Chemistry					
Study Day	Fasting	Creatinine Clearance (mL/min)	Creatine Kinase (U/L)	Glucose (mg/dL)	C-Reactive Protein (hs-CRP) (mg/L)
1	Yes	121.8 (H)	75 (N)	81 (N)	2.11 (N)
15	No	117.6 (H)	72 (N)	94 (N)	
29	No	106.8 (N)	74 (N)	95 (N)	
84	No	99.6 (N)	76 (N)	92 (N)	
170	Yes	117.6 (H)	95 (N)	89 (N)	2.04 (N)
253	No	114.6 (N)	129 (N)	100 (N)	
330	No	114.6 (N)	120 (N)	94 (N)	2.05 (N)
415	No	106.8 (N)	100 (N)	88 (N)	
504	Yes	108.6 (N)	35 (N)	101 (H)	14.6 (H)
589	No	112.2 (N)	91 (N)	102 (H)	
673	Yes	113.4 (N)	123 (N)	94 (N)	2.43 (N)
757	No	118.8 (H)	114 (N)	92 (N)	
H = High; L = Low; N = Normal.					

Lipid Panel					
Study Day	Fasting	Total Cholesterol (mg/dL)	HDL Cholesterol (mg/dL)	LDL Cholesterol (mg/dL)	Triglycerides (mg/dL)
1	Yes	199 (N)	64 (N)	107 (N)	204 (N)
170	Yes	190 (N)	60 (N)	104 (N)	181 (N)
330	No	195 (N)	62 (N)	114 (N)	165 (N)
504	Yes	195 (N)	53 (N)	111 (N)	229 (N)
673	Yes	180 (L)	60 (N)	94 (N)	137 (N)
H = High; L = Low; N = Normal.					

被験者識別番号：[redacted]

投与群：フィルゴチニブ 200 mg 群（非盲検）

治験薬の投与状況：被験者の判断により投与中止（Day 593）

ベースライン特性：本被験者は 2[redacted] 歳の白人女性であった。その他の特性として、民族に関する情報は取得できず、ウクライナからの参加であった。

潰瘍性大腸炎（Day 156～160）（試験治療下の重篤な有害事象［TE-SAE］）：
Day 156、Grade 3 の重篤な潰瘍性大腸炎が発現した。フィルゴチニブ 200 mg/プラセボに対する処置は非該当であった。フィルゴチニブ 100 mg/プラセボに対する処置は非該当であった。フィルゴチニブ 200 mg（非盲検）に対する処置は投与中断であった。フィルゴチニブ 100 mg（非盲検）に対する処置は非該当であった。本事象は治験薬と関連なしと判断された。Day 160、Grade 3 の本事象は回復した。

上咽頭炎（Day 241～252）（試験治療下の注目すべき有害事象）：
Day 241、Grade 1 の非重篤な上咽頭炎が発現した。フィルゴチニブ 200 mg/プラセボに対する処置は非該当であった。フィルゴチニブ 100 mg/プラセボに対する処置は非該当であった。フィルゴチニブ 200 mg（非盲検）に対する処置は変更なし。フィルゴチニブ 100 mg（非盲検）に対する処置は非該当であった。本事象は治験薬と関連なしと判断された。Day 252、Grade 1 の本事象は回復した。

潰瘍性大腸炎（Day 331～337）（TE-SAE）：
Day 331、Grade 3 の重篤な潰瘍性大腸炎が発現した。フィルゴチニブ 200 mg/プラセボに対する処置は非該当であった。フィルゴチニブ 100 mg/プラセボに対する処置は非該当であった。フィルゴチニブ 200 mg（非盲検）に対する処置は変更なし。フィルゴチニブ 100 mg（非盲検）に対する処置は非該当であった。本事象は治験薬と関連なしと判断された。Day 337、Grade 3 の本事象は回復した。

その他の関連情報：特になし。

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
ethinylestradiol;gestodene	CONTACEPTION	ORAL	-206 days	Ongoing
ascorbic acid;ferrous sulfate;folic acid;protease	ANEMIA	ORAL	559 days	Ongoing
mesalazine	ULCERATIVE COLITIS	ORAL	559 days	Ongoing
pantoprazole sodium sesquihydrate	GASTRITIS PEVENTION	ORAL	559 days	Ongoing
saccharomyces boulardii	ULCERATIVE COLITIS	ORAL	559 days	Ongoing
methylprednisolone	ULCERATIVE COLITIS	ORAL	587 days	Ongoing
levofloxacin	ULCERATIVE COLITIS	ORAL	157 days	161 days
paracetamol	COLD	ORAL	241 days	245 days
ascorbic acid	COLD	ORAL	241 days	250 days
eucalyptus globulus oil;glycerol;mentha x piperita oil;sulfanilamide;sulfathiazole;thymol	COLD	OROPHARYNGEAL	241 days	250 days
methylprednisolone	ULCERATIVE COLITIS WORSENING	ORAL	314 days	363 days
methylprednisolone	ULCERATIVE COLITIS WORSENING	ORAL	364 days	391 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
methylprednisolone	ULCERATIVE COLITIS WORSENING	ORAL	392 days	419 days
mesalazine	ULCERATIVE COLITIS	ORAL	-1295 days	558 days
methylprednisolone	ULCERATIVE COLITIS WORSENING	ORAL	420 days	559 days
methylprednisolone	ULCERATIVE COLITIS	ORAL	560 days	586 days

All Adverse Events					
Preferred Term	Onset Day	Resolution Day	Toxicity Grade	Causality	Action taken with Filgotinib 200mg/Placebo
Colitis ulcerative	156	160	3	not related	not applicable
Weight increased	161	314	1	related	not applicable
Colitis ulcerative	217	248	2	not related	not applicable
Nasopharyngitis	241	252	1	not related	not applicable
Colitis ulcerative	312	330	2	not related	not applicable
Myalgia	312	337	2	not related	not applicable
Colitis ulcerative	331	337	3	not related	not applicable
Colitis ulcerative	338	349	2	not related	not applicable
Colitis ulcerative	538	Ongoing	2	not related	not applicable
Erythema nodosum	559	Ongoing	1	not related	not applicable
Hypochromic anaemia	559	Ongoing	2	not related	not applicable
Osteoarthritis	559	Ongoing	1	not related	not applicable

All Adverse Events				
Preferred Term	Action taken with Filgotinib 100mg/Placebo	Action taken with Filgotinib 200mg Open Label	Action taken with Filgotinib 100mg Open Label	Action - Other
Colitis ulcerative	not applicable	drug interrupted	not applicable	medication required
Weight increased	not applicable	dose not changed	not applicable	none
Colitis ulcerative	not applicable	dose not changed	not applicable	none
Nasopharyngitis	not applicable	dose not changed	not applicable	medication required
Colitis ulcerative	not applicable	dose not changed	not applicable	medication required
Myalgia	not applicable	dose not changed	not applicable	none
Colitis ulcerative	not applicable	dose not changed	not applicable	medication required
Colitis ulcerative	not applicable	dose not changed	not applicable	medication required
Colitis ulcerative	not applicable	dose not changed	not applicable	medication required
Erythema nodosum	not applicable	dose not changed	not applicable	none
Hypochromic anaemia	not applicable	dose not changed	not applicable	medication required
Osteoarthritis	not applicable	dose not changed	not applicable	none

Hematology						
Study Day	Hemoglobin (g/dL)	Hematocrit (%)	Erythrocytes (x10^6/uL)	Platelets (x10^3/uL)	Reticulocytes (x10^6/uL)	Ery. Mean Corpuscular Volume (fL)
1	11.8 (N)	37 (N)	4.7 (N)	362 (N)	0.074 (N)	77 (L)
13	11.1 (L)	37 (N)	4.4 (N)	455 (H)	0.053 (N)	84 (N)
29	11.1 (L)	38 (N)	4.4 (N)	371 (N)	0.054 (N)	85 (N)
83	11.1 (L)	37 (N)	4.5 (N)	329 (N)	0.074 (N)	83 (N)
161	12 (N)	36 (N)	4.5 (N)	347 (N)	0.075 (N)	80 (N)
224	11.9 (N)	36 (N)	4.4 (N)	412 (H)	0.07 (N)	81 (N)
252	11.9 (N)	37 (N)	4.4 (N)	440 (H)	0.07 (N)	83 (N)
314	12.8 (N)	39 (N)	4.6 (N)	405 (H)	0.056 (N)	85 (N)
343	11.7 (N)	34 (N)	4.3 (N)	402 (H)	0.073 (N)	80 (N)
434	11.4 (L)	38 (N)	4.5 (N)	382 (N)	0.037 (N)	85 (N)
510	11.4 (L)	37 (N)	4.7 (N)	301 (N)	0.052 (N)	80 (N)
594	10.7 (L)	35 (N)	4.6 (N)	474 (H)	0.079 (N)	76 (L)
H = High; L = Low; N = Normal.						

Hematology						
Study Day	Leukocytes (x10^3/uL)	Neutrophils, Segmented (x10^3/uL)	Lymphocytes (x10^3/uL)	Monocytes (x10^3/uL)	Basophils (x10^3/uL)	Eosinophils (x10^3/uL)
1	8.71 (N)	6.09 (N)	1.7 (N)	0.51 (N)	0.26 (H)	0.14 (N)
13	6.25 (N)	3.78 (N)	2.1 (N)	0.31 (N)	0.04 (N)	0.03 (N)
29	7.95 (N)	5.68 (N)	1.77 (N)	0.35 (N)	0.03 (N)	0.12 (N)
83	6.4 (N)	4.15 (N)	1.83 (N)	0.35 (N)	0.03 (N)	0.03 (N)
161	4.95 (N)	3.53 (N)	0.89 (L)	0.36 (N)	0.09 (N)	0.07 (N)
224	7.07 (N)	4.44 (N)	2.04 (N)	0.46 (N)	0.02 (N)	0.12 (N)
252	6.82 (N)	4.48 (N)	1.74 (N)	0.46 (N)	0.04 (N)	0.09 (N)
314	6.82 (N)	5.34 (N)	0.84 (L)	0.55 (N)	0.03 (N)	0.07 (N)
343	7.3 (N)	4.6 (N)	1.83 (N)	0.68 (N)	0.1 (N)	0.09 (N)
434	5.82 (N)	3.71 (N)	1.55 (N)	0.39 (N)	0.08 (N)	0.09 (N)
510	9.56 (N)	7.79 (H)	1.27 (N)	0.36 (N)	0.06 (N)	0.07 (N)
594	14.69 (H)	9.18 (H)	4.65 (H)	0.6 (N)	0.16 (N)	0.09 (N)
H = High; L = Low; N = Normal.						

Chemistry						
Study Day	Fasting	Alanine Aminotransferase (U/L)	Aspartate Aminotransferase (U/L)	Alkaline Phosphatase (U/L)	Bilirubin (mg/dL)	Creatinine (mg/dL)
1	Yes	13 (N)	15 (N)	91 (N)	0.4 (N)	0.62 (N)
13	Yes	12 (N)	16 (N)	84 (N)	0.2 (N)	0.6 (N)
29	Yes	12 (N)	16 (N)	77 (N)	0.3 (N)	0.58 (N)
83	Yes	12 (N)	17 (N)	64 (N)	0.4 (N)	0.63 (N)
161	Yes	14 (N)	18 (N)	67 (N)	0.5 (N)	0.66 (N)
224	Yes	17 (N)	22 (N)	67 (N)	0.3 (N)	0.66 (N)
252	Yes	19 (N)	18 (N)	68 (N)	0.4 (N)	0.71 (N)
314	Yes	14 (N)	17 (N)	77 (N)	0.7 (N)	0.67 (N)
343	Yes	19 (N)	12 (N)	69 (N)	<0.2 (L)	0.68 (N)
434	Yes	21 (N)	28 (N)	69 (N)	0.4 (N)	0.72 (N)
510	Yes	12 (N)	16 (N)	80 (N)	0.5 (N)	0.59 (N)
594	Yes	14 (N)	9 (N)	73 (N)	<0.2 (L)	0.68 (N)
H = High; L = Low; N = Normal.						

Chemistry					
Study Day	Fasting	Creatinine Clearance (mL/min)	Creatine Kinase (U/L)	Glucose (mg/dL)	C-Reactive Protein (hs-CRP) (mg/L)
1	Yes	118.2 (H)	54 (N)	84 (N)	4.14 (N)
13	Yes	122.4 (H)	89 (N)	83 (N)	
29	Yes	127.2 (H)	62 (N)	89 (N)	
83	Yes	120 (H)	101 (N)	79 (N)	
161	Yes	121.2 (H)	90 (N)	75 (N)	4.82 (N)
224	Yes	121.8 (H)	85 (N)	78 (N)	4.19 (N)
252	Yes	109.2 (N)	64 (N)	87 (N)	
314	Yes	112.8 (N)	63 (N)	94 (N)	20.5 (H)
343	Yes	106.8 (N)	<18 (L)	67 (L)	12.9 (H)
434	Yes	102 (N)	81 (N)	93 (N)	
510	Yes	128.4 (H)	63 (N)	88 (N)	4.52 (N)
594	Yes	110.4 (N)	24 (L)	70 (L)	
H = High; L = Low; N = Normal.					

Lipid Panel					
Study Day	Fasting	Total Cholesterol (mg/dL)	HDL Cholesterol (mg/dL)	LDL Cholesterol (mg/dL)	Triglycerides (mg/dL)
-9	Yes	177 (N)	75 (N)	79 (N)	89 (N)
13	Yes	201 (N)	91 (H)	99 (N)	60 (N)
161	Yes	148 (N)	73 (N)	71 (N)	38 (N)
224	Yes	128 (N)	65 (N)	46 (N)	74 (N)
252	Yes	173 (N)	62 (N)	96 (N)	116 (N)
343	Yes	170 (N)	70 (N)	77 (N)	144 (N)
434	Yes	194 (N)	78 (N)	113 (N)	92 (N)
510	Yes	170 (N)	80 (N)	91 (N)	53 (N)
594	Yes	157 (N)	64 (N)	60 (N)	201 (H)
H = High; L = Low; N = Normal.					

被験者識別番号：[redacted]

投与群：フィルゴチニブ 200 mg 群（非盲検）

治験薬の投与状況：有害事象により投与中止（Day 170）

ベースライン特性：本被験者は 5[redacted] 歳のアジア系女性であった。その他の特性として、民族は非ヒスパニック／ラテン系、英国からの参加であった。

蜂巣炎（Day 170～189）（試験治療下の重篤な有害事象、投与中止に至った有害事象、試験治療下の注目すべき有害事象）：
Day 170、Grade 3 の重篤な蜂巣炎が発現した。フィルゴチニブ 200 mg/プラセボに対する処置は非該当であった。フィルゴチニブ 100 mg/プラセボに対する処置は非該当であった。フィルゴチニブ 200 mg（非盲検）に対する処置は投与中止であった。フィルゴチニブ 100 mg（非盲検）に対する処置は非該当であった。本事象は治験薬と関連ありと判断された。Day 189、Grade 3 の本事象は回復した。

その他の関連情報：発熱が認められ、被験者は入院し、左脚の蜂巣炎と診断された。抗生剤が投与された。蜂巣炎の紅斑及び腫脹は軽減した。治験責任医師によると、蜂巣炎発症前に白血球減少症及び好中球減少症が認められていた。血液内科を受診した結果、本事象は治験薬とアザチオプリンの併用投与による可能性があると診断された。その他のリスク因子として、糖尿病が挙げられた。被験者は回復し、退院した。

Medical History	
Medical History	**Resolution**
hypertension	Ongoing
musculoskeletal pain	Ongoing

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
folic acid	ANAEMIA	ORAL	-4382 days	Ongoing
lansoprazole	EXCESS BILE	ORAL	-3476 days	Ongoing
calcium carbonate;colecalciferol	BONE PROTECTION	ORAL	-2184 days	Ongoing
metformin	DIABETES	ORAL	About -1294 days	Ongoing
ferrous fumarate	ANAEMIA	ORAL	-123 days	Ongoing
co-trimoxazole	IMMUNOSUPPRESSION PROPHYLLAXIS	ORAL	-28 days	Ongoing
furosemide	BILATERAL LEG OEDEMA	ORAL	64 days	Ongoing
colecalciferol	VITAMIN D DEFICIENCY	ORAL	170 days	Ongoing
prednisolone	ULCERATIVE COLITIS	ORAL	193 days	Ongoing
prednisolone	ULCERATIVE COLITIS	ORAL	-130 days	16 days
prednisolone	ULCERATIVE COLITIS	ORAL	17 days	30 days
prednisolone	ULCERATIVE COLITIS	ORAL	31 days	49 days
prednisolone	ULCERATIVE COLITIS	ORAL	50 days	57 days
nitrous oxide;oxygen	SIGMOIDOSCOPY	RESPIRATORY (INHALATION)	78 days	78 days
sodium phosphate	SIGMOIDOSCOPY PREPARATION	RECTAL	78 days	78 days
azathioprine	ULCERATIVE COLITIS	ORAL	-582 days	169 days
piperacillin sodium;tazobactam sodium	CELLULITIS	INTRAVENOUS	170 days	170 days

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
flucloxacillin	CELLULITIS	ORAL	170 days	177 days
tramadol	GALLSTONE PAIN	ORAL	-3804 days	183 days
prednisolone	ULCERATIVE COLITIS	ORAL	185 days	185 days
prednisolone	ULCERATIVE COLITIS	ORAL	191 days	192 days

All Adverse Events						
Preferred Term	Onset Day	Resolution Day	Toxicity Grade	Causality	Action taken with Filgotinib 200mg/Placebo	Action taken with Filgotinib 100mg/Placebo
Chills	64	107	1	not related	not applicable	not applicable
Oedema peripheral	64	Ongoing	1	not related	not applicable	not applicable
Chills	156	160	2	not related	not applicable	not applicable
Leukopenia	164	189	2	related	not applicable	not applicable
Neutropenia	164	204	2	not related	not applicable	not applicable
Cellulitis	170	189	3	related	not applicable	not applicable
Vitamin D deficiency	170	Ongoing	2	not related	not applicable	not applicable
Colitis ulcerative	185	Ongoing	2	not related	not applicable	not applicable

All Adverse Events			
Preferred Term	Action taken with Filgotinib 200mg Open Label	Action taken with Filgotinib 100mg Open Label	Action - Other
Chills	dose not changed	not applicable	none
Oedema peripheral	dose not changed	not applicable	medication required
Chills	dose not changed	not applicable	none
Leukopenia	dose not changed	not applicable	other treatment required
Neutropenia	dose not changed	not applicable	none
Cellulitis	drug withdrawn	not applicable	medication required + permanent study discontinuation
Vitamin D deficiency	dose not changed	not applicable	medication required
Colitis ulcerative	not applicable	not applicable	medication required

Hematology						
Study Day	Hemoglobin (g/dL)	Hematocrit (%)	Erythrocytes (x10^6/uL)	Platelets (x10^3/uL)	Reticulocytes (x10^6/uL)	Ery. Mean Corpuscular Volume (fL)
1	12.1 (N)	40 (N)	4.4 (N)	268 (N)	0.134 (H)	91 (N)
15	13 (N)	43 (N)	4.7 (N)	328 (N)	0.082 (N)	91 (N)
30	12.7 (N)	41 (N)	4.4 (N)	304 (N)	0.069 (N)	93 (N)
78	11.1 (L)	35 (N)	3.7 (L)	437 (H)	0.057 (N)	94 (N)
164	11.3 (L)	35 (N)	3.6 (L)	375 (N)	0.053 (N)	97 (N)
183	10.8 (L)	34 (N)	3.6 (L)	457 (H)	0.085 (N)	95 (N)
204	11.5 (L)	37 (N)	4 (L)	291 (N)	0.119 (N)	93 (N)
H = High; L = Low; N = Normal.						

Hematology						
Study Day	Leukocytes (x10^3/uL)	Neutrophils, Segmented (x10^3/uL)	Lymphocytes (x10^3/uL)	Monocytes (x10^3/uL)	Basophils (x10^3/uL)	Eosinophils (x10^3/uL)
1	6.36 (N)	3.61 (N)	2.19 (N)	0.47 (N)	0.02 (N)	0.07 (N)
15	6.89 (N)	4.88 (N)	1.72 (N)	0.24 (N)	0.02 (N)	0.02 (N)
30	4.71 (N)	2.81 (N)	1.69 (N)	0.17 (N)	0.01 (N)	0.04 (N)
78	4.06 (N)	2.08 (N)	1.73 (N)	0.16 (N)	0.01 (N)	0.08 (N)
164	2.71 (L)	1.1 (L)	1.38 (N)	0.11 (L)	0.01 (N)	0.1 (N)
183	3.58 (L)	1.1 (L)	1.85 (N)	0.48 (N)	0.02 (N)	0.14 (N)
204	8.92 (N)	6.61 (N)	1.97 (N)	0.28 (N)	0.02 (N)	0.05 (N)
H = High; L = Low; N = Normal.						

Chemistry						
Study Day	Fasting	Alanine Aminotransferase (U/L)	Aspartate Aminotransferase (U/L)	Alkaline Phosphatase (U/L)	Bilirubin (mg/dL)	Creatinine (mg/dL)
1	No	26 (N)	24 (N)	92 (N)	0.4 (N)	0.52 (N)
15	No	28 (N)	30 (N)	92 (N)	0.4 (N)	0.62 (N)
30	No	22 (N)	27 (N)	76 (N)	0.4 (N)	0.64 (N)
78	Yes	11 (N)	26 (N)	77 (N)	0.4 (N)	0.78 (N)
164	Yes	13 (N)	26 (N)	109 (N)	0.5 (N)	0.71 (N)
183	No	9 (N)	19 (N)	98 (N)	0.2 (N)	0.77 (N)
204	No	19 (N)	15 (N)	104 (N)	0.2 (N)	0.54 (N)
H = High; L = Low; N = Normal.						

Chemistry					
Study Day	Fasting	Creatinine Clearance (mL/min)	Creatine Kinase (U/L)	Glucose (mg/dL)	C-Reactive Protein (hs-CRP) (mg/L)
1	No	196.2 (H)	28 (N)	90 (N)	5.98 (N)
15	No	159.6 (H)	65 (N)	73 (N)	
30	No	157.2 (H)	87 (N)	98 (N)	
78	Yes	131.4 (H)	88 (N)	93 (N)	
164	Yes	135 (H)	80 (N)	96 (N)	9.35 (N)
183	No	125.4 (H)	55 (N)	116 (H)	
204	No	177 (H)	29 (N)	144 (H)	
H = High; L = Low; N = Normal.					

Lipid Panel					
Study Day	Fasting	Total Cholesterol (mg/dL)	HDL Cholesterol (mg/dL)	LDL Cholesterol (mg/dL)	Triglycerides (mg/dL)
-7	Yes	221 (N)	84 (N)	120 (N)	168 (N)
78	Yes	205 (N)	63 (N)	113 (N)	162 (N)
164	Yes	187 (N)	77 (N)	102 (N)	116 (N)
H = High; L = Low; N = Normal.					

被験者識別番号：[redacted]

投与群：フィルゴチニブ 200 mg 群

治験薬の投与状況：継続

ベースライン特性：本被験者は 5[redacted] 歳の白人男性であった。その他の特性として、民族は非ヒスパニック／ラテン系、英国からの参加であった。

処置後出血（Day 18～19）（試験治療下の重篤な有害事象）：
Day 18、Grade 1 の重篤な処置後出血が発現した。フィルゴチニブ 200 mg/プラセボに対する処置は変更なし。フィルゴチニブ 100 mg/プラセボに対する処置は変更なし。フィルゴチニブ 200 mg（非盲検）に対する処置は非該当であった。フィルゴチニブ 100 mg（非盲検）に対する処置は非該当であった。本事象は治験薬と関連なしと判断された。Day 19、Grade 1 の本事象は回復した。

その他の関連情報：特になし。

Medical History	
Medical History	**Resolution**
hypertension	Ongoing
nonalcoholic fatty liver disease	Ongoing
type 2 diabetes mellitus	Ongoing
vitamin b12 deficiency	Ongoing

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
hydroxocobalamin	VITAMIN B12 DEFICIENCY	INTRAMUSCULAR	Unknown	Ongoing
amlodipine	HYPERTENSION	ORAL	-557 days	Ongoing
losartan	HYPERTENSION	ORAL	-535 days	Ongoing
mesalazine	ULCERATIVE COLITIS	ORAL	About -519 days	Ongoing
chlorhexidine gluconate;lidocaine hydrochloride	PAIN RELIEF (BIOPSY WOUND SITE)-SEE SAE	TOPICAL	18 days	Ongoing
paracetamol	CONDYLOMATA ACUMINATUM (AE#1) - POST-OPERATIVE PAIN RELIEF	ORAL	12 days	19 days
chlorhexidine gluconate;lidocaine hydrochloride	LOCAL ANAESTHETIC FOR POST EUA AND EXCISION OF PERI-ANAL WART GROWTH (AE#1)	RECTAL	19 days	26 days
paracetamol	CONDYLOMATA ACUMINATUM (AE#1)	ORAL	19 days	26 days
mercaptopurine	ULCERATIVE COLITIS	ORAL	-445 days	112 days
metronidazole	CONDYLOMATA ACUMINATUM (AE#1)	ORAL	119 days	126 days
morphine	CONDYLOMATA ACUMINATUM (AE#1)	INTRAVENOUS	147 days	147 days
paracetamol	CONDYLOMATA ACUMINATUM (AE#1)-PAIN RELIEF	INTRAVENOUS	147 days	147 days
teicoplanin	CONDYLOMATA ACUMINATUM (AE#1)	INTRAVENOUS	147 days	147 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
enoxaparin	PROPHYLACTIC ANTICOAGULATION	SUBCUTANEOUS	147 days	148 days
paracetamol	CONDYLOMATA ACUMINATUM (AE#1	ORAL	147 days	149 days
macrogol 3350;potassium chloride;sodium bicarbonate;sodium chloride	LAXATIVE (IMPROVE HEALING AT SITE OF SURGERY)	ORAL	148 days	149 days
dihydrocodeine	CONDYLOMATA ACUMINATUM (AE#1)	ORAL	148 days	155 days
benzalkonium chloride;dimeticone;hydrocortisone;nystatin	CONDYLOMATA ACUMINATUM (AE#1)	TOPICAL	147 days	196 days
enoxaparin	PROPHYLATIC ANTICOAGULATION	SUBCUTANEOUS	196 days	196 days
morphine	CONDYLOMATA ACUMINATUM (AE#1)-PAIN RELIEF	INTRAVENOUS	196 days	196 days
paracetamol	CONDYLOMATA ACUMINATUM (AE#1)-PAIN RELIEF	INTRAVENOUS	196 days	196 days
teicoplanin	PROPHYLACTIC ANTIBIOTIC (CONDYLOMATA ACUMINATUM-AE#1)	INTRAVENOUS	196 days	196 days
paracetamol	CONDYLOMATA ACUMINATUM (AE#1)-PAIN RELIEF	ORAL	196 days	197 days
dihydrocodeine	CONDYLOMATA ACUMINATUM (AE #1) - POST-OPERATIVE ANALGESIA	ORAL	197 days	204 days
amitriptyline	CONDYLOMATA ACUMINATUM (AE#1)	ORAL	119 days	210 days

All Adverse Events						
Preferred Term	Onset Day	Resolution Day	Toxicity Grade	Causality	Action taken with Filgotinib 200mg/Placebo	Action taken with Filgotinib 100mg/Placebo
Anogenital warts	1	196	1	not related	dose not changed	dose not changed
Post procedural haemorrhage	18	19	1	not related	dose not changed	dose not changed

All Adverse Events			
Preferred Term	Action taken with Filgotinib 200mg Open Label	Action taken with Filgotinib 100mg Open Label	Action - Other
Anogenital warts	not applicable	not applicable	medication required + other treatment required
Post procedural haemorrhage	not applicable	not applicable	medication required

Hematology						
Study Day	Hemoglobin (g/dL)	Hematocrit (%)	Erythrocytes (x10^6/uL)	Platelets (x10^3/uL)	Reticulocytes (x10^6/uL)	Ery. Mean Corpuscular Volume (fL)
1	15.3 (N)	43 (N)	4.2 (L)	243 (N)	0.065 (N)	102 (H)
12	15.4 (N)	44 (N)	4.2 (L)	222 (N)	0.074 (N)	103 (H)
26	14.4 (N)	41 (N)	4 (L)	242 (N)	0.095 (N)	103 (H)
78	15.2 (N)	43 (N)	4.3 (L)	238 (N)	0.058 (N)	101 (H)
165	14.4 (N)	42 (N)	4.2 (L)	236 (N)	0.071 (N)	99 (H)
250	15.4 (N)	45 (N)	4.7 (N)	272 (N)	0.081 (N)	95 (N)
343	15.4 (N)	44 (N)	4.7 (N)	218 (N)	0.08 (N)	95 (N)
H = High; L = Low; N = Normal.						

Hematology						
Study Day	Leukocytes (x10^3/uL)	Neutrophils, Segmented (x10^3/uL)	Lymphocytes (x10^3/uL)	Monocytes (x10^3/uL)	Basophils (x10^3/uL)	Eosinophils (x10^3/uL)
1	3.47 (L)	2.52 (N)	0.54 (L)	0.29 (N)	0.01 (N)	0.12 (N)
12	3.96 (N)	2.87 (N)	0.64 (L)	0.34 (N)	0.02 (N)	0.08 (N)
26	3.66 (L)	2.8 (N)	0.47 (L)	0.25 (N)	0.02 (N)	0.12 (N)
78	4.32 (N)	3.34 (N)	0.54 (L)	0.31 (N)	0.02 (N)	0.12 (N)
165	4.73 (N)	3.34 (N)	0.83 (L)	0.39 (N)	0.07 (N)	0.1 (N)
250	4.56 (N)	3.22 (N)	0.84 (L)	0.34 (N)	0.04 (N)	0.13 (N)
343	5.68 (N)	3.9 (N)	1.17 (N)	0.45 (N)	0.03 (N)	0.12 (N)
H = High; L = Low; N = Normal.						

Chemistry						
Study Day	Fasting	Alanine Aminotransferase (U/L)	Aspartate Aminotransferase (U/L)	Alkaline Phosphatase (U/L)	Bilirubin (mg/dL)	Creatinine (mg/dL)
1	Yes	120 (H)	63 (H)	47 (N)	2.1 (H)	0.96 (N)
12	Yes	126 (H)	68 (H)	49 (N)	1.1 (N)	0.89 (N)
26	No	70 (H)	41 (H)	56 (N)	0.6 (N)	0.86 (N)
78	No	128 (H)	59 (H)	55 (N)	0.7 (N)	0.94 (N)
165	No	42 (N)	32 (N)	68 (N)	0.4 (N)	1.06 (N)
250	No	58 (H)	34 (N)	64 (N)	0.4 (N)	0.92 (N)
343	Yes	63 (H)	34 (N)	55 (N)	0.5 (N)	1.04 (N)
413	No			72 (N)		1.15 (N)
H = High; L = Low; N = Normal.						

Chemistry					
Study Day	Fasting	Creatinine Clearance (mL/min)	Creatine Kinase (U/L)	Glucose (mg/dL)	C-Reactive Protein (hs-CRP) (mg/L)
1	Yes	128.4 (H)	219 (N)	100 (N)	0.23 (N)
12	Yes	136.8 (H)	168 (N)	119 (H)	
26	No	146.4 (H)	165 (N)	141 (H)	
78	No	135 (H)	155 (N)	109 (H)	
165	No	120 (N)	166 (N)	121 (H)	0.38 (N)
250	No	138.6 (H)	175 (N)	167 (H)	
343	Yes	127.2 (H)	242 (N)	118 (H)	0.37 (N)
413	No	118.8 (N)			
H = High; L = Low; N = Normal.					

Lipid Panel					
Study Day	Fasting	Total Cholesterol (mg/dL)	HDL Cholesterol (mg/dL)	LDL Cholesterol (mg/dL)	Triglycerides (mg/dL)
1	Yes	157 (L)	52 (N)	99 (N)	73 (N)
78	No	160 (L)	63 (N)	85 (N)	102 (N)
165	No	182 (N)	75 (H)	96 (N)	123 (N)
343	Yes	172 (N)	61 (N)	92 (N)	115 (N)
H = High; L = Low; N = Normal.					

被験者識別番号：[redacted]

投与群：フィルゴチニブ 200 mg 群（非盲検）

治験薬の投与状況：有害事象により投与中止（Day 401）

ベースライン特性：本被験者は 4[redacted]歳の男性であり、人種に関する情報は取得できなかった。その他の特性として、民族は非ヒスパニック／ラテン系、フランスからの参加であった。

関節痛（Day 122～継続）（試験治療下の重篤な有害事象、投与中止に至った有害事象）：
Day 122、Grade 3 の重篤な関節痛が発現した。フィルゴチニブ 200 mg/プラセボに対する処置は非該当であった。フィルゴチニブ 100 mg/プラセボに対する処置は非該当であった。フィルゴチニブ 200 mg（非盲検）に対する処置は投与中止であった。フィルゴチニブ 100 mg（非盲検）に対する処置は非該当であった。本事象は治験薬と関連なしと判断された。試験のデータカットオフ日時点で本事象は未回復であった。

ライム病（Day 233～継続）（試験治療下の注目すべき有害事象）：
Day 233、Grade 1 の非重篤なライム病が発現した。フィルゴチニブ 200 mg/プラセボに対する処置は非該当であった。フィルゴチニブ 100 mg/プラセボに対する処置は非該当であった。フィルゴチニブ 200 mg（非盲検）に対する処置は投与中断であった。フィルゴチニブ 100 mg（非盲検）に対する処置は非該当であった。本事象は治験薬と関連なしと判断された。試験のデータカットオフ日時点で本事象は未回復であった。

その他の関連情報：特になし。

Medical History	
Medical History	**Resolution**
bundle branch block left	Ongoing
hypokalaemia	Ongoing
muscle spasms	Ongoing
skin papilloma	Ongoing
colitis ulcerative	8 days

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
glycerol;paraffin, liquid;white soft paraffin	PROPHYLAXY HAND FEET SYNDROM	TOPICAL	-223 days	Ongoing
collodion	RIGHT HAND WARTS	TOPICAL	-27 days	Ongoing
prednisolone	ULCERATIVE COLITIS	ORAL	-8 days	Ongoing
amoxicillin trihydrate	LYME DISEASE	ORAL	242 days	Ongoing

All Adverse Events					
Preferred Term	Onset Day	Resolution Day	Toxicity Grade	Causality	Action taken with Filgotinib 200mg/Placebo
Arthralgia	33	Ongoing	2	not related	not applicable
Arthralgia	122	Ongoing	3	not related	not applicable
Vertigo	124	Ongoing	1	not related	not applicable
Asthenia	192	308	1	not related	not applicable
Lyme disease	233	Ongoing	1	not related	not applicable
Asthenia	309	Ongoing	2	not related	not applicable

All Adverse Events				
Preferred Term	Action taken with Filgotinib 100mg/Placebo	Action taken with Filgotinib 200mg Open Label	Action taken with Filgotinib 100mg Open Label	Action - Other
Arthralgia	not applicable	dose not changed	not applicable	none
Arthralgia	not applicable	drug withdrawn	not applicable	permanent study discontinuation
Vertigo	not applicable	dose not changed	not applicable	none
Asthenia	not applicable	dose not changed	not applicable	none
Lyme disease	not applicable	drug interrupted	not applicable	medication required
Asthenia	not applicable	dose not changed	not applicable	none

Hematology						
Study Day	Hemoglobin (g/dL)	Hematocrit (%)	Erythrocytes (x10^6/uL)	Platelets (x10^3/uL)	Reticulocytes (x10^6/uL)	Ery. Mean Corpuscular Volume (fL)
1	13.7 (N)	40 (N)	4.6 (N)	260 (N)	0.103 (N)	86 (N)
15	13.8 (N)	42 (N)	4.7 (N)	301 (N)	0.103 (N)	89 (N)
29	14.2 (N)	44 (N)	4.9 (N)	228 (N)	0.09 (N)	91 (N)
85	13.3 (N)	39 (N)	4.5 (N)	228 (N)	0.078 (N)	86 (N)
170	13.8 (N)	40 (N)	4.7 (N)	245 (N)	0.071 (N)	86 (N)
254	14.1 (N)	40 (N)	4.7 (N)	243 (N)	0.09 (N)	86 (N)
338	14.7 (N)	41 (N)	4.9 (N)	208 (N)	0.081 (N)	85 (N)
H = High; L = Low; N = Normal.						

Hematology						
Study Day	Leukocytes (x10^3/uL)	Neutrophils, Segmented (x10^3/uL)	Lymphocytes (x10^3/uL)	Monocytes (x10^3/uL)	Basophils (x10^3/uL)	Eosinophils (x10^3/uL)
1	9.31 (N)	5.8 (N)	2.78 (N)	0.55 (N)	0.04 (N)	0.14 (N)
15	10.71 (H)	6.86 (N)	3.2 (N)	0.47 (N)	0.06 (N)	0.12 (N)
29	8.42 (N)	5.09 (N)	2.65 (N)	0.56 (N)	0.04 (N)	0.08 (N)
85	8.31 (N)	5.84 (N)	1.92 (N)	0.33 (N)	0.04 (N)	0.18 (N)
170	7.36 (N)	4.33 (N)	2.33 (N)	0.48 (N)	0.04 (N)	0.18 (N)
254	4.64 (N)	2.57 (N)	1.56 (N)	0.37 (N)	0.02 (N)	0.12 (N)
338	5.02 (N)	2.56 (N)	2.02 (N)	0.3 (N)	0.03 (N)	0.12 (N)
H = High; L = Low; N = Normal.						

Chemistry						
Study Day	Fasting	Alanine Aminotransferase (U/L)	Aspartate Aminotransferase (U/L)	Alkaline Phosphatase (U/L)	Bilirubin (mg/dL)	Creatinine (mg/dL)
1	Yes	7 (N)	11 (N)	75 (N)	0.8 (N)	0.78 (N)
15	No	11 (N)	16 (N)	78 (N)	0.5 (N)	0.79 (N)
29	No	11 (N)	15 (N)	73 (N)	1.1 (N)	0.95 (N)
85	No	11 (N)	18 (N)	82 (N)	0.6 (N)	0.8 (N)
170	No	25 (N)	24 (N)	91 (N)	0.7 (N)	0.85 (N)
254	No	27 (N)	25 (N)	73 (N)	0.6 (N)	0.83 (N)
338	Yes	18 (N)	21 (N)	99 (N)	0.7 (N)	0.88 (N)
H = High; L = Low; N = Normal.						

Chemistry					
Study Day	Fasting	Creatinine Clearance (mL/min)	Creatine Kinase (U/L)	Glucose (mg/dL)	C-Reactive Protein (hs-CRP) (mg/L)
1	Yes	122.4 (N)	21 (L)	81 (N)	2.6 (N)
15	No	120.6 (N)	30 (L)	85 (N)	
29	No	99 (N)	34 (L)	76 (N)	
85	No	119.4 (N)	32 (L)	86 (N)	
170	No	117.6 (N)	49 (N)	94 (N)	0.28 (N)
254	No	124.2 (N)	38 (L)	79 (N)	
338	Yes	110.4 (N)	54 (N)	95 (N)	<0.20 (N)
H = High; L = Low; N = Normal.					

Lipid Panel					
Study Day	Fasting	Total Cholesterol (mg/dL)	HDL Cholesterol (mg/dL)	LDL Cholesterol (mg/dL)	Triglycerides (mg/dL)
-83	No	189 (N)	73 (H)	105 (N)	102 (N)
29	No	182 (N)	80 (H)	92 (N)	73 (N)
170	No	200 (N)	80 (H)	120 (N)	79 (N)
338	Yes	191 (N)	85 (H)	115 (N)	50 (L)
H = High; L = Low; N = Normal.					

被験者識別番号：[redacted]

投与群：フィルゴチニブ 200 mg 群（非盲検）

治験薬の投与状況：有害事象により投与中止（Day 142）

ベースライン特性：本被験者は 3[redacted] 歳の白人男性であった。その他の特性として、民族は非ヒスパニック／ラテン系、英国からの参加であった。

皮下組織膿瘍（Day 132～140）（試験治療下の重篤な有害事象、投与中止に至った有害事象、試験治療下の注目すべき有害事象）：
Day 132、Grade 2 の重篤な皮下組織膿瘍が発現した。フィルゴチニブ 200 mg/プラセボに対する処置は非該当であった。フィルゴチニブ 100 mg/プラセボに対する処置は非該当であった。フィルゴチニブ 200 mg（非盲検）に対する処置は投与中止であった。フィルゴチニブ 100 mg（非盲検）に対する処置は非該当であった。本事象は治験薬と関連なしと判断された。Day 140、Grade 2 の本事象は回復した。

その他の関連情報：被験者は腰背部及び臀部上位に有痛性腫瘤の症状が認められたため、総合診療医を受診し、膿瘍と診断された。切開術及びドレナージ術の入院治療が予定された。被験者はこれらの施術のため一晩入院し、退院した。

Prior and Concomitant Medications

Concomitant Med	Indication	Route	Start Day	Stop Day
prednisolone	ULCERATIVE COLITIS	RECTAL	92 days	Ongoing
budesonide	ULCERATIVE COLITIS	ORAL	-182 days	14 days
ferric carboxymaltose	IRON DEFICIENCY ANAEMIA	INTRAVENOUS	24 days	24 days
budesonide	ULCERATIVE COLITIS	ORAL	15 days	27 days
sodium phosphate monobasic (anhydrous)	HYPOPHOSPHATAEMIA	ORAL	61 days	65 days
budesonide	ULCERATIVE COLITIS	ORAL	30 days	88 days
amoxicillin trihydrate;clavulanate potassium	INFECTION-ABSCESS	ORAL	135 days	139 days
dihydrocodeine	PAIN RELIEF	ORAL	135 days	141 days

All Adverse Events						
Preferred Term	Onset Day	Resolution Day	Toxicity Grade	Causality	Action taken with Filgotinib 200mg/Placebo	Action taken with Filgotinib 100mg/Placebo
Iron deficiency anaemia	14	30	1	not related	not applicable	not applicable
Hypophosphataemia	29	91	1	not related	not applicable	not applicable
Subcutaneous abscess	132	140	2	not related	not applicable	not applicable

All Adverse Events			
Preferred Term	Action taken with Filgotinib 200mg Open Label	Action taken with Filgotinib 100mg Open Label	Action - Other
Iron deficiency anaemia	dose not changed	not applicable	medication required
Hypophosphataemia	dose not changed	not applicable	medication required + other treatment required
Subcutaneous abscess	drug withdrawn	not applicable	medication required + other treatment required + permanent study discontinuation

Hematology						
Study Day	Hemoglobin (g/dL)	Hematocrit (%)	Erythrocytes (x10^6/uL)	Platelets (x10^3/uL)	Reticulocytes (x10^6/uL)	Ery. Mean Corpuscular Volume (fL)
1	12.1 (L)	38 (L)	4.7 (N)	466 (H)	0.039 (N)	81 (N)
14	12.9 (N)	41 (N)	5 (N)	549 (H)	0.041 (N)	81 (N)
28	12.9 (N)	40 (N)	5 (N)	645 (H)	0.053 (N)	80 (N)
91	14.3 (N)	43 (N)	5.2 (N)	468 (H)	0.077 (N)	83 (N)
148	14.5 (N)	44 (N)	5 (N)	506 (H)	0.059 (N)	87 (N)
175	14.6 (N)	44 (N)	5 (N)	495 (H)	0.048 (N)	88 (N)
H = High; L = Low; N = Normal.						

Hematology						
Study Day	Leukocytes (x10^3/uL)	Neutrophils, Segmented (x10^3/uL)	Lymphocytes (x10^3/uL)	Monocytes (x10^3/uL)	Basophils (x10^3/uL)	Eosinophils (x10^3/uL)
1	7.49 (N)	4.12 (N)	2.85 (N)	0.45 (N)	0 (N)	0.07 (N)
14	6.6 (N)	3.46 (N)	2.58 (N)	0.36 (N)	0.07 (N)	0.13 (N)
28	6.72 (N)	4.27 (N)	1.84 (N)	0.44 (N)	0.04 (N)	0.13 (N)
91	9.38 (N)	6.59 (N)	2.03 (N)	0.58 (N)	0.06 (N)	0.12 (N)
148	7.87 (N)	5.68 (N)	1.39 (N)	0.51 (N)	0.1 (N)	0.19 (N)
175	8.21 (N)	5.78 (N)	1.54 (N)	0.49 (N)	0.18 (N)	0.21 (N)
H = High; L = Low; N = Normal.						

Chemistry						
Study Day	Fasting	Alanine Aminotransferase (U/L)	Aspartate Aminotransferase (U/L)	Alkaline Phosphatase (U/L)	Bilirubin (mg/dL)	Creatinine (mg/dL)
1	Yes	13 (N)	17 (N)	71 (N)	<0.2 (L)	0.9 (N)
14	Yes	12 (N)	19 (N)	64 (N)	<0.2 (L)	0.94 (N)
28	Yes	7 (N)	12 (N)	72 (N)	0.2 (N)	0.96 (N)
91	Yes	11 (N)	16 (N)	85 (N)	0.2 (N)	0.89 (N)
148	No	11 (N)	15 (N)	89 (N)	0.2 (N)	0.92 (N)
175	Yes	7 (N)	13 (N)	104 (N)	0.4 (N)	1.03 (N)
H = High; L = Low; N = Normal.						

Chemistry					
Study Day	Fasting	Creatinine Clearance (mL/min)	Creatine Kinase (U/L)	Glucose (mg/dL)	C-Reactive Protein (hs-CRP) (mg/L)
1	Yes	128.4 (H)	157 (N)	80 (N)	8.38 (N)
14	Yes	121.8 (N)	179 (N)	102 (H)	
28	Yes	117.6 (N)	57 (N)	86 (N)	
91	Yes	133.8 (H)	109 (N)	108 (H)	
148	No	134.4 (H)	83 (N)	86 (N)	
175	Yes	115.2 (N)	66 (N)	93 (N)	
H = High; L = Low; N = Normal.					

Lipid Panel					
Study Day	Fasting	Total Cholesterol (mg/dL)	HDL Cholesterol (mg/dL)	LDL Cholesterol (mg/dL)	Triglycerides (mg/dL)
1	Yes	194 (N)	90 (H)	99 (N)	62 (N)
14	Yes	201 (N)	83 (H)	83 (N)	151 (N)
28	Yes	183 (N)	77 (H)	84 (N)	108 (N)
91	Yes	182 (N)	69 (H)	85 (N)	159 (N)
H = High; L = Low; N = Normal.					

被験者識別番号：[redacted]

投与群：フィルゴチニブ 200 mg 群（非盲検）

治験薬の投与状況：有害事象により投与中止（Day 171）

ベースライン特性：本被験者は 4[redacted] 歳のアジア系女性であった。その他の特性として、民族は非ヒスパニック／ラテン系、日本からの参加であった。

憩室炎（Day 158～166）（試験治療下の重篤な有害事象、投与中止に至った有害事象、試験治療下の注目すべき有害事象）：
Day 158、Grade 3 の重篤な憩室炎が発現した。フィルゴチニブ 200 mg/プラセボに対する処置は非該当であった。フィルゴチニブ 100 mg/プラセボに対する処置は非該当であった。フィルゴチニブ 200 mg（非盲検）に対する処置は投与中止であった。フィルゴチニブ 100 mg（非盲検）に対する処置は非該当であった。本事象は治験薬と関連ありと判断された。Day 166、Grade 3 の本事象は回復した。

その他の関連情報：心窩部痛が認められ、被験者は入院した。腹部のコンピューター断層撮影検査の結果、横行結腸壁肥厚が認められ、憩室炎の所見と一致していると考えられた。治療として食事療法、輸液及び抗生剤投与が行われた。結腸内視鏡検査の結果、横行結腸の肝彎曲部近傍に発赤がみられ、憩室炎と考えられた。潰瘍性大腸炎の増悪が疑われる所見は認められなかった。被験者は飲食が可能となり、退院した。

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
mesalazine	ULCERATIVE COLITIS	ORAL	-2437 days	Ongoing
famotidine	REFLUX ESOPHAGITIS	ORAL	-50 days	Ongoing
azelnidipine;olmesartan medoxomil	HYPERTENSION	ORAL	146 days	Ongoing
prednisolone	ULCERATIVE COLITIS	ORAL	-127 days	28 days
prednisolone	ULCERATIVE COLITIS	ORAL	29 days	55 days
prednisolone	ULCERATIVE COLITIS	ORAL	56 days	84 days
telmisartan	HYPERTENSION	ORAL	-50 days	145 days
calcium chloride dihydrate;potassium chloride;sodium acetate trihydrate;sodium chloride	DIVERTICULITIS (TRANSVERSE COLON)	INTRAVENOUS DRIP	158 days	158 days
glucose;potassium chloride;sodium chloride;sodium lactate	DIVERTICULITIS (TRANSVERSE COLON)	INTRAVENOUS DRIP	158 days	158 days
pentazocine	DIVERTICULITIS (TRANSVERSE COLON)	INTRAVENOUS	160 days	160 days
calcium gluconate monohydrate;glucose;magnesium chloride hexahydrate;potassium chloride;sodium acetate;sodium chloride;sodium citrate dihydrate	DIVERTICULITIS (TRANSVERSE COLON)	INTRAVENOUS DRIP	158 days	163 days
amino acids nos;electrolytes nos;glucose;thiamine hydrochloride	DIVERTICULITIS (TRANSVERSE COLON)	INTRAVENOUS DRIP	159 days	163 days
citric acid;magnesium oxide;sodium picosulfate	COLONOSCOPY	ORAL	163 days	163 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
flumazenil	COLONOSCOPY	INTRAVENOUS	163 days	163 days
lidocaine	COLONOSCOPY	TOPICAL	163 days	163 days
midazolam	COLONOSCOPY	INTRAVENOUS	163 days	163 days
cefmetazole sodium	DIVERTICULITIS (TRANSVERSE COLON)	INTRAVENOUS DRIP	158 days	164 days
sodium chloride	DIVERTICULITIS (TRANSVERSE COLON)	OTHER	158 days	164 days

All Adverse Events						
Preferred Term	Onset Day	Resolution Day	Toxicity Grade	Causality	Action taken with Filgotinib 200mg/Placebo	Action taken with Filgotinib 100mg/Placebo
Diverticulitis	158	166	3	related	not applicable	not applicable

All Adverse Events			
Preferred Term	Action taken with Filgotinib 200mg Open Label	Action taken with Filgotinib 100mg Open Label	Action - Other
Diverticulitis	drug withdrawn	not applicable	medication required + other treatment required + permanent study discontinuation

Hematology						
Study Day	Hemoglobin (g/dL)	Hematocrit (%)	Erythrocytes (x10^6/uL)	Platelets (x10^3/uL)	Reticulocytes (x10^6/uL)	Ery. Mean Corpuscular Volume (fL)
-1	15 (N)	49 (H)	5.1 (N)	214 (N)	0.092 (N)	96 (N)
14	14.8 (N)	46 (N)	4.9 (N)	227 (N)	0.096 (N)	94 (N)
28	15.7 (N)	48 (N)	5.1 (N)		0.094 (N)	95 (N)
77	15.1 (N)	47 (N)	4.8 (N)	209 (N)	0.115 (N)	98 (N)
175	13.9 (N)	44 (N)	4.5 (N)	329 (N)	0.064 (N)	97 (N)
203	13.7 (N)	42 (N)	4.4 (N)	225 (N)	0.087 (N)	97 (N)
H = High; L = Low; N = Normal.						

Hematology						
Study Day	Leukocytes (x10^3/uL)	Neutrophils, Segmented (x10^3/uL)	Lymphocytes (x10^3/uL)	Monocytes (x10^3/uL)	Basophils (x10^3/uL)	Eosinophils (x10^3/uL)
-1	10.94 (H)	9.68 (H)	0.94 (N)	0.25 (N)	0.03 (N)	0.03 (N)
14	7.37 (N)	5.65 (N)	1.42 (N)	0.24 (N)	0.03 (N)	0.03 (N)
28	6.1 (N)	4.07 (N)	1.69 (N)	0.26 (N)	0.03 (N)	0.05 (N)
77	3.65 (L)	2.23 (N)	1.22 (N)	0.15 (N)	0.01 (N)	0.04 (N)
175	3.81 (N)	2.27 (N)	1.29 (N)	0.17 (N)	0.03 (N)	0.06 (N)
203	3.84 (N)	2.11 (N)	1.4 (N)	0.17 (N)	0.04 (N)	0.14 (N)
H = High; L = Low; N = Normal.						

Chemistry						
Study Day	Fasting	Alanine Aminotransferase (U/L)	Aspartate Aminotransferase (U/L)	Alkaline Phosphatase (U/L)	Bilirubin (mg/dL)	Creatinine (mg/dL)
-1	No	17 (N)	17 (N)	64 (N)	0.3 (N)	0.74 (N)
14	Yes	21 (N)	19 (N)	62 (N)	0.5 (N)	0.83 (N)
28	Yes	23 (N)	22 (N)	62 (N)	0.4 (N)	0.83 (N)
77	Yes	27 (N)	28 (N)	70 (N)	0.7 (N)	0.7 (N)
175	Yes	18 (N)	23 (N)	64 (N)	0.4 (N)	0.71 (N)
203	No	21 (N)	23 (N)	62 (N)	0.5 (N)	0.72 (N)
H = High; L = Low; N = Normal.						

Chemistry					
Study Day	Fasting	Creatinine Clearance (mL/min)	Creatine Kinase (U/L)	Glucose (mg/dL)	C-Reactive Protein (hs-CRP) (mg/L)
-1	No	67.2 (L)	67 (N)	79 (N)	0.44 (N)
14	Yes	60.6 (L)	111 (N)	74 (N)	
28	Yes	60.6 (L)	90 (N)	75 (N)	
77	Yes	72 (L)	168 (N)	76 (N)	
175	Yes	66.6 (L)	119 (N)	82 (N)	1.75 (N)
203	No	67.2 (L)	125 (N)	83 (N)	
H = High; L = Low; N = Normal.					

Lipid Panel					
Study Day	Fasting	Total Cholesterol (mg/dL)	HDL Cholesterol (mg/dL)	LDL Cholesterol (mg/dL)	Triglycerides (mg/dL)
-8	Yes	239 (N)	75 (N)	167 (H)	59 (N)
175	Yes	186 (N)	53 (N)	132 (H)	90 (N)
H = High; L = Low; N = Normal.					

被験者識別番号：[redacted]

投与群：フィルゴチニブ 200 mg 群（非盲検）

治験薬の投与状況：有害事象により投与中止（Day 601）

ベースライン特性：本被験者は 4[redacted] 歳の白人男性であった。その他の特性として、民族は非ヒスパニック／ラテン系、フランスからの参加であった。

歯膿瘍（Day 145～258）（試験治療下の注目すべき有害事象［TE-AEI］）：
Day 145、Grade 2 の非重篤な歯膿瘍が発現した。フィルゴチニブ 200 mg/プラセボに対する処置は非該当であった。フィルゴチニブ 100 mg/プラセボに対する処置は非該当であった。フィルゴチニブ 200 mg（非盲検）に対する処置は投与中断であった。フィルゴチニブ 100 mg（非盲検）に対する処置は非該当であった。本事象は治験薬と関連なしと判断された。Day 258、Grade 2 の本事象は回復した。

気管支炎（Day 200～253 頃）（TE-AEI）：
Day 200、Grade 2 の非重篤な気管支炎が発現した。フィルゴチニブ 200 mg/プラセボに対する処置は非該当であった。フィルゴチニブ 100 mg/プラセボに対する処置は非該当であった。フィルゴチニブ 200 mg（非盲検）に対する処置は変更なし。フィルゴチニブ 100 mg（非盲検）に対する処置は非該当であった。本事象は治験薬と関連ありと判断された。Day 253 頃に、Grade 2 の本事象は回復した。

皮膚真菌感染（Day 416～438）（TE-AEI）：
Day 416、Grade 2 の非重篤な皮膚真菌感染が発現した。フィルゴチニブ 200 mg/プラセボに対する処置は非該当であった。フィルゴチニブ 100 mg/プラセボに対する処置は非該当であった。フィルゴチニブ 200 mg（非盲検）に対する処置は変更なし。フィルゴチニブ 100 mg（非盲検）に対する処置は非該当であった。本事象は治験薬と関連なしと判断された。Day 438、Grade 2 の本事象は回復した。

肺炎（Day 600～607）（試験治療下の重篤な有害事象、投与中止に至った有害事象、TE-AEI）：
Day 600、Grade 3 の重篤な肺炎が発現した。フィルゴチニブ 200 mg/プラセボに対する処置は非該当であった。フィルゴチニブ 100 mg/プラセボに対する処置は非該当であった。フィルゴチニブ 200 mg（非盲検）に対する処置は投与中止であった。フィルゴチニブ 100 mg（非盲検）に対する処置は非該当であった。本事象は治験薬と関連ありと判断された。Day 607、Grade 3 の本事象は回復した。

その他の関連情報：被験者は当初、背部痛及び発熱が認められたため入院した。C 反応性タンパク値及び白血球数値の上昇が認められた。胸部及び腹部のコンピューター断層撮影検査の結果、腹骨盤底に進行性病変の所見は認められず、肺実質にいくつかの病巣及び下肺野に実質性感染が

認められた。抗生剤を含む薬物療法による治療が行われた。インフルエンザ感染及びレジオネラ症は認められなかった。血液培養検査の結果は陰性であった。その後、発熱、咳嗽及び疼痛はみられず、肺の検査結果は正常であった。被験者は退院し、抗生剤が処方された。本事象は回復したと考えられた。

Medical History	
Medical History	**Resolution**
headache	Ongoing
muscle spasms	Ongoing

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
salbutamol	ASTHMA	RESPIRATORY (INHALATION)	About -12224 days	Ongoing
paracetamol	HEADACHE	ORAL	-11 days	Ongoing
mesalazine	ULCERATIVE COLITIS	ORAL	470 days	Ongoing
chlorhexidine gluconate;chlorocresol;hexamidine isetionate	CUTANEOUS MACULES	CUTANEOUS	499 days	Ongoing
mupirocin	CUTANEOUS MACULES	CUTANEOUS	499 days	Ongoing

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
fondaparinux sodium	SUPERFICIAL VENOUS THROMBOSIS	SUBCUTANEOUS	605 days	Ongoing
diflucortolone valerate	CUTANEOUS MACULE	CUTANEOUS	609 days	Ongoing
prednisolone	ULCERATIVE COLITIS	ORAL	-118 days	28 days
prednisolone	ULCERATIVE COLITIS	ORAL	29 days	35 days
prednisolone	ULCERATIVE COLITIS	ORAL	36 days	42 days
prednisolone	ULCERATIVE COLITIS	ORAL	43 days	49 days
prednisolone	ULCERATIVE COLITIS	ORAL	50 days	56 days
prednisolone	ULCERATIVE COLITIS	ORAL	64 days	70 days
prednisolone	ULCERATIVE COLITIS	ORAL	71 days	77 days
apixaban	THROMBOEMBOLIC PREVENTION	ORAL	-140 days	84 days
hydrocortisone	ULCERATIVE COLITIS	ORAL	82 days	84 days
influenza vaccine inact split virion 3v	FLU PREVENTION	INTRAMUSCULAR	139 days	139 days
amoxicillin	DENTAL ABCESS	ORAL	147 days	153 days
chlorhexidine gluconate;chlorobutanol	DENTAL ABCESS	BUCCAL	147 days	153 days
metronidazole;spiramycin	DENTAL ABCESS	ORAL	157 days	162 days
prednisolone	OTALGY	ORAL	189 days	193 days
fludrocortisone acetate;lidocaine hydrochloride;neomycin sulfate;polymyxin b sulfate	OTALGY	AURICULAR (OTIC)	189 days	195 days
prednisolone	OTALGY	ORAL	194 days	198 days
acetylcysteine	BRONCHITIS	ORAL	201 days	205 days
amoxicillin	BRONCHITIS	ORAL	201 days	206 days
amphotericin b	DENTAL ABCESS	BUCCAL	157 days	About 253 days
chlorhexidine gluconate	DENTAL ABCESS	BUCCAL	157 days	About 253 days
bilastine	OTALGY	ORAL	189 days	About 253 days
avena sativa;copper sulfate;zinc oxide;zinc sulfate	CUTANEOUS MACULES	CUTANEOUS	338 days	345 days
mupirocin	CUTANEOUS MACULES	CUTANEOUS	338 days	345 days
amoxicillin	CUTANEOUS MACULES	ORAL	379 days	384 days
avena sativa;copper sulfate;zinc oxide;zinc sulfate	CUTANEOUS MACULES	CUTANEOUS	379 days	386 days
mupirocin	CUTANEOUS MACULES	CUTANEOUS	379 days	386 days
pristinamycin	CUTANEOUS MACULES	ORAL	402 days	409 days
prednisolone	ULCERATIVE COLITIS	ORAL	422 days	428 days
doxycycline	CUTANEOUS MACULES	ORAL	410 days	431 days
econazole	CUTANEOUS MACULES	CUTANEOUS	422 days	438 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
econazole	INGUINAL FUNGUS	CUTANEOUS	422 days	438 days
chlorhexidine gluconate;chlorocresol;hexamidine isetionate	CUTANEOUS MACULES	CUTANEOUS	338 days	450 days
aminosalicylate sodium	ULCERATIVE COLITIS	RECTAL	470 days	About 559 days
diflucortolone valerate	CUTANEOUS MACULE	CUTANEOUS	583 days	599 days
doxycycline	CUTANEOUS MACULE	ORAL	583 days	599 days
paracetamol	PARENCHYMAL INFECTION OF THE LOW PULMONARY SPHERE	INTRAVENOUS	600 days	601 days
spiramycin	PARENCHYMAL INFECTION OF THE LOW PULMONARY SPHERE	ORAL	601 days	About 601 days
morphine	PARENCHYMAL INFECTION OF THE LOW PULMONARY SPHERE	INTRAVENOUS	600 days	602 days
enoxaparin sodium	PROPHYLAXIA THROBOEMBOLIC	SUBCUTANEOUS	602 days	604 days
morphine	PARENCHYMAL INFECTION OF THE LOW PULMONARY SPHERE	ORAL	603 days	606 days
amoxicillin trihydrate;clavulanate potassium	PARENCHYMAL INFECTION OF THE LOW PULMONARY SPHERE	INTRAVENOUS	603 days	608 days
nefopam hydrochloride	PARENCHYMAL INFECTION OF THE LOW PULMONARY SPHERE	INTRAVENOUS	600 days	610 days
amoxicillin	PARENCHYMAL INFECTION OF THE LOW PULMONARY SPHERE	ORAL	603 days	617 days
amoxicillin trihydrate;clavulanate potassium	PARENCHYMAL INFECTION OF THE LOW PULMONARY SPHERE	ORAL	608 days	617 days
mesalazine	ULCERATIVE COLITIS	RECTAL	615 days	620 days

All Adverse Events						
Preferred Term	Onset Day	Resolution Day	Toxicity Grade	Causality	Action taken with Filgotinib 200mg/Placebo	Action taken with Filgotinib 100mg/Placebo
Tooth abscess	145	258	2	not related	not applicable	not applicable
Ear pain	178	About 253	2	related	not applicable	not applicable
Bronchitis	200	About 253	2	related	not applicable	not applicable
Dental caries	258	258	1	not related	not applicable	not applicable
Headache	322	329	2	related	not applicable	not applicable
Rash macular	322	Ongoing	1	related	not applicable	not applicable
Fungal skin infection	416	438	2	not related	not applicable	not applicable
Colitis ulcerative	468	504	2	not related	not applicable	not applicable
Pneumonia	600	607	3	related	not applicable	not applicable
Thrombophlebitis superficial	605	Ongoing	2	related	not applicable	not applicable

All Adverse Events			
Preferred Term	Action taken with Filgotinib 200mg Open Label	Action taken with Filgotinib 100mg Open Label	Action - Other
Tooth abscess	drug interrupted	not applicable	medication required + other treatment required
Ear pain	dose not changed	not applicable	medication required
Bronchitis	dose not changed	not applicable	medication required
Dental caries	drug interrupted	not applicable	other treatment required
Headache	dose not changed	not applicable	medication required
Rash macular	dose not changed	not applicable	medication required + other treatment required
Fungal skin infection	dose not changed	not applicable	medication required
Colitis ulcerative	dose not changed	not applicable	medication required
Pneumonia	drug withdrawn	not applicable	medication required + permanent study discontinuation
Thrombophlebitis superficial	not applicable	not applicable	medication required

Hematology						
Study Day	Hemoglobin (g/dL)	Hematocrit (%)	Erythrocytes (x10^6/uL)	Platelets (x10^3/uL)	Reticulocytes (x10^6/uL)	Ery. Mean Corpuscular Volume (fL)
-1	12.6 (L)	39 (N)	4.8 (N)	228 (N)	0.085 (N)	82 (N)
14	12.1 (L)	39 (N)	4.6 (N)	232 (N)	0.079 (N)	84 (N)
28	12.1 (L)	39 (N)	4.6 (N)	206 (N)	0.08 (N)	85 (N)
84	13.6 (N)	43 (N)	5 (N)	237 (N)	0.055 (N)	86 (N)
161	14.8 (N)	43 (N)	5.1 (N)	278 (N)	0.096 (N)	85 (N)
245	15.1 (N)	44 (N)	5 (N)	215 (N)	0.084 (N)	89 (N)
336	15 (N)	44 (N)	4.9 (N)	216 (N)	0.102 (N)	88 (N)
428	15.4 (N)	46 (N)	5.1 (N)	216 (N)	0.075 (N)	92 (N)
470	15.8 (N)	46 (N)	5.1 (N)	220 (N)	0.088 (N)	89 (N)
504	15.5 (N)	45 (N)	5.1 (N)	230 (N)	0.097 (N)	88 (N)
582	15.6 (N)	44 (N)	5 (N)	227 (N)	0.087 (N)	88 (N)
H = High; L = Low; N = Normal.						

Hematology						
Study Day	Leukocytes (x10^3/uL)	Neutrophils, Segmented (x10^3/uL)	Lymphocytes (x10^3/uL)	Monocytes (x10^3/uL)	Basophils (x10^3/uL)	Eosinophils (x10^3/uL)
-1	5.03 (N)	3.54 (N)	1.06 (N)	0.33 (N)	0.03 (N)	0.08 (N)
14	4.78 (N)	3.18 (N)	1.36 (N)	0.18 (N)	0.02 (N)	0.03 (N)
28	4.99 (N)	3.18 (N)	1.53 (N)	0.22 (N)	0.02 (N)	0.03 (N)
84	5.08 (N)	3.55 (N)	1.13 (N)	0.3 (N)	0.03 (N)	0.08 (N)
161	5.61 (N)	3.43 (N)	1.67 (N)	0.37 (N)	0.04 (N)	0.1 (N)
245	3.63 (L)	2.3 (N)	0.99 (N)	0.23 (N)	0.02 (N)	0.09 (N)
336	4.96 (N)	3.04 (N)	1.46 (N)	0.28 (N)	0.02 (N)	0.15 (N)
428	6.15 (N)	3.98 (N)	1.45 (N)	0.42 (N)	0.04 (N)	0.26 (N)
470	7.14 (N)	5.26 (N)	1.33 (N)	0.4 (N)	0.02 (N)	0.13 (N)
504	5.81 (N)	3.75 (N)	1.51 (N)	0.32 (N)	0.03 (N)	0.21 (N)
582	6.8 (N)	4.8 (N)	1.29 (N)	0.38 (N)	0.02 (N)	0.31 (N)
H = High; L = Low; N = Normal.						

Chemistry						
Study Day	Fasting	Alanine Aminotransferase (U/L)	Aspartate Aminotransferase (U/L)	Alkaline Phosphatase (U/L)	Bilirubin (mg/dL)	Creatinine (mg/dL)
-1	No	15 (N)	13 (N)	52 (N)	0.2 (N)	1 (N)
14	No	16 (N)	12 (N)	54 (N)	0.3 (N)	1.05 (N)
28	No	17 (N)	15 (N)	58 (N)	0.2 (N)	1.02 (N)
84	No	25 (N)	20 (N)	62 (N)	0.4 (N)	1.06 (N)
161	Yes	54 (H)	36 (N)	74 (N)	0.4 (N)	1.06 (N)
245	No	49 (H)	30 (N)	66 (N)	0.4 (N)	0.98 (N)
336	Yes	44 (H)	27 (N)	62 (N)	0.5 (N)	1.07 (N)
428	No	43 (N)	25 (N)	69 (N)	0.4 (N)	1.05 (N)
470		43 (N)	25 (N)	62 (N)	0.5 (N)	1.13 (N)
504	Yes	34 (N)	22 (N)	58 (N)	0.5 (N)	1.05 (N)
582	No	57 (H)	27 (N)	66 (N)	0.3 (N)	1.04 (N)
H = High; L = Low; N = Normal.						

Chemistry					
Study Day	Fasting	Creatinine Clearance (mL/min)	Creatine Kinase (U/L)	Glucose (mg/dL)	C-Reactive Protein (hs-CRP) (mg/L)
-1	No	124.8 (N)	103 (N)	97 (N)	0.62 (N)
14	No	118.8 (N)	100 (N)	92 (N)	
28	No	122.4 (N)	113 (N)	97 (N)	
84	No	120 (N)	131 (N)	92 (N)	
161	Yes	121.2 (N)	141 (N)	87 (N)	1.33 (N)
245	No	136.2 (H)	211 (N)	95 (N)	
336	Yes	123.6 (N)	157 (N)	92 (N)	1.01 (N)
428	No	126.6 (H)	119 (N)	92 (N)	
470		114.6 (N)	122 (N)	95 (N)	1.49 (N)
504	Yes	125.4 (H)	112 (N)	90 (N)	1.73 (N)
582	No	127.8 (H)	169 (N)	133 (H)	
H = High; L = Low; N = Normal.					

Lipid Panel					
Study Day	Fasting	Total Cholesterol (mg/dL)	HDL Cholesterol (mg/dL)	LDL Cholesterol (mg/dL)	Triglycerides (mg/dL)
-9	Yes	180 (N)	72 (H)	101 (N)	73 (N)
161	Yes	202 (N)	69 (H)	127 (N)	78 (N)
336	Yes	210 (N)	55 (N)	135 (H)	151 (N)
470		227 (N)	58 (N)	158 (H)	108 (N)

Lipid Panel					
Study Day	Fasting	Total Cholesterol (mg/dL)	HDL Cholesterol (mg/dL)	LDL Cholesterol (mg/dL)	Triglycerides (mg/dL)
504	Yes	210 (N)	56 (N)	134 (H)	111 (N)
H = High; L = Low; N = Normal.					

被験者識別番号：[redacted]

投与群：フィルゴチニブ 200 mg 群（非盲検）

治験薬の投与状況：継続

ベースライン特性：本被験者は 3[redacted] 歳の白人女性であった。その他の特性として、民族はヒスパニック／ラテン系、フランスからの参加であった。

副鼻腔炎（Day 146～150）（試験治療下の注目すべき有害事象［TE-AEI］）：
Day 146、Grade 2 の非重篤な副鼻腔炎が発現した。フィルゴチニブ 200 mg/プラセボに対する処置は非該当であった。フィルゴチニブ 100 mg/プラセボに対する処置は非該当であった。フィルゴチニブ 200 mg（非盲検）に対する処置は変更なし。フィルゴチニブ 100 mg（非盲検）に対する処置は非該当であった。本事象は治験薬と関連ありと判断された。Day 150、Grade 2 の本事象は回復した。

手首関節骨折（Day 378～447）（試験治療下の重篤な有害事象）：
Day 378、Grade 3 の重篤な手首関節骨折が発現した。フィルゴチニブ 200 mg/プラセボに対する処置は非該当であった。フィルゴチニブ 100 mg/プラセボに対する処置は非該当であった。フィルゴチニブ 200 mg（非盲検）に対する処置は変更なし。フィルゴチニブ 100 mg（非盲検）に対する処置は非該当であった。本事象は治験薬と関連なしと判断された。Day 447、Grade 3 の本事象は回復した。

鼻炎（Day 555～573）（TE-AEI）：
Day 555、Grade 1 の非重篤な鼻炎が発現した。フィルゴチニブ 200 mg/プラセボに対する処置は非該当であった。フィルゴチニブ 100 mg/プラセボに対する処置は非該当であった。フィルゴチニブ 200 mg（非盲検）に対する処置は変更なし。フィルゴチニブ 100 mg（非盲検）に対する処置は非該当であった。本事象は治験薬と関連ありと判断された。Day 573、Grade 1 の本事象は回復した。

鼻炎（Day 585～継続）（TE-AEI）：
Day 585、Grade 1 の非重篤な鼻炎が発現した。フィルゴチニブ 200 mg/プラセボに対する処置は非該当であった。フィルゴチニブ 100 mg/プラセボに対する処置は非該当であった。フィルゴチニブ 200 mg（非盲検）に対する処置は変更なし。フィルゴチニブ 100 mg（非盲検）に対する処置は非該当であった。本事象は治験薬と関連ありと判断された。試験のデータカットオフ日時点で本事象は未回復であった。

その他の関連情報：特になし。

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
desogestrel	CONTRACEPTIVE	ORAL	-213 days	Ongoing
apixaban	PREVENTION CIRCULATORY DISORDERS	ORAL	About 354 days	Ongoing
prednisolone	ULCERATIVE COLITIS	ORAL	-213 days	19 days
diosmin;hesperidin	PREVENTION CIRCULATORY DISORDERS	ORAL	-536 days	20 days
diosmectite	ULCERATIVE COLITIS	ORAL	-59 days	20 days
prednisolone	ULCERATIVE COLITIS	ORAL	20 days	35 days
thiocolchicoside	FRACTURE OF THE RIGHT ILIOPUBIC BRANCH	ORAL	35 days	37 days
prednisolone	ULCERATIVE COLITIS	ORAL	36 days	37 days
paracetamol	FRACTURE OF THE RIGHT ILIOPUBIC BRANCH	ORAL	35 days	40 days
tramadol	FRACTURE OF THE RIGHT ILIOPUBIC BRANCH	ORAL	35 days	40 days
prednisolone	ULCERATIVE COLITIS	ORAL	38 days	47 days
papaver somniferum;paracetamol	LOMBALGY	ORAL	-74 days	About 50 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
prednisolone	ULCERATIVE COLITIS	ORAL	48 days	52 days
prednisolone	ULCERATIVE COLITIS	ORAL	53 days	71 days
amoxicillin	SINUSITIS	ORAL	146 days	150 days
tixocortol pivalate	SINUSITIS	RESPIRATORY (INHALATION)	146 days	150 days
prednisolone	ULCERATIVE COLITIS	ORAL	72 days	155 days
diosmin;hesperidin	HEMOROIDIS	ORAL	159 days	161 days
ascorbic acid;herbal extract nos;hesperidin methyl chalcone;pancreas extract	HEMOROIDIS	RECTAL	160 days	163 days
protectives against uv-radiation for topical use	ROSACEE FACE	TOPICAL	159 days	About 172 days
valaciclovir hydrochloride	ROSACEE FACE	ORAL	160 days	About 172 days
prednisolone	ULCERATIVE COLITIS	ORAL	156 days	194 days
potassium chloride	PROPHYLAXIA HYPOKALIEMA	ORAL	-536 days	195 days
calcium carbonate;colecalciferol	PROPHYLAXIA HYPOCALCEMIA	ORAL	26 days	215 days
prednisolone	ULCERATIVE COLITIS	ORAL	195 days	225 days
protectives against uv-radiation for topical use	ROSACEE FACE	TOPICAL	252 days	About 292 days
dexchlorpheniramine maleate	CUTANEOUS REACTION TO MORPHINE INJECTION	INTRAVENOUS	378 days	378 days
morphine	RIGHT WRIST FRACTURE	INTRAVENOUS	378 days	378 days
paracetamol	RIGHT WRIST FRACTURE	INTRAVENOUS	378 days	378 days
fluindione	PREVENTION CIRCULATORY DISORDERS	ORAL	About -438 days	About 384 days
nefopam hydrochloride	RIGHT WRIST FRACTURE	INTRAVENOUS	384 days	384 days
tramadol	RIGHT WRIST FRACTURE	INTRAVENOUS	384 days	384 days
paracetamol	RIGHT WRIST FRACTURE	INTRAVENOUS	384 days	385 days
paracetamol;tramadol hydrochloride	RIGHT WRIST FRACTURE	ORAL	378 days	392 days
paracetamol	RIGHT WRIST FRACTURE	ORAL	385 days	392 days
mesalazine	ULCERATIVE COLITIS	ORAL	About -438 days	About 415 days
calcium carbonate	PROPHYLAXIA HYPOCALCEMIA	ORAL	216 days	About 506 days
domperidone	STOMACH PAIN	ORAL	534 days	542 days
esomeprazole	STOMACH PAIN	ORAL	534 days	548 days
oxymetazoline	RHINITIS	NASAL	557 days	562 days
cough and cold preparations	RHINITIS	ORAL	557 days	573 days
helicidine	RHINITIS	ORAL	557 days	573 days
budesonide;formoterol fumarate	RHINITIS	NASAL	568 days	575 days

All Adverse Events					
Preferred Term	Onset Day	Resolution Day	Toxicity Grade	Causality	Action taken with Filgotinib 200mg/Placebo
Rash macular	20	140	1	not related	not applicable
Pubis fracture	35	41	2	not related	not applicable
Radius fracture	35	160	2	not related	not applicable
Sinusitis	146	150	2	related	not applicable
Haemorrhoids	159	163	1	not related	not applicable
Asthenia	195	Ongoing	1	related	not applicable
Aphthous ulcer	238	About 323	1	not related	not applicable
Meniscus injury	323	354	1	not related	not applicable
Drug hypersensitivity	378	378	1	not related	not applicable
Wrist fracture	378	447	3	not related	not applicable
Abdominal pain upper	530	552	1	not related	not applicable
Rhinitis	555	573	1	related	not applicable
Rhinitis	585	Ongoing	1	related	not applicable

All Adverse Events				
Preferred Term	Action taken with Filgotinib 100mg/Placebo	Action taken with Filgotinib 200mg Open Label	Action taken with Filgotinib 100mg Open Label	Action - Other
Rash macular	not applicable	dose not changed	not applicable	other treatment required
Pubis fracture	not applicable	dose not changed	not applicable	medication required + other treatment required
Radius fracture	not applicable	dose not changed	not applicable	other treatment required
Sinusitis	not applicable	dose not changed	not applicable	medication required
Haemorrhoids	not applicable	dose not changed	not applicable	medication required
Asthenia	not applicable	dose not changed	not applicable	none
Aphthous ulcer	not applicable	dose not changed	not applicable	none
Meniscus injury	not applicable	dose not changed	not applicable	none
Drug hypersensitivity	not applicable	dose not changed	not applicable	medication required
Wrist fracture	not applicable	dose not changed	not applicable	medication required + other treatment required
Abdominal pain upper	not applicable	dose not changed	not applicable	medication required
Rhinitis	not applicable	dose not changed	not applicable	medication required
Rhinitis	not applicable	dose not changed	not applicable	none

Hematology						
Study Day	Hemoglobin (g/dL)	Hematocrit (%)	Erythrocytes (x10^6/uL)	Platelets (x10^3/uL)	Reticulocytes (x10^6/uL)	Ery. Mean Corpuscular Volume (fL)
-1	13.9 (N)	41 (N)	4.4 (N)	273 (N)	0.112 (N)	93 (N)
18	13.7 (N)	41 (N)	4.2 (N)	264 (N)	0.087 (N)	97 (N)
25	13.7 (N)	42 (N)	4.2 (N)	251 (N)	0.085 (N)	101 (H)
77	14.3 (N)	41 (N)	4.4 (N)	282 (N)	0.064 (N)	94 (N)
160	14.2 (N)	41 (N)	4.3 (N)	248 (N)	0.046 (N)	95 (N)
245	13.4 (N)	39 (N)	4.1 (N)	226 (N)	0.043 (N)	94 (N)
342	14 (N)	42 (N)	4.5 (N)	178 (N)	0.044 (N)	94 (N)
420	13.4 (N)	39 (N)	4.2 (N)	242 (N)	0.045 (N)	94 (N)
503	13.9 (N)	41 (N)	4.4 (N)	224 (N)	0.057 (N)	93 (N)
586	13.1 (N)	38 (N)	4.1 (N)	234 (N)	0.073 (N)	92 (N)
H = High; L = Low; N = Normal.						

Hematology						
Study Day	Leukocytes (x10^3/uL)	Neutrophils, Segmented (x10^3/uL)	Lymphocytes (x10^3/uL)	Monocytes (x10^3/uL)	Basophils (x10^3/uL)	Eosinophils (x10^3/uL)
-1	9.37 (N)	7.26 (H)	1.62 (N)	0.45 (N)	0.02 (N)	0.02 (N)
18	8.72 (N)	4.97 (N)	3.03 (N)	0.63 (N)	0.04 (N)	0.04 (N)
25	7.37 (N)	3.91 (N)	2.6 (N)	0.75 (N)	0.02 (N)	0.09 (N)
77	6.91 (N)	5.91 (N)	0.71 (L)	0.27 (N)	0.01 (N)	0.02 (N)
160	6.87 (N)	4.03 (N)	2.2 (N)	0.54 (N)	0.04 (N)	0.07 (N)
245	4.56 (N)	2.51 (N)	1.59 (N)	0.32 (N)	0.03 (N)	0.1 (N)
342	3.85 (N)	2.21 (N)	1.26 (N)	0.25 (N)	0.02 (N)	0.11 (N)
420	5.95 (N)	3.94 (N)	1.59 (N)	0.32 (N)	0.04 (N)	0.05 (N)
503	5.1 (N)	3.32 (N)	1.23 (N)	0.28 (N)	0.05 (N)	0.22 (N)
586	6.1 (N)	3.74 (N)	1.3 (N)	0.61 (N)	0.01 (N)	0.44 (N)
H = High; L = Low; N = Normal.						

Chemistry						
Study Day	Fasting	Alanine Aminotransferase (U/L)	Aspartate Aminotransferase (U/L)	Alkaline Phosphatase (U/L)	Bilirubin (mg/dL)	Creatinine (mg/dL)
-1	No	23 (N)	15 (N)	48 (N)	0.4 (N)	1.14 (N)
18	No	16 (N)	17 (N)	42 (N)	0.5 (N)	0.89 (N)
25	No	19 (N)	20 (N)	41 (N)	0.6 (N)	0.92 (N)
77	No	27 (N)	21 (N)	49 (N)	0.6 (N)	1 (N)
160	Yes	19 (N)	21 (N)	52 (N)	0.5 (N)	0.89 (N)
245	No	37 (H)	40 (H)	59 (N)	0.3 (N)	0.81 (N)
342	Yes	30 (N)	29 (N)	63 (N)	0.4 (N)	0.8 (N)
420	No	20 (N)	24 (N)	55 (N)	0.6 (N)	0.88 (N)
503	Yes	23 (N)	23 (N)	59 (N)	0.8 (N)	0.85 (N)
586	No	19 (N)	23 (N)	68 (N)	0.4 (N)	0.81 (N)
H = High; L = Low; N = Normal.						

Chemistry					
Study Day	Fasting	Creatinine Clearance (mL/min)	Creatine Kinase (U/L)	Glucose (mg/dL)	C-Reactive Protein (hs-CRP) (mg/L)
-1	No	72 (L)	64 (N)	82 (N)	3.2 (N)
18	No	90.6 (N)	93 (N)	81 (N)	
25	No	86.4 (N)	95 (N)	71 (N)	
77	No	76.8 (N)	79 (N)	71 (N)	
160	Yes	82.8 (N)	135 (N)	82 (N)	0.99 (N)
245	No	90.6 (N)	201 (H)	82 (N)	
342	Yes	91.2 (N)	184 (N)	84 (N)	0.68 (N)
420	No	81 (N)	146 (N)	87 (N)	
503	Yes	86.4 (N)	165 (N)	79 (N)	0.69 (N)
586	No	90.6 (N)	141 (N)	67 (L)	
H = High; L = Low; N = Normal.					

Lipid Panel					
Study Day	Fasting	Total Cholesterol (mg/dL)	HDL Cholesterol (mg/dL)	LDL Cholesterol (mg/dL)	Triglycerides (mg/dL)
-3	Yes	185 (N)	70 (N)	98 (N)	123 (N)
25	No	172 (N)	75 (N)	88 (N)	81 (N)
77	No	177 (N)	77 (N)	94 (N)	80 (N)
160	Yes	164 (N)	79 (H)	73 (N)	76 (N)
342	Yes	181 (N)	75 (N)	96 (N)	72 (N)

Lipid Panel					
Study Day	Fasting	Total Cholesterol (mg/dL)	HDL Cholesterol (mg/dL)	LDL Cholesterol (mg/dL)	Triglycerides (mg/dL)
503	Yes	157 (N)	71 (N)	80 (N)	58 (N)
H = High; L = Low; N = Normal.					

被験者識別番号：[redacted]

投与群：フィルゴチニブ 100 mg 群

治験薬の投与状況：継続

ベースライン特性：本被験者は 3[redacted] 歳のアジア系男性であった。その他の特性として、民族は非ヒスパニック／ラテン系、インドからの参加であった。

腹痛（Day 404～409）（試験治療下の重篤な有害事象［TE-SAE］）：
Day 404、Grade 2 の重篤な腹痛が発現した。フィルゴチニブ 200 mg/プラセボに対する処置は変更なし。フィルゴチニブ 100 mg/プラセボに対する処置は変更なし。フィルゴチニブ 200 mg（非盲検）に対する処置は非該当であった。フィルゴチニブ 100 mg（非盲検）に対する処置は非該当であった。本事象は治験薬と関連なしと判断された。Day 409、Grade 2 の本事象は回復した。

腎細胞癌（Day 407～428）（TE-SAE、投与中止に至った有害事象、試験治療下の注目すべき有害事象）：
Day 407、Grade 3 の重篤な腎細胞癌が発現した。フィルゴチニブ 200 mg/プラセボに対する処置は投与中止であった。フィルゴチニブ 100 mg/プラセボに対する処置は投与中止であった。フィルゴチニブ 200 mg（非盲検）に対する処置は非該当であった。フィルゴチニブ 100 mg（非盲検）に対する処置は非該当であった。本事象は治験薬と関連なしと判断された。Day 428、Grade 3 の本事象は回復した。

その他の関連情報：腹痛が認められ、被験者は精密検査のため入院した。腹部のコンピューター断層撮影検査の結果、境界が明瞭な濃縮嚢胞性の占拠性病変（大きさ：3.8 × 4.3 × 3.6 cm）が、左腎上極中央の後部及び外側腎皮質に沿って隆起した、軽度の増強効果がみられる充実性で器質化された内容物として認められた。組織生検の結果、低異型度腎細胞癌が示唆された。腎摘除術が実施された。病理報告書によると、尿細管-乳頭パターン及び細胞外ムチンを有する低異型度腎細胞癌と診断された。喫煙歴、高血圧及び慢性腎臓病の病歴並びに腎癌の家族歴はなかった。被験者は肥満ではなかった。カドミウム又は除草剤等の特定の化学物質への職業性曝露はなかった。

Medical History	
Medical History	**Resolution**
colitis ulcerative	Ongoing
depression	Ongoing

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
amitriptyline	DEPRESSION PROPHYLAXIS	ORAL	-766 days	Ongoing
chlordiazepoxide	DEPRESSION PROPHYLAXIS	ORAL	-766 days	Ongoing
folic acid	PROPHYLAXIS FOR GASTRITIS	ORAL	-540 days	Ongoing
ferrous ascorbate;folic acid	ANEMIA	ORAL	-171 days	Ongoing
azathioprine	ULCERATIVE COLITIS	ORAL	407 days	Ongoing
mesalazine	ULCERATIVE COLITIS	ORAL	407 days	Ongoing
domperidone	PROPHYLAXIS FOR GASTRITIS	ORAL	410 days	Ongoing
pantoprazole	PROPHYLAXIS FOR GASTRITIS	ORAL	410 days	Ongoing
azathioprine	ULCERATIVE COLITIS	ORAL	-766 days	406 days
mesalazine	ULCERATIVE COLITIS	ORAL	-766 days	406 days
glucose	SUPPLEMENT	INTRAVENOUS	407 days	408 days
paracetamol	ABDOMINAL PAIN	INTRAVENOUS	407 days	408 days
pantoprazole	PROPHYLAXIS FOR GASTRITIS	INTRAVENOUS	407 days	409 days
paracetamol	ABDOMINAL PAIN	INTRAVENOUS	409 days	409 days
ketorolac	ABDOMINAL PAIN	ORAL	409 days	412 days

All Adverse Events						
Preferred Term	**Onset Day**	**Resolution Day**	**Toxicity Grade**	**Causality**	**Action taken with Filgotinib 200mg/Placebo**	**Action taken with Filgotinib 100mg/Placebo**
Abdominal pain	404	409	2	not related	dose not changed	dose not changed
Renal cell carcinoma	407	428	3	not related	drug withdrawn	drug withdrawn

All Adverse Events			
Preferred Term	**Action taken with Filgotinib 200mg Open Label**	**Action taken with Filgotinib 100mg Open Label**	**Action - Other**
Abdominal pain	not applicable	not applicable	none
Renal cell carcinoma	not applicable	not applicable	other treatment required + permanent study discontinuation

Hematology						
Study Day	Hemoglobin (g/dL)	Hematocrit (%)	Erythrocytes (x10^6/uL)	Platelets (x10^3/uL)	Reticulocytes (x10^6/uL)	Ery. Mean Corpuscular Volume (fL)
-7	14.4 (N)	44 (N)	5 (N)	348 (N)	0.07 (N)	90 (N)
17	13.9 (N)	42 (N)	4.6 (N)	223 (N)	0.038 (N)	92 (N)
24	14.1 (N)	44 (N)	4.7 (N)	257 (N)	0.061 (N)	92 (N)
86	13.2 (N)	44 (N)	4.5 (N)	290 (N)	0.036 (N)	97 (H)
164	12.6 (L)	43 (N)	4.6 (N)	256 (N)	0.047 (N)	93 (N)
241	12.6 (L)	41 (N)	4.4 (L)	254 (N)	0.06 (N)	93 (N)
340	12.8 (N)	40 (N)	4.4 (L)	187 (N)	0.026 (L)	91 (N)
407	13 (N)	42 (N)	4.5 (N)	217 (N)	0.029 (L)	92 (N)
H = High; L = Low; N = Normal.						

Hematology						
Study Day	Leukocytes (x10^3/uL)	Neutrophils, Segmented (x10^3/uL)	Lymphocytes (x10^3/uL)	Monocytes (x10^3/uL)	Basophils (x10^3/uL)	Eosinophils (x10^3/uL)
-7	6.44 (N)	4.96 (N)	0.97 (N)	0.27 (N)	0.07 (N)	0.17 (N)
17	5.15 (N)	3.67 (N)	1.1 (N)	0.21 (N)	0.05 (N)	0.12 (N)
24	6.5 (N)	5.17 (N)	0.96 (N)	0.22 (N)	0.05 (N)	0.1 (N)
86	6.58 (N)	5.31 (N)	0.86 (L)	0.27 (N)	0.05 (N)	0.09 (N)
164	4.67 (N)	3.21 (N)	1.03 (N)	0.3 (N)	0.05 (N)	0.07 (N)
241	4.42 (N)	3 (N)	1.03 (N)	0.2 (N)	0.05 (N)	0.14 (N)
340	6.82 (N)	4.81 (N)	1.5 (N)	0.32 (N)	0.12 (N)	0.07 (N)
407	7.18 (N)	5.53 (N)	1.3 (N)	0.17 (N)	0.05 (N)	0.12 (N)
H = High; L = Low; N = Normal.						

Chemistry						
Study Day	Fasting	Alanine Aminotransferase (U/L)	Aspartate Aminotransferase (U/L)	Alkaline Phosphatase (U/L)	Bilirubin (mg/dL)	Creatinine (mg/dL)
-7	Yes	37 (N)	30 (N)	101 (N)	0.4 (N)	0.72 (N)
17	Yes	14 (N)	18 (N)	79 (N)	0.3 (N)	0.75 (N)
24	Yes	17 (N)	23 (N)	77 (N)	0.5 (N)	0.66 (N)
86	Yes	15 (N)	22 (N)	78 (N)	0.5 (N)	0.81 (N)
164	Yes	17 (N)	23 (N)	85 (N)	0.5 (N)	0.72 (N)
241	Yes	17 (N)	22 (N)	96 (N)	0.5 (N)	0.84 (N)
340	Yes	15 (N)	24 (N)	84 (N)	0.5 (N)	0.78 (N)
407	Yes	16 (N)	24 (N)	96 (N)	0.3 (N)	0.63 (N)
H = High; L = Low; N = Normal.						

Chemistry					
Study Day	Fasting	Creatinine Clearance (mL/min)	Creatine Kinase (U/L)	Glucose (mg/dL)	C-Reactive Protein (hs-CRP) (mg/L)
-7	Yes	104.4 (N)	149 (N)	84 (N)	0.23 (N)
17	Yes	101.4 (N)	160 (N)	96 (N)	
24	Yes	115.8 (N)	243 (N)	107 (H)	
86	Yes	93.6 (N)	229 (N)	106 (H)	
164	Yes	109.2 (N)	235 (N)	80 (N)	<0.20 (N)
241	Yes	93.6 (N)	183 (N)	68 (L)	
340	Yes	100.8 (N)	201 (N)	80 (N)	1.51 (N)
407	Yes	123 (N)	441 (H)	86 (N)	
H = High; L = Low; N = Normal.					

Lipid Panel					
Study Day	Fasting	Total Cholesterol (mg/dL)	HDL Cholesterol (mg/dL)	LDL Cholesterol (mg/dL)	Triglycerides (mg/dL)
-7	Yes	200 (N)	51 (N)	143 (H)	107 (N)
17	Yes	232 (N)	72 (H)	153 (H)	152 (N)
24	Yes	236 (N)	74 (H)	162 (H)	133 (N)
86	Yes	196 (N)	65 (H)	128 (N)	105 (N)
164	Yes	181 (N)	60 (N)	104 (N)	146 (N)
241	Yes	160 (N)	66 (H)	101 (N)	58 (N)
340	Yes	167 (N)	75 (H)	92 (N)	76 (N)
H = High; L = Low; N = Normal.					

被験者識別番号：[redacted]

投与群：プラセボ群

治験薬の投与状況：有害事象により投与中止（Day 176）

ベースライン特性：本被験者は 2[redacted]歳のアジア系男性であった。その他の特性として、民族はヒスパニック／ラテン系、インドからの参加であった。

潰瘍性大腸炎（Day 169～172）（試験治療下の重篤な有害事象、投与中止に至った有害事象）：Day 169、Grade 3 の重篤な潰瘍性大腸炎が発現した。フィルゴチニブ 200 mg/プラセボに対する処置は投与中止であった。フィルゴチニブ 100 mg/プラセボに対する処置は投与中止であった。フィルゴチニブ 200 mg（非盲検）に対する処置は非該当であった。フィルゴチニブ 100 mg（非盲検）に対する処置は非該当であった。本事象は治験薬と関連なしと判断された。Day 172、Grade 3 の本事象は回復した。

その他の関連情報：特になし。

Medical History	
Medical History	**Resolution**
colitis ulcerative	Ongoing

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
folic acid	ULCERATIVE COLITIS	ORAL	-569 days	Ongoing
azathioprine	ULCERATIVE COLITIS	ORAL	-524 days	Ongoing
amitriptyline;chlordiazepoxide	ANXIETY	ORAL	169 days	Ongoing
mesalazine	ULCERATIVE COLITIS	ORAL	169 days	Ongoing
mesalazine	ULCERATIVE COLITIS	ORAL	-524 days	168 days
dexamethasone	SHIVERING	INTRAVENOUS	169 days	169 days
pheniramine maleate	SHIVERING	INTRAVENOUS	169 days	169 days
other drugs for functional gastrointestinal disorders	GASTRITIS	ORAL	169 days	170 days
prednisolone	ULCERATIVE COLITIS	INTRAVENOUS	169 days	170 days
ofloxacin	PROPHYLAXIS FOR ULCERATIVE COLITIS	INTRAVENOUS	169 days	171 days
metronidazole	PROPHYLAXIS ULCERATIVE COLITIS	INTRAVENOUS	169 days	172 days
pantoprazole	GASTRITIS	INTRAVENOUS	169 days	172 days
prednisolone	ULCERATIVE COLITIS	ORAL	169 days	223 days

All Adverse Events					
Preferred Term	Onset Day	Resolution Day	Toxicity Grade	Causality	Action taken with Filgotinib 200mg/Placebo
Colitis ulcerative	169	172	3	not related	drug withdrawn

All Adverse Events				
Preferred Term	Action taken with Filgotinib 100mg/Placebo	Action taken with Filgotinib 200mg Open Label	Action taken with Filgotinib 100mg Open Label	Action - Other
Colitis ulcerative	drug withdrawn	not applicable	not applicable	medication required + permanent study discontinuation

Hematology						
Study Day	Hemoglobin (g/dL)	Hematocrit (%)	Erythrocytes (x10^6/uL)	Platelets (x10^3/uL)	Reticulocytes (x10^6/uL)	Ery. Mean Corpuscular Volume (fL)
-56	11.5 (L)	43 (N)	5.3 (N)	272 (N)	0.082 (N)	81 (N)
14	11.6 (L)	41 (N)	5.1 (N)	307 (N)		80 (N)
20	11.6 (L)	41 (N)	5.2 (N)		0.108 (N)	79 (N)
29	11.9 (L)	42 (N)	5.4 (N)	281 (N)	0.125 (N)	79 (N)
85	12.2 (L)	44 (N)	5.5 (N)	330 (N)	0.113 (N)	79 (N)
168	12.5 (L)	44 (N)	5.8 (N)	437 (H)	0.067 (N)	77 (L)
183	13 (N)	45 (N)	5.8 (N)	392 (N)	0.081 (N)	77 (L)
H = High; L = Low; N = Normal.						

Hematology						
Study Day	Leukocytes (x10^3/uL)	Neutrophils, Segmented (x10^3/uL)	Lymphocytes (x10^3/uL)	Monocytes (x10^3/uL)	Basophils (x10^3/uL)	Eosinophils (x10^3/uL)
-56	12.71 (H)	7.75 (H)	4.01 (N)	0.61 (N)	0.18 (N)	0.16 (N)
14	18.62 (H)	14.94 (H)	2.64 (N)	0.8 (N)	0.2 (N)	0.05 (N)
20	19.24 (H)	12.12 (H)	5.96 (H)	0.77 (N)	0 (N)	0 (N)
29	20.48 (H)	14.68 (H)	4.68 (H)	0.9 (N)	0.15 (N)	0.07 (N)
85	17.45 (H)	11.78 (H)	4.68 (H)	0.73 (N)	0.17 (N)	0.08 (N)
168	13.72 (H)	8.3 (H)	4.49 (H)	0.57 (N)	0.22 (H)	0.14 (N)
183	20.1 (H)	13.98 (H)	4.89 (H)	0.95 (H)	0.19 (N)	0.08 (N)
H = High; L = Low; N = Normal.						

Chemistry						
Study Day	Fasting	Alanine Aminotransferase (U/L)	Aspartate Aminotransferase (U/L)	Alkaline Phosphatase (U/L)	Bilirubin (mg/dL)	Creatinine (mg/dL)
-1	Yes	61 (H)	25 (N)	71 (N)	0.3 (N)	0.88 (N)
20	Yes	62 (H)	25 (N)	64 (N)	0.4 (N)	0.89 (N)
29	Yes	69 (H)	28 (N)	67 (N)	0.4 (N)	0.97 (N)
85	Yes	60 (H)	30 (N)	79 (N)	0.3 (N)	0.98 (N)
168	Yes	60 (H)	31 (N)	75 (N)	0.2 (N)	0.79 (N)
183	Yes	73 (H)	29 (N)	54 (N)	0.4 (N)	0.89 (N)
H = High; L = Low; N = Normal.						

Chemistry					
Study Day	Fasting	Creatinine Clearance (mL/min)	Creatine Kinase (U/L)	Glucose (mg/dL)	C-Reactive Protein (hs-CRP) (mg/L)
-1	Yes	123 (N)	52 (N)	86 (N)	4.19 (N)
20	Yes	121.2 (N)	51 (N)	108 (H)	
29	Yes	111 (N)	47 (N)	114 (H)	
85	Yes	109.8 (N)	96 (N)	135 (H)	
168	Yes	137.4 (H)	83 (N)	106 (H)	4.99 (N)
183	Yes	122.4 (N)	60 (N)	126 (H)	
H = High; L = Low; N = Normal.					

Lipid Panel					
Study Day	Fasting	Total Cholesterol (mg/dL)	HDL Cholesterol (mg/dL)	LDL Cholesterol (mg/dL)	Triglycerides (mg/dL)
-1	Yes	260 (H)	58 (N)	181 (H)	235 (N)
85	Yes	248 (H)	49 (N)	169 (H)	422 (H)
168	Yes	246 (H)	40 (N)	174 (H)	374 (H)
H = High; L = Low; N = Normal.					

被験者識別番号：[redacted]

投与群：フィルゴチニブ 200 mg 群（非盲検）

治験薬の投与状況：継続

ベースライン特性：本被験者は 5[redacted] 歳のアジア系男性であった。その他の特性として、民族は非ヒスパニック／ラテン系、日本からの参加であった。

ヘリコバクター性胃炎（Day 177～330）（試験治療下の注目すべき有害事象）：
Day 177、Grade 2 の非重篤なヘリコバクター性胃炎が発現した。フィルゴチニブ 200 mg/プラセボに対する処置は非該当であった。フィルゴチニブ 100 mg/プラセボに対する処置は非該当であった。フィルゴチニブ 200 mg（非盲検）に対する処置は変更なし。フィルゴチニブ 100 mg（非盲検）に対する処置は非該当であった。本事象は治験薬と関連なしと判断された。Day 330、Grade 2 の本事象は回復した。

胃腺腫（Day 249～259）（試験治療下の重篤な有害事象）：
Day 249、Grade 3 の重篤な胃腺腫が発現した。フィルゴチニブ 200 mg/プラセボに対する処置は非該当であった。フィルゴチニブ 100 mg/プラセボに対する処置は非該当であった。フィルゴチニブ 200 mg（非盲検）に対する処置は変更なし。フィルゴチニブ 100 mg（非盲検）に対する処置は非該当であった。本事象は治験薬と関連なしと判断された。Day 259、Grade 3 の本事象は回復した。

その他の関連情報：特になし。

Medical History	
Medical History	**Resolution**
hypercholesterolaemia	Ongoing

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
benidipine hydrochloride	HYPERTENSION	ORAL	-939 days	Ongoing
hydrochlorothiazide;valsartan	HYPERTENSION	ORAL	-939 days	Ongoing
butyric acid	ULCERATIVE COLITIS	ORAL	-735 days	Ongoing
risedronate sodium	PREVENTION OF OSTEOPOROSIS	ORAL	-570 days	Ongoing
mercaptopurine	ULCERATIVE COLITIS	ORAL	-441 days	Ongoing
rosuvastatin calcium	HYPERCHOLESTEROLAEMIA	ORAL	-22 days	Ongoing
ferrous sodium citrate	ANAEMIA	ORAL	28 days	Ongoing
vonoprazan fumarate	GASTRIC ADENOMA	ORAL	250 days	Ongoing
ferrous sulfate	ANAEMIA	ORAL	-336 days	27 days
dimeticone;silicon dioxide	ENDOSCOPY	ORAL	177 days	177 days
hyoscine butylbromide	ENDOSCOPY	INTRAMUSCULAR	177 days	177 days
indigo carmine	ENDOSCOPY	TOPICAL	177 days	177 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
lidocaine	ENDOSCOPY	TOPICAL	177 days	177 days
amoxicillin trihydrate	HELICOBACTER CHRONIC GASTRITIS	ORAL	205 days	211 days
clarithromycin	HELICOBACTER CHRONIC GASTRITIS	ORAL	205 days	211 days
vonoprazan fumarate	HELICOBACTER CHRONIC GASTRITIS	ORAL	205 days	211 days
hyoscine butylbromide	GASTRIC ADENOMA	INTRAMUSCULAR	249 days	250 days
calcium chloride dihydrate;potassium chloride;sodium chloride;sodium lactate	GASTRIC ADENOMA	INTRAVENOUS DRIP	250 days	250 days
carbazochrome sodium sulfonate	GASTRIC ADENOMA	INTRAVENOUS DRIP	250 days	250 days
chlorpromazine hydrochloride	GASTRIC ADENOMA	INTRAMUSCULAR	250 days	250 days
diazepam	GASTRIC ADENOMA	INTRAVENOUS	250 days	250 days
epinephrine	GASTRIC ADENOMA	OTHER	250 days	250 days
fructose;glycerol	GASTRIC ADENOMA	INTRAVENOUS DRIP	250 days	250 days
hyaluronate sodium	GASTRIC ADENOMA	OTHER	250 days	250 days
indigo carmine	GASTRIC ADENOMA	TOPICAL	250 days	250 days
pronase	GASTRIC ADENOMA	ORAL	250 days	250 days
sodium bicarbonate	GASTRIC ADENOMA	ORAL	250 days	250 days
calcium chloride;potassium chloride;sodium chloride;sodium lactate;sorbitol	GASTRIC ADENOMA	INTRAVENOUS DRIP	250 days	251 days
dimeticone;silicon dioxide	GASTRIC ADENOMA	ORAL	250 days	251 days
lidocaine	GASTRIC ADENOMA	TOPICAL	250 days	251 days
oxygen	GASTRIC ADENOMA	NASAL	250 days	251 days
pethidine hydrochloride	GASTRIC ADENOMA	INTRAVENOUS	250 days	251 days
sodium chloride	GASTRIC ADENOMA	INTRAVENOUS	250 days	251 days
midazolam	GASTRIC ADENOMA	INTRAVENOUS	251 days	251 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
12662302001:acetylcysteine;alanine;arginine;ascorbic acid;aspartic acid;biotin;calcium chloride dihydrate;cyanocobalamin;folic acid;glucose;glutamic acid;glycine;histidine;isoleucine;leucine;lysine hy	GASTRIC ADENOMA	INTRAVENOUS DRIP	251 days	252 days
dimeticone;silicon dioxide	ENDOSCOPY	ORAL	309 days	309 days
hyoscine butylbromide	ENDOSCOPY	INTRAMUSCULAR	309 days	309 days
lidocaine	ENDOSCOPY	TOPICAL	309 days	309 days

All Adverse Events					
Preferred Term	Onset Day	Resolution Day	Toxicity Grade	Causality	Action taken with Filgotinib 200mg/Placebo
Gastric adenoma	177	249	2	not related	not applicable
Helicobacter gastritis	177	330	2	not related	not applicable
Gastric adenoma	249	259	3	not related	not applicable

All Adverse Events				
Preferred Term	Action taken with Filgotinib 100mg/Placebo	Action taken with Filgotinib 200mg Open Label	Action taken with Filgotinib 100mg Open Label	Action - Other
Gastric adenoma	not applicable	dose not changed	not applicable	none
Helicobacter gastritis	not applicable	dose not changed	not applicable	medication required
Gastric adenoma	not applicable	dose not changed	not applicable	medication required + other treatment required

Hematology						
Study Day	Hemoglobin (g/dL)	Hematocrit (%)	Erythrocytes (x10^6/uL)	Platelets (x10^3/uL)	Reticulocytes (x10^6/uL)	Ery. Mean Corpuscular Volume (fL)
-1	16.1 (N)	46 (N)	4.7 (N)	285 (N)	0.103 (N)	97 (H)
14	15.2 (N)	44 (N)	4.5 (N)	260 (N)	0.105 (N)	98 (H)
28	15.1 (N)	43 (N)	4.4 (L)	292 (N)	0.094 (N)	99 (H)
84	15.2 (N)	46 (N)	4.7 (N)	242 (N)	0.092 (N)	100 (H)
168	14.5 (N)	44 (N)	4.4 (L)	244 (N)	0.107 (N)	99 (H)
254	14.6 (N)	43 (N)	4.4 (L)	219 (N)	0.074 (N)	98 (H)
330	15.2 (N)	44 (N)	4.5 (N)	266 (N)	0.098 (N)	97 (H)
H = High; L = Low; N = Normal.						

Hematology						
Study Day	Leukocytes (x10^3/uL)	Neutrophils, Segmented (x10^3/uL)	Lymphocytes (x10^3/uL)	Monocytes (x10^3/uL)	Basophils (x10^3/uL)	Eosinophils (x10^3/uL)
-1	4.48 (N)	2.84 (N)	1.11 (N)	0.31 (N)	0.04 (N)	0.18 (N)
14	5.92 (N)	3.59 (N)	1.62 (N)	0.35 (N)	0.06 (N)	0.29 (N)
28	4.99 (N)	3 (N)	1.24 (N)	0.29 (N)	0.06 (N)	0.41 (N)
84	4.68 (N)	2.74 (N)	1.37 (N)	0.32 (N)	0.08 (N)	0.17 (N)
168	4.63 (N)	3.08 (N)	1.1 (N)	0.27 (N)	0.05 (N)	0.14 (N)
254	4.91 (N)	3.46 (N)	1.07 (N)	0.23 (N)	0.05 (N)	0.11 (N)
330	3.85 (N)	2.27 (N)	1.08 (N)	0.27 (N)	0.05 (N)	0.19 (N)
H = High; L = Low; N = Normal.						

Chemistry						
Study Day	Fasting	Alanine Aminotransferase (U/L)	Aspartate Aminotransferase (U/L)	Alkaline Phosphatase (U/L)	Bilirubin (mg/dL)	Creatinine (mg/dL)
-1	No	44 (H)	39 (H)	38 (N)	0.8 (N)	0.96 (N)
14	No	54 (H)	47 (H)	38 (N)	0.7 (N)	0.95 (N)
28	No	38 (N)	43 (H)	38 (N)	0.8 (N)	0.96 (N)
84	No	34 (N)	33 (N)	38 (N)	0.5 (N)	0.85 (N)
168	Yes	71 (H)	52 (H)	40 (N)	0.8 (N)	0.88 (N)
254	Yes	119 (H)	77 (H)	47 (N)	1.2 (N)	1.07 (N)
330	Yes	29 (N)	29 (N)	31 (L)	0.5 (N)	0.94 (N)
H = High; L = Low; N = Normal.						

Chemistry					
Study Day	Fasting	Creatinine Clearance (mL/min)	Creatine Kinase (U/L)	Glucose (mg/dL)	C-Reactive Protein (hs-CRP) (mg/L)
-1	No	75 (L)	118 (N)	100 (N)	<0.20 (N)
14	No	75.6 (L)	117 (N)	97 (N)	
28	No	75.6 (L)	230 (N)	91 (N)	
84	No	85.2 (N)	128 (N)	103 (H)	
168	Yes	78.6 (L)	146 (N)	91 (N)	<0.20 (N)
254	Yes	63.6 (L)	155 (N)	84 (N)	
330	Yes	74.4 (L)	91 (N)	101 (H)	<0.20 (N)
H = High; L = Low; N = Normal.					

Lipid Panel					
Study Day	Fasting	Total Cholesterol (mg/dL)	HDL Cholesterol (mg/dL)	LDL Cholesterol (mg/dL)	Triglycerides (mg/dL)
168	Yes	205 (N)	96 (H)	108 (N)	74 (N)
330	Yes	192 (N)	92 (H)	103 (N)	74 (N)
H = High; L = Low; N = Normal.					

被験者識別番号：[redacted]

投与群：フィルゴチニブ 200 mg 群（非盲検）

治験薬の投与状況：有害事象により投与中止（Day 488）

ベースライン特性：本被験者は 4[redacted]歳の白人男性であった。その他の特性として、民族は非ヒスパニック／ラテン系、英国からの参加であった。

潰瘍性大腸炎（Day 337～489）（試験治療下の重篤な有害事象、投与中止に至った有害事象）：Day 337、Grade 3 の重篤な潰瘍性大腸炎が発現した。フィルゴチニブ 200 mg/プラセボに対する処置は非該当であった。フィルゴチニブ 100 mg/プラセボに対する処置は非該当であった。フィルゴチニブ 200 mg（非盲検）に対する処置は投与中止であった。フィルゴチニブ 100 mg（非盲検）に対する処置は非該当であった。本事象は治験薬と関連なしと判断された。Day 489、Grade 3 の本事象は回復した。

その他の関連情報：特になし。

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
calcium carbonate;colecalciferol	PREVENTION OF OSTEOPOROSIS	ORAL	-714 days	Ongoing
mesalazine	ULCERATIVE COLITIS	ORAL	-707 days	Ongoing
calcium carbonate	PREVENTION OF OSTEOPOROSIS	ORAL	-301 days	Ongoing
potassium bicarbonate;sodium bicarbonate;sodium phosphate monobasic (anhydrous)	LOW PHOSPHATE	ORAL	16 days	Ongoing
prednisolone	ULCERATIVE COLITIS	ORAL	348 days	Ongoing
prednisolone	ULCERATIVE COLITIS	ORAL	About -1280 days	347 days
azathioprine	ULCERATIVE COLITIS	ORAL	About -64 days	488 days
mesalazine	ULCERATIVE COLITIS	RECTAL	About 182 days	About 488 days

All Adverse Events						
Preferred Term	Onset Day	Resolution Day	Toxicity Grade	Causality	Action taken with Filgotinib 200mg/Placebo	Action taken with Filgotinib 100mg/Placebo
Blood phosphorus decreased	14	Ongoing	3	not related	not applicable	not applicable
Colitis ulcerative	337	489	3	not related	not applicable	not applicable

All Adverse Events			
Preferred Term	Action taken with Filgotinib 200mg Open Label	Action taken with Filgotinib 100mg Open Label	Action - Other
Blood phosphorus decreased	dose not changed	not applicable	medication required
Colitis ulcerative	drug withdrawn	not applicable	medication required + permanent study discontinuation

Hematology						
Study Day	Hemoglobin (g/dL)	Hematocrit (%)	Erythrocytes (x10^6/uL)	Platelets (x10^3/uL)	Reticulocytes (x10^6/uL)	Ery. Mean Corpuscular Volume (fL)
1	13.6 (N)	41 (N)	4.3 (L)	219 (N)	0.11 (N)	94 (N)
13	14.1 (N)	42 (N)	4.5 (N)	212 (N)	0.186 (H)	94 (N)
28	14.8 (N)	44 (N)	4.5 (N)	213 (N)	0.114 (N)	97 (H)
83	14.7 (N)		4.4 (L)	230 (N)	0.115 (N)	
168	15.1 (N)	44 (N)	4.5 (N)	261 (N)	0.104 (N)	97 (H)
265	15.5 (N)	48 (N)	4.8 (N)	236 (N)	0.067 (N)	101 (H)
337	15.5 (N)	45 (N)	4.8 (N)	265 (N)	0.13 (N)	93 (N)
420	15.3 (N)	48 (N)	4.7 (N)	251 (N)	0.083 (N)	102 (H)
H = High; L = Low; N = Normal.						

Hematology						
Study Day	Leukocytes (x10^3/uL)	Neutrophils, Segmented (x10^3/uL)	Lymphocytes (x10^3/uL)	Monocytes (x10^3/uL)	Basophils (x10^3/uL)	Eosinophils (x10^3/uL)
1	5.69 (N)	4.75 (N)	0.69 (L)	0.17 (N)	0.03 (N)	0.06 (N)
13	6.74 (N)	5.72 (N)	0.73 (L)	0.21 (N)	0.03 (N)	0.04 (N)
28	6.83 (N)	5.28 (N)	1.1 (N)	0.35 (N)	0.03 (N)	0.08 (N)
83	6.06 (N)	4.82 (N)	0.82 (L)	0.28 (N)	0.03 (N)	0.12 (N)
168	7.29 (N)	6.32 (N)	0.68 (L)	0.24 (N)	0.02 (N)	0.03 (N)
265	6.57 (N)	5.43 (N)	0.81 (L)	0.21 (N)	0.07 (N)	0.05 (N)
337	9.31 (N)	7.68 (H)	1.03 (N)	0.48 (N)	0.04 (N)	0.08 (N)
420	6.83 (N)	5.74 (N)	0.75 (L)	0.34 (N)	0 (N)	0 (N)
H = High; L = Low; N = Normal.						

Chemistry						
Study Day	Fasting	Alanine Aminotransferase (U/L)	Aspartate Aminotransferase (U/L)	Alkaline Phosphatase (U/L)	Bilirubin (mg/dL)	Creatinine (mg/dL)
1	No	15 (N)	17 (N)	55 (N)	0.5 (N)	0.94 (N)
13	Yes	15 (N)	18 (N)	60 (N)	0.5 (N)	0.9 (N)
28	No	14 (N)	16 (N)	57 (N)	0.8 (N)	0.96 (N)
83	No	17 (N)	20 (N)	65 (N)	0.8 (N)	0.93 (N)
168	Yes	15 (N)	18 (N)	60 (N)	0.6 (N)	0.94 (N)
265	No	16 (N)	17 (N)	61 (N)	0.3 (N)	0.9 (N)
337	No	19 (N)	16 (N)	68 (N)	0.4 (N)	1.03 (N)
420	No	17 (N)	15 (N)	60 (N)	0.6 (N)	0.97 (N)
H = High; L = Low; N = Normal.						

Chemistry					
Study Day	Fasting	Creatinine Clearance (mL/min)	Creatine Kinase (U/L)	Glucose (mg/dL)	C-Reactive Protein (hs-CRP) (mg/L)
1	No	150 (H)	86 (N)	92 (N)	0.24 (N)
13	Yes	154.8 (H)	67 (N)	98 (N)	
28	No	145.8 (H)	94 (N)	85 (N)	
83	No	153 (H)	100 (N)	72 (N)	
168	Yes	151.2 (H)	95 (N)	91 (N)	2.17 (N)
265	No	154.8 (H)	108 (N)	91 (N)	
337	No	135 (H)	61 (N)	79 (N)	1.09 (N)
420	No	142.8 (H)	71 (N)	89 (N)	0.55 (N)
H = High; L = Low; N = Normal.					

Lipid Panel					
Study Day	Fasting	Total Cholesterol (mg/dL)	HDL Cholesterol (mg/dL)	LDL Cholesterol (mg/dL)	Triglycerides (mg/dL)
-22	No	165 (N)	47 (N)	98 (N)	101 (N)
168	Yes	140 (L)	41 (N)	99 (N)	71 (N)
337	No	135 (L)	37 (N)	90 (N)	76 (N)
H = High; L = Low; N = Normal.					