被験者識別番号：[redacted]

投与群：寛解導入試験－フィルゴチニブ 200 mg 群（コホート A）

治験薬の投与状況：寛解導入試験－完了；寛解維持試験－不参加

ベースライン特性：本被験者は 3[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、台湾からの参加であった。

胃腸出血（Day 71～74）（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）（寛解導入試験）：
Day 71、Grade 3 の重篤な胃腸出血が発現した。寛解導入治験薬に対する処置は投与中止であった。寛解維持治験薬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 74、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**
abdominal pain lower	Ongoing
benign ovarian tumour	Ongoing
cervical dysplasia	Ongoing
colitis ulcerative	Ongoing
gastrooesophageal reflux disease	Ongoing
insomnia	Ongoing
pelvic inflammatory disease	Ongoing
iron deficiency anaemia	-1000 days
constipation	-238 days

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
mesalazine	ULCERATIVE COLITIS	ORAL	-238 days	Ongoing
ranitidine	GASTROESOPHAGEAL REFLUX DISEASE	ORAL	-230 days	Ongoing
magnesium oxide	CONSTIPATION WORSENING	ORAL	29 days	Ongoing
gadoteric acid	MRI EXAM	INTRAVENOUS BOLUS	-18 days	-18 days
hyoscine butylbromide	MRI EXAM	INTRAVENOUS BOLUS	-18 days	-18 days
lidocaine	PERFORM BIOPSY	TOPICAL	-15 days	-15 days
sulpiride	GASTROESOPHAGEAL REFLUX DISEASE	ORAL	-174 days	-13 days
bisacodyl	PERFORM ENDOSCOPY	ORAL	-8 days	-8 days
citric acid;magnesium oxide;sodium picosulfate	PERFORM ENDOSCOPY	ORAL	-8 days	-7 days
glucose	PERFORM ENDOSCOPY	INTRAVENOUS BOLUS	-7 days	-7 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
midazolam	PERFORM ENDOSCOPY	INTRAVENOUS BOLUS	-7 days	-7 days
pethidine	PERFORM ENDOSCOPY	INTRAVENOUS BOLUS	-7 days	-7 days
bisacodyl	PERFORM ENDOSCOPY	ORAL	70 days	70 days
citric acid;magnesium oxide;sodium picosulfate	PERFORM ENDOSCOPY	ORAL	70 days	71 days
glucose	PERFORM ENDOSCOPY	INTRAVENOUS BOLUS	71 days	71 days
midazolam	PERFORM ENDOSCOPY	INTRAVENOUS BOLUS	71 days	71 days
pethidine	PERFORM ENDOSCOPY	INTRAVENOUS BOLUS	71 days	71 days
tranexamic acid	GI BLEEDING	INTRAVENOUS DRIP	71 days	73 days
saccharated iron oxide	GI BLEEDING	INTRAVENOUS DRIP	73 days	74 days
adalimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	106 days	106 days

All Adverse Events							
Preferred Term	Onset Day	Resolution Day	Toxicity Grade	Causality	Action taken with Induction Drug	Action taken with Maintenance Drug	Action - Other
Constipation	14	Ongoing	2	related	dose not changed	not applicable	medication required
Gastrointestinal haemorrhage	71	74	3	not related	drug withdrawn	not applicable	medication required + other treatment required + permanent study discontinuation
* denotes the Maintenance study day.							

Hematology						
Study Day	Hemoglobin (g/dL)	Hematocrit (%)	Erythrocytes (x10^6/uL)	Platelets (x10^3/uL)	Reticulocytes (x10^6/uL)	Ery. Mean Corpuscular Volume (fL)
-25	10.8 (L)	36 (N)	4.6 (N)	382 (N)	0.045 (N)	77 (L)
1	10 (L)	34 (N)	4.4 (N)	367 (N)	0.065 (N)	77 (L)
13	8.8 (L)	31 (L)	4 (L)	400 (N)	0.049 (N)	78 (L)
29	9.4 (L)	33 (L)	4.4 (N)	419 (H)	0.077 (N)	77 (L)
43	8.4 (L)	29 (L)	4 (L)	335 (N)	0.046 (N)	71 (L)
71	9.1 (L)	32 (L)	4.4 (N)	379 (N)	0.093 (N)	72 (L)
78	8.7 (L)	31 (L)	3.9 (L)	285 (N)	0.146 (H)	82 (N)
106	9.2 (L)	34 (N)	4.3 (N)	253 (N)	0.08 (N)	80 (N)
* denotes the Maintenance study day. 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)
-25	6.82 (N)	3.31 (N)	2.64 (N)	0.46 (N)	0.02 (N)	0.39 (N)
1	6.56 (N)	3.58 (N)	2.27 (N)	0.38 (N)	0.02 (N)	0.3 (N)
13	5.95 (N)	2.93 (N)	2.53 (N)	0.28 (N)	0.02 (N)	0.19 (N)
29	6.15 (N)	3.35 (N)	2.41 (N)	0.27 (N)	0.01 (N)	0.11 (N)
43	4.61 (N)	2.02 (N)	2.15 (N)	0.35 (N)	0.01 (N)	0.08 (N)
71	6.34 (N)	3.55 (N)	2.34 (N)	0.33 (N)	0.02 (N)	0.09 (N)
78	6.03 (N)	3.29 (N)	2.4 (N)	0.25 (N)	0.02 (N)	0.06 (N)
106	5.54 (N)	3.88 (N)	1.24 (N)	0.35 (N)	0.02 (N)	0.05 (N)
* denotes the Maintenance study day. 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)
-25	Yes	9 (N)	14 (N)	61 (N)	0.3 (N)	0.66 (N)
1	Yes	7 (N)	14 (N)	58 (N)	0.4 (N)	0.66 (N)
13	Yes	8 (N)	15 (N)	52 (N)	0.4 (N)	0.68 (N)
29	Yes	6 (N)	14 (N)	55 (N)	<0.2 (L)	0.7 (N)
43	Yes	7 (N)	15 (N)	50 (N)	0.4 (N)	0.64 (N)
71	Yes	7 (N)	16 (N)	63 (N)	0.4 (N)	0.72 (N)
78	Yes	6 (N)	15 (N)	51 (N)	0.2 (N)	0.66 (N)
106	Yes	9 (N)	13 (N)	51 (N)	0.3 (N)	0.64 (N)
* denotes the Maintenance study day. 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)
-25	Yes	94.2 (N)	59 (N)	91 (N)	6.41 (N)
1	Yes	91.2 (N)	61 (N)	86 (N)	2.02 (N)
13	Yes	91.8 (N)	80 (N)	89 (N)	0.52 (N)
29	Yes	88.2 (N)	74 (N)	97 (N)	3.51 (N)
43	Yes	97.2 (N)	68 (N)	85 (N)	0.27 (N)
71	Yes	85.8 (N)	84 (N)	94 (N)	1.5 (N)
78	Yes	95.4 (N)	72 (N)	85 (N)	4.04 (N)
106	Yes	98.4 (N)	73 (N)	83 (N)	2.3 (N)
* denotes the Maintenance study day. 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	145 (N)	55 (N)	75 (N)	89 (N)
71	Yes	167 (N)	85 (H)	82 (N)	78 (N)
78	Yes	153 (N)	71 (N)	77 (N)	69 (N)
* denotes the Maintenance study day. H = High; L = Low; N = Normal.					

被験者識別番号：[redacted]

投与群：寛解導入試験－フィルゴチニブ 200 mg 群（コホート A）；寛解維持試験－フィルゴチニブ 200 mg 群

治験薬の投与状況：寛解導入試験－完了；寛解維持試験－有害事象により投与中止（Day 73*）

ベースライン特性：本被験者は 5[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、オーストラリアからの参加であった。

憩室炎（Day 72*～78*）（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）（寛解維持試験）：
Day 72*、Grade 2 の重篤な憩室炎が発現した。寛解導入治験薬に対する処置は非該当であった。寛解維持治験薬に対する処置は投与中止であった。本事象は治験薬と関連なしと判断された。Day 78*、Grade 2 の本事象は回復した。

その他の関連情報：被験者は、急性憩室炎のため入院した。治療として抗生剤の静脈内投与が行われ、被験者は容体が安定した状態で退院した。
*寛解維持試験における study day

Medical History	
Medical History	**Resolution**
colitis ulcerative	Ongoing
diverticulum	Ongoing
hypertension	Ongoing
obesity	Ongoing
postmenopause	Ongoing

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
perindopril erbumine	HYPERTENSION	ORAL	About -3899 days	Ongoing
lercanidipine hydrochloride	HYPERTENSION	ORAL	About -977 days	Ongoing
mesalazine	ULCERATIVE COLITIS	ORAL	About -977 days	Ongoing
metoprolol	HYPERTENSION	ORAL	About -977 days	Ongoing
prednisolone	ULCERATIVE COLITIS	ORAL	About -307 days	About -247 days
alfentanil	ANAESTHETIC AGENT FOR ENDOSCOPY	INTRAVENOUS	-5 days	-5 days
propofol	ANAESTHETIC AGENT FOR ENDOSCOPY	INTRAVENOUS	-5 days	-5 days
sodium phosphate dibasic;sodium phosphate monobasic	BOWEL PREPARATION	RECTAL	-5 days	-5 days
alfentanil	SEDATION FOR PROCEDURE	INTRAVENOUS	73 days	73 days
midazolam	SEDATION FOR PROCEDURE	INTRAVENOUS	73 days	73 days
propofol	SEDATION FOR PROCEDURE	INTRAVENOUS	73 days	73 days
cefalexin	POST DENTAL EXTRACTION	ORAL	127 days	134 days
codeine phosphate;paracetamol	POST DENTAL EXTRACTION	ORAL	127 days	134 days
fentanyl	PAIN FROM DIVERTICULITIS	INTRAVENOUS	150 days	150 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
gentamicin	DIVERTICULITIS	INTRAVENOUS	150 days	150 days
ondansetron	NAUSEA RELATED TO DIVERTICULITIS	INTRAVENOUS	150 days	150 days
oxycodone	PAIN RELATED TO DIVERTICULITIS	ORAL	150 days	150 days
paracetamol	PAIN RELATED TO DIVERTICULITIS	ORAL	150 days	150 days
ampicillin	DIVERTICULITIS	INTRAVENOUS	150 days	152 days
metronidazole	DIVERTICULITIS	INTRAVENOUS	150 days	152 days
amoxicillin trihydrate;clavulanate potassium	DIVERTICULITS	ORAL	152 days	162 days

All Adverse Events							
Preferred Term	Onset Day	Resolution Day	Toxicity Grade	Causality	Action taken with Induction Drug	Action taken with Maintenance Drug	Action - Other
Breath odour	About 59	Ongoing	1	not related	not applicable	dose not changed	none
Diverticulitis	72*	78*	2	not related	not applicable	drug withdrawn	medication required + permanent study discontinuation
* denotes the Maintenance study day.							

Hematology						
Study Day	Hemoglobin (g/dL)	Hematocrit (%)	Erythrocytes (x10^6/uL)	Platelets (x10^3/uL)	Reticulocytes (x10^6/uL)	Ery. Mean Corpuscular Volume (fL)
-21	14.5 (N)	42 (N)	5 (N)	309 (N)	0.087 (N)	85 (N)
1	14 (N)	42 (N)	4.9 (N)	274 (N)	0.077 (N)	85 (N)
15	14.1 (N)	42 (N)	4.9 (N)	365 (N)	0.08 (N)	86 (N)
29	14.1 (N)	42 (N)	4.9 (N)	272 (N)	0.046 (N)	86 (N)
43	13.4 (N)	41 (N)	4.7 (N)	256 (N)	0.04 (N)	89 (N)
73	14.2 (N)	44 (N)	4.9 (N)	305 (N)	0.06 (N)	90 (N)
-5*	14.2 (N)	44 (N)	4.9 (N)	305 (N)	0.06 (N)	90 (N)
29*	14.4 (N)	43 (N)	4.9 (N)	317 (N)	0.04 (N)	88 (N)
71*	13.2 (N)	41 (N)	4.5 (N)	302 (N)	0.074 (N)	91 (N)
78*	13.2 (N)	40 (N)	4.4 (N)	318 (N)		90 (N)

* denotes the Maintenance study day.
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)
-21	8.37 (N)	5.2 (N)	2.19 (N)	0.59 (N)	0.09 (N)	0.3 (N)
1	6.8 (N)	3.83 (N)	2.03 (N)	0.56 (N)	0.07 (N)	0.31 (N)
15	10.93 (H)	6.44 (N)	3.42 (N)	0.7 (N)	0.1 (N)	0.27 (N)
29	8.44 (N)	4.62 (N)	3.04 (N)	0.5 (N)	0.07 (N)	0.23 (N)
43	7.39 (N)	3.98 (N)	2.76 (N)	0.49 (N)	0.06 (N)	0.11 (N)
73	5.68 (N)	2.72 (N)	2.44 (N)	0.38 (N)	0.05 (N)	0.09 (N)
-5*	5.68 (N)	2.72 (N)	2.44 (N)	0.38 (N)	0.05 (N)	0.09 (N)
29*	6.04 (N)	3.23 (N)	2.15 (N)	0.45 (N)	0.05 (N)	0.16 (N)
71*	7.03 (N)	4.39 (N)	1.99 (N)	0.49 (N)	0.05 (N)	0.1 (N)
78*	6.24 (N)	3.59 (N)	1.92 (N)	0.52 (N)	0.05 (N)	0.16 (N)

* denotes the Maintenance study day.
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)
-21	No	10 (N)	16 (N)	99 (N)	<0.2 (L)	0.71 (N)
1	Yes	12 (N)	16 (N)	106 (N)	0.2 (N)	0.61 (N)
15	No	11 (N)	15 (N)	95 (N)	0.2 (N)	0.71 (N)
29	No	21 (N)	25 (N)	85 (N)	0.4 (N)	0.85 (N)
43	No	18 (N)	21 (N)	77 (N)	0.3 (N)	0.78 (N)
73	Yes	15 (N)	18 (N)	77 (N)	0.2 (N)	0.77 (N)
-5*	Yes	15 (N)	18 (N)	77 (N)	0.2 (N)	0.77 (N)
29*	No	12 (N)	16 (N)	68 (N)	0.3 (N)	0.94 (N)
71*	No	9 (N)	15 (N)	73 (N)	0.2 (N)	0.74 (N)
78*	No	9 (N)	18 (N)	78 (N)	<0.2 (L)	0.78 (N)
106*	No	11 (N)	16 (N)	89 (N)	0.3 (N)	0.62 (N)
* denotes the Maintenance study day. 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)
-21	No	147.6 (H)	54 (N)	86 (N)	7.85 (N)
1	Yes	170.4 (H)	63 (N)	98 (N)	37.9 (H)
15	No	148.2 (H)	71 (N)	92 (N)	3.34 (N)
29	No	118.2 (H)	107 (N)	97 (N)	2.37 (N)
43	No	126 (H)	100 (N)	85 (N)	2.25 (N)
73	Yes	120.6 (H)	91 (N)	93 (N)	8.97 (N)
-5*	Yes	120.6 (H)	91 (N)	93 (N)	8.97 (N)
29*	No	95.4 (N)	78 (N)	89 (N)	1.12 (N)
71*	No	114.6 (N)	75 (N)	81 (N)	6.42 (N)
78*	No	109.2 (N)	56 (N)	90 (N)	
106*	No	129.6 (H)	40 (N)	86 (N)	8.24 (N)
* denotes the Maintenance study day. 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	234 (N)	38 (N)	164 (H)	260 (N)
43	No	222 (N)	49 (N)	147 (H)	174 (N)
73	Yes	246 (N)	42 (N)	173 (H)	179 (N)
-5*	Yes	246 (N)	42 (N)	173 (H)	179 (N)
78*	No	234 (N)	40 (N)	154 (H)	220 (N)
* denotes the Maintenance study day. H = High; L = Low; N = Normal.					

被験者識別番号：[redacted]

投与群：寛解導入試験－フィルゴチニブ 100 mg 群（コホート B）

治験薬の投与状況：寛解導入試験－有害事象により投与中止（Day 11）；寛解維持試験－不参加

ベースライン特性：本被験者は 4[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、オーストラリアからの参加であった。

潰瘍性大腸炎（Day 11～18）（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）（寛解導入試験）：
Day 11、Grade 3 の重篤な潰瘍性大腸炎が発現した。寛解導入治験薬に対する処置は投与中止であった。寛解維持治験薬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 18、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
depression	Ongoing
gastrooesophageal reflux disease	Unknown
haemangioma of liver	Ongoing
iron deficiency	Unknown
pancreatitis	About -978 days
appendicitis	-390 days

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
mercaptopurine	ULCERATIVE COLITIS	ORAL	-824 days	Ongoing
mesalazine	ULCERATIVE COLITIS	ORAL	-236 days	Ongoing
magnesium	SUPPLEMENT	ORAL	About -95 days	Ongoing
tioguanine	ULCERATIVE COLITIS	ORAL	16 days	Ongoing
budesonide	ULCERATIVE COLITIS	RECTAL	-824 days	About -765 days
adalimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	About -977 days	About -612 days
mesalazine	ULCERATIVE COLITIS	RECTAL	About -703 days	About -612 days
mesalazine	ULCERATIVE COLITIS	ORAL	-908 days	-335 days
prednisolone	ULCERATIVE COLITIS	ORAL	About -65 days	-28 days
prednisolone	ULCERATIVE COLITIS	ORAL	-27 days	-22 days
prednisone	ULCERATIVE COLITIS	ORAL	-21 days	11 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
macrogol 3350;potassium chloride;sodium bicarbonate;sodium chloride	ULCERATIVE COLITIS	ORAL	14 days	17 days
prednisone	ULCERATIVE COLITIS	ORAL	17 days	18 days

All Adverse Events							
Preferred Term	Onset Day	Resolution Day	Toxicity Grade	Causality	Action taken with Induction Drug	Action taken with Maintenance Drug	Action - Other
Colitis ulcerative	11	18	3	not related	drug withdrawn	not applicable	medication required + permanent study discontinuation
* denotes the Maintenance study day.							

Hematology						
Study Day	Hemoglobin (g/dL)	Hematocrit (%)	Erythrocytes (x10^6/uL)	Platelets (x10^3/uL)	Reticulocytes (x10^6/uL)	Ery. Mean Corpuscular Volume (fL)
-27	14.6 (N)	43 (N)	4.5 (N)	278 (N)	0.075 (N)	96 (N)
1	13.8 (N)	41 (N)	4.3 (N)	232 (N)	0.035 (N)	95 (N)
15	14.6 (N)	44 (N)	4.5 (N)	283 (N)	0.064 (N)	98 (N)
* denotes the Maintenance study day. 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)
-27	7.83 (N)	5.88 (N)	1.61 (N)	0.3 (N)	0.02 (N)	0.01 (N)
1	7.03 (N)	4.59 (N)	1.98 (N)	0.26 (N)	0.02 (N)	0.18 (N)
15	11.9 (H)	10.7 (H)	0.9 (L)	0.27 (N)	0.01 (N)	0.02 (N)
* denotes the Maintenance study day. 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)
-27	No	11 (N)	13 (N)	68 (N)	0.5 (N)	0.76 (N)
1	No	13 (N)	17 (N)	91 (N)	0.4 (N)	0.68 (N)
15	Yes	11 (N)	12 (N)	71 (N)	0.3 (N)	0.72 (N)
* denotes the Maintenance study day. 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)
-27	No	107.4 (N)	27 (N)	88 (N)	<0.20 (N)
1	No	118.8 (H)	51 (N)	83 (N)	0.62 (N)
15	Yes	112.8 (N)	18 (L)	114 (H)	1.57 (N)
* denotes the Maintenance study day. 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	No	269 (H)	72 (N)	177 (H)	114 (N)
15	Yes	253 (N)	86 (N)	161 (H)	164 (N)
* denotes the Maintenance study day. H = High; L = Low; N = Normal.					

被験者識別番号：[redacted]

投与群：寛解導入試験－プラセボ群（コホート A）；寛解維持試験－プラセボ群

治験薬の投与状況：寛解導入試験－完了；寛解維持試験－有害事象により投与中止（Day 161*）

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、オーストラリアからの参加であった。

上気道感染（Day 20*～22*）（試験治療下の注目すべき有害事象）（寛解維持試験）：
Day 20*、Grade 1 の非重篤な上気道感染が発現した。寛解導入治験薬に対する処置は非該当であった。寛解維持治験薬に対する処置は変更なし。本事象は治験薬と関連なしと判断された。Day 22*、Grade 1 の本事象は回復した。

急性腎障害（Day 157*～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）（寛解維持試験）：
Day 157*、Grade 3 の重篤な急性腎障害が発現した。寛解導入治験薬に対する処置は非該当であった。寛解維持治験薬に対する処置は投与中止であった。本事象は治験薬と関連なしと判断された。試験終了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。
*寛解維持試験における study day

Medical History	
Medical History	**Resolution**
colitis ulcerative	Ongoing
haemorrhoids	Ongoing
osteopenia	Ongoing
vitiligo	Ongoing
iron deficiency anaemia	-2100 days
eye pain	About -2074 days
polyarthritis	About -2074 days
iritis	About -1983 days

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
minerals nos;vitamins nos	VITAMIN REPLACEMENT	ORAL	About -2438 days	Ongoing
vitamin d nos	VITAMIN D SUPPLEMENTATION	ORAL	About -1191 days	Ongoing
mesalazine	ULCERATIVE COLITIS	ORAL	-206 days	Ongoing
prednisolone	ULCERATIVE COLITIS	ORAL	-2175 days	-2109 days
hydrocortisone acetate	ULCERATIVE COLITIS	RECTAL	-206 days	-180 days
mesalazine	ULCERATIVE COLITIS	RECTAL	-206 days	-101 days
fentanyl	ANASTHESIA	INTRAVENOUS	-7 days	-7 days
midazolam	ANESTHESIA	INTRAVENOUS	-7 days	-7 days
fentanyl	ANAESTHESIA	INTRAVENOUS	71 days	71 days
midazolam	ANAESHESIA	INTRAVENOUS	71 days	71 days

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
sodium phosphate dibasic;sodium phosphate monobasic	BOWEL PREPARATION	RECTAL	71 days	71 days
fentanyl	ANAESTHESIA	INTRAVENOUS	74 days	74 days
midazolam	ANAESTHESIA	INTRAVENOUS	74 days	74 days
propofol	ANAESTHESIA	INTRAVENOUS	74 days	74 days
sodium phosphate dibasic;sodium phosphate monobasic	BOWEL PREPARATION	RECTAL	74 days	74 days
fexofenadine hydrochloride	ITCHY SKIN NECK, BACK AND ELBOW CREASES	ORAL	124 days	125 days
pneumococcal vaccine polysacch 23v	PNEUMONIA VACCINE AS PROPHYLAXIS	INTRAMUSCULAR	147 days	147 days
typhoid vaccine	TRAVEL VACCINATION	INTRAMUSCULAR	147 days	147 days
atovaquone;proguanil hydrochloride	MALARIA PROPHYLAXIS	ORAL	201 days	212 days
enoxaparin	HAEMORRHOIDS	RECTAL	239 days	245 days
oxycodone	PAIN RELIEF	ORAL	240 days	245 days
paracetamol	PAIN RELIEF	ORAL	240 days	245 days
colecalciferol	ACUTE RENAL DISEASE	ORAL	241 days	245 days
vitamins nos	PROPHYLACTIC	ORAL	241 days	245 days

All Adverse Events							
Preferred Term	Onset Day	Resolution Day	Toxicity Grade	Causality	Action taken with Induction Drug	Action taken with Maintenance Drug	Action - Other
Headache	36	40	1	not related	dose not changed	not applicable	none
Headache	72	72	1	related	dose not changed	not applicable	none
Rash pruritic	74	83	1	not related	dose not changed	dose not changed	none
Headache	78	78	1	related	dose not changed	not applicable	none
Upper respiratory tract infection	20*	22*	1	not related	not applicable	dose not changed	none
Pruritus	45*	46*	1	not related	not applicable	dose not changed	medication required
Rectal haemorrhage	103*	Ongoing	1	not related	not applicable	dose not changed	none
Diarrhoea	134*	135*	2	related	not applicable	dose not changed	none
Acute kidney injury	157*	Ongoing	3	not related	not applicable	drug withdrawn	medication required + permanent study discontinuation
* denotes the Maintenance study day.							

Hematology						
Study Day	Hemoglobin (g/dL)	Hematocrit (%)	Erythrocytes (x10^6/uL)	Platelets (x10^3/uL)	Reticulocytes (x10^6/uL)	Ery. Mean Corpuscular Volume (fL)
-17	12.6 (N)	39 (N)	4.9 (N)	283 (N)	0.057 (N)	80 (N)
1	13.1 (N)	40 (N)	5.1 (N)	318 (N)	0.073 (N)	80 (N)
15	12.3 (N)	38 (N)	4.8 (N)	340 (N)	0.074 (N)	80 (N)
30	12.1 (N)	37 (N)	4.7 (N)	307 (N)	0.061 (N)	80 (N)
43	12.8 (N)	40 (N)	5 (N)	332 (N)	0.057 (N)	81 (N)
74	12.7 (N)	39 (N)	4.9 (N)	280 (N)	0.062 (N)	78 (L)
-6*	12.7 (N)	39 (N)	4.9 (N)	280 (N)	0.062 (N)	78 (L)
24*	12.5 (N)	38 (N)	4.8 (N)	311 (N)	0.058 (N)	79 (N)
59*	12.2 (N)	39 (N)	4.7 (N)	333 (N)	0.061 (N)	84 (N)
104*	12.5 (N)	40 (N)	4.9 (N)	315 (N)	0.043 (N)	81 (N)
160*	11.2 (L)	35 (N)	4.3 (N)	341 (N)	0.043 (N)	80 (N)
216*	11.4 (L)	36 (N)	4.4 (N)	304 (N)	0.071 (N)	81 (N)
* denotes the Maintenance study day. 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)
-17	6.16 (N)	3.83 (N)	1.56 (N)	0.38 (N)	0.06 (N)	0.32 (N)
1	7.16 (N)	3.88 (N)	2.16 (N)	0.41 (N)	0.08 (N)	0.64 (H)
15	6.45 (N)	3.53 (N)	1.8 (N)	0.38 (N)	0.07 (N)	0.66 (H)
30	6.12 (N)	2.9 (N)	2.22 (N)	0.3 (N)	0.1 (N)	0.59 (H)
43	6.84 (N)	3.32 (N)	2.61 (N)	0.4 (N)	0.1 (N)	0.41 (N)
74	6.52 (N)	2.91 (N)	2.66 (N)	0.38 (N)	0.09 (N)	0.48 (N)
-6*	6.52 (N)	2.91 (N)	2.66 (N)	0.38 (N)	0.09 (N)	0.48 (N)
24*	6.93 (N)	3.66 (N)	2.5 (N)	0.41 (N)	0.08 (N)	0.27 (N)
59*	6.7 (N)	3.33 (N)	2.64 (N)	0.35 (N)	0.09 (N)	0.29 (N)
104*	5.23 (N)	2.75 (N)	1.87 (N)	0.35 (N)	0.07 (N)	0.18 (N)
160*	7.03 (N)	4.3 (N)	2.07 (N)	0.29 (N)	0.04 (N)	0.33 (N)
216*	5.31 (N)	3.06 (N)	1.74 (N)	0.27 (N)	0.03 (N)	0.2 (N)
* denotes the Maintenance study day. 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)
-17	No	22 (N)	21 (N)	101 (N)	0.4 (N)	0.71 (N)
1	No	24 (N)	21 (N)	119 (N)	0.4 (N)	0.72 (N)
15	No	21 (N)	19 (N)	103 (N)	0.3 (N)	0.7 (N)
30	No	17 (N)	18 (N)	101 (N)	0.4 (N)	0.69 (N)
43	No	17 (N)	21 (N)	107 (N)	0.4 (N)	0.68 (N)
74	Yes	14 (N)	19 (N)	109 (N)	0.5 (N)	0.68 (N)
-6*	Yes	14 (N)	19 (N)	109 (N)	0.5 (N)	0.68 (N)
24*	No	13 (N)	18 (N)	103 (N)	0.4 (N)	0.7 (N)
59*	No	14 (N)	19 (N)	95 (N)	0.4 (N)	0.71 (N)
104*	No	15 (N)	20 (N)	110 (N)	0.6 (N)	0.69 (N)
160*	No	9 (N)	14 (N)	103 (N)	0.2 (N)	1.79 (H)
175*	No	14 (N)	19 (N)	105 (N)	0.3 (N)	1.3 (H)
216*	No	13 (N)	18 (N)	95 (N)	0.3 (N)	1.1 (N)
* denotes the Maintenance study day. 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)
-17	No	75.6 (N)	53 (N)	111 (H)	1.63 (N)
1	No	75.6 (N)	38 (N)	112 (H)	1.13 (N)
15	No	78 (N)	47 (N)	147 (H)	1.45 (N)
30	No	80.4 (N)	47 (N)	118 (H)	0.85 (N)
43	No	81 (N)	52 (N)	122 (H)	1.28 (N)
74	Yes	76.8 (N)	61 (N)	120 (H)	2.75 (N)
-6*	Yes	76.8 (N)	61 (N)	120 (H)	2.75 (N)
24*	No	75.6 (N)	51 (N)	129 (H)	1.73 (N)
59*	No	74.4 (L)	49 (N)	120 (H)	0.59 (N)
104*	No	74.4 (L)	52 (N)	103 (H)	0.97 (N)
160*	No	29.4 (L)	42 (N)	157 (H)	6.78 (N)
175*	No	39 (L)	65 (N)	121 (H)	
216*	No	46.8 (L)	52 (N)	137 (H)	1.21 (N)
* denotes the Maintenance study day. 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)
-17	No	222 (N)	43 (N)	159 (H)	112 (N)
1	No	209 (N)	41 (N)	155 (H)	121 (N)
15	No	207 (N)	42 (N)	146 (H)	127 (N)
30	No	212 (N)	41 (N)	141 (H)	178 (N)
43	No	189 (N)	41 (N)	134 (H)	116 (N)
74	Yes	209 (N)	43 (N)	143 (H)	97 (N)
-6*	Yes	209 (N)	43 (N)	143 (H)	97 (N)
24*	No	207 (N)	39 (N)	138 (H)	163 (N)
59*	No	208 (N)	45 (N)	143 (H)	116 (N)
104*	No	232 (N)	48 (N)	162 (H)	157 (N)
216*	No	186 (N)	41 (N)	150 (H)	43 (L)
* denotes the Maintenance study day. H = High; L = Low; N = Normal.					

被験者識別番号：[redacted]

投与群：寛解導入試験－フィルゴチニブ 100 mg 群（コホート B）

治験薬の投与状況：寛解導入試験－妊娠により投与中止（Day 14）；寛解維持試験－不参加

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、民族は非ヒスパニック／ラテン系、ドイツからの参加であった。

異所性妊娠（Day 12～22）（試験治療下の重篤な有害事象）（寛解導入試験）：
Day 12、Grade 4 の重篤な異所性妊娠が発現した。寛解導入治験薬に対する処置は非該当であった。寛解維持治験薬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 22、Grade 4 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
gastritis	Ongoing

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
colecalciferol	PROPHYLAXIS OF VITAMIN D DEFICIENCY	ORAL	-681 days	Ongoing
mesalazine	ULCERATIVE COLITIS	ORAL	-681 days	Ongoing
pantoprazole sodium sesquihydrate	GASTRITIS	ORAL	-28 days	Ongoing
infliximab	ULCERATIVE COLITIS	INTRAVENOUS	About -2897 days	About -1164 days
azathioprine	ULCERATIVE COLITIS	ORAL	-1386 days	-672 days
prednisolone	ULCERATIVE COLITIS	ORAL	-672 days	-636 days

All Adverse Events							
Preferred Term	**Onset Day**	**Resolution Day**	**Toxicity Grade**	**Causality**	**Action taken with Induction Drug**	**Action taken with Maintenance Drug**	**Action - Other**
Ectopic pregnancy	12	22	4	not related	not applicable	not applicable	other treatment required
* denotes the Maintenance study day.							

Hematology						
Study Day	Hemoglobin (g/dL)	Hematocrit (%)	Erythrocytes (x10^6/uL)	Platelets (x10^3/uL)	Reticulocytes (x10^6/uL)	Ery. Mean Corpuscular Volume (fL)
-28	12.8 (N)	38 (N)	4.4 (N)	502 (H)	0.066 (N)	87 (N)
1	11.9 (N)	35 (N)	4.2 (N)	473 (H)	0.08 (N)	84 (N)
15	10.9 (L)	33 (L)	3.8 (L)	449 (H)	0.078 (N)	86 (N)
* denotes the Maintenance study day. 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)
-28	8.9 (N)	6.14 (N)	1.56 (N)	0.51 (N)	0.06 (N)	0.63 (H)
1	9.33 (N)	6.78 (N)	1.63 (N)	0.47 (N)	0.04 (N)	0.41 (N)
15	10.02 (N)	6.8 (N)	1.61 (N)	0.64 (N)	0.09 (N)	0.87 (H)
* denotes the Maintenance study day. 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)
-28	No	14 (N)	14 (N)	91 (N)	0.2 (N)	0.64 (N)
1	No	11 (N)	12 (N)	80 (N)	<0.2 (L)	0.55 (N)
15	No	10 (N)	11 (N)	85 (N)	<0.2 (L)	0.61 (N)
* denotes the Maintenance study day. 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)
-28	No	159.6 (H)	51 (N)	93 (N)	48.5 (H)
1	No	192 (H)	41 (N)	95 (N)	34.5 (H)
15	No	174 (H)	48 (N)	64 (L)	27.4 (H)
* denotes the Maintenance study day. 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)
-28	No	145 (N)	57 (N)	73 (N)	98 (N)
1	No	146 (N)	54 (N)	80 (N)	83 (N)
15	No	142 (N)	46 (N)	74 (N)	125 (N)
* denotes the Maintenance study day. H = High; L = Low; N = Normal.					

被験者識別番号：[redacted]

投与群：寛解導入試験－フィルゴチニブ 200 mg 群（コホート A）；寛解維持試験－フィルゴチニブ 200 mg 群

治験薬の投与状況：寛解導入試験－完了；寛解維持試験－完了

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、ポーランドからの参加であった。

気管支炎（Day 68～75）（試験治療下の注目すべき有害事象［TE-AEI］）（寛解導入試験）：
Day 68、Grade 2 の非重篤な気管支炎が発現した。寛解導入治験薬に対する処置は変更なし。寛解維持治験薬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 75、Grade 2 の本事象は回復した。

咽頭炎（Day 154*～214*）（TE-AEI）（寛解維持試験）：
Day 154*、Grade 2 の非重篤な咽頭炎が発現した。寛解導入治験薬に対する処置は非該当であった。寛解維持治験薬に対する処置は変更なし。本事象は治験薬と関連なしと判断された。Day 214*、Grade 2 の本事象は回復した。

胸痛（Day 207*～211*）（試験治療下の重篤な有害事象）（寛解維持試験）：
Day 207*、Grade 1 の重篤な胸痛が発現した。寛解導入治験薬に対する処置は非該当であった。寛解維持治験薬に対する処置は変更なし。本事象は治験薬と関連なしと判断された。Day 211*、Grade 1 の本事象は回復した。

その他の関連情報：特になし。
*寛解維持試験における study day

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

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
mesalazine	ULCERATIVE COLITIS	ORAL	-101 days	Ongoing
bisoprolol fumarate	SUPRAVENTRICULAR ARRHYTHMIA	ORAL	293 days	Ongoing
mesalazine	ULCERATIVE COLITIS	ORAL	-3165 days	-3008 days
prednisone	ULCERATIVE COLITIS	ORAL	-2683 days	-2592 days
sulfasalazine	ULCERATIVE COLITIS	ORAL	-3008 days	About -2491 days
citric acid;magnesium oxide;sodium picosulfate	PREPARATION BEFORE COLONOSCOPY	ORAL	-7 days	-7 days
citric acid;magnesium oxide;sodium picosulfate	PREPARATION BEFORE COLONOSCOPY	ORAL	74 days	74 days
cefuroxime	BRONCHITIS	ORAL	69 days	76 days
prednisone	ULCERATIVE COLITIS	ORAL	-31 days	103 days
prednisone	ULCERATIVE COLITIS	ORAL	104 days	117 days
prednisone	ULCERATIVE COLITIS	ORAL	118 days	131 days
prednisone	ULCERATIVE COLITIS	ORAL	132 days	145 days

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
azithromycin	PHARYNGITIS	ORAL	237 days	239 days
citric acid;magnesium oxide;sodium picosulfate	PREPARATION BEFORE COLONOSCOPY	ORAL	406 days	406 days

All Adverse Events							
Preferred Term	**Onset Day**	**Resolution Day**	**Toxicity Grade**	**Causality**	**Action taken with Induction Drug**	**Action taken with Maintenance Drug**	**Action - Other**
Bronchitis	68	75	2	not related	dose not changed	not applicable	medication required
Blood cholesterol increased	22*	Ongoing	3	not related	dose not changed	dose not changed	none
Pharyngitis	154*	214*	2	not related	not applicable	dose not changed	medication required
Chest pain	207*	211*	1	not related	not applicable	dose not changed	none
Arrhythmia supraventricular	210*	Ongoing	1	not related	not applicable	dose not changed	medication required
Obesity	211*	Ongoing	1	not related	not applicable	dose not changed	none
Varicose vein	211*	Ongoing	1	not related	not applicable	dose not changed	none
* denotes the Maintenance study day.							

Hematology						
Study Day	Hemoglobin (g/dL)	Hematocrit (%)	Erythrocytes (x10^6/uL)	Platelets (x10^3/uL)	Reticulocytes (x10^6/uL)	Ery. Mean Corpuscular Volume (fL)
-17	12.5 (N)	36 (N)	4.1 (N)	215 (N)	0.048 (N)	90 (N)
1	11.9 (N)	35 (N)	3.9 (N)	238 (N)	0.068 (N)	89 (N)
15	12.4 (N)	37 (N)	3.9 (N)	191 (N)	0.073 (N)	95 (N)
29	12.7 (N)	37 (N)	3.9 (N)	170 (N)	0.064 (N)	93 (N)
43	12.7 (N)	38 (N)	4.1 (N)	228 (N)	0.09 (N)	94 (N)
75	13.7 (N)	40 (N)	4.3 (N)	253 (N)	0.07 (N)	94 (N)
-8*	13.7 (N)	40 (N)	4.3 (N)	253 (N)	0.07 (N)	94 (N)
22*	13.1 (N)	39 (N)	4.1 (N)	173 (N)	0.083 (N)	95 (N)
63*	13.1 (N)	38 (N)	4 (N)	208 (N)	0.068 (N)	94 (N)
102*	12.9 (N)	39 (N)	4 (N)	203 (N)	0.066 (N)	97 (N)
158*	12.5 (N)	38 (N)	3.9 (N)	201 (N)	0.047 (N)	97 (N)
214*	12.6 (N)	40 (N)	4 (N)	197 (N)	0.029 (L)	101 (H)
302*	13 (N)	39 (N)	4 (N)	208 (N)	0.067 (N)	96 (N)
325*	12.8 (N)	37 (N)	3.8 (L)	213 (N)	0.05 (N)	97 (N)
* denotes the Maintenance study day. 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)
-17	4.63 (N)	2.29 (N)	1.85 (N)	0.34 (N)	0.02 (N)	0.12 (N)
1	6.31 (N)	2.81 (N)	2.72 (N)	0.42 (N)	0.05 (N)	0.32 (N)
15	7.4 (N)	3.14 (N)	3.47 (H)	0.41 (N)	0.08 (N)	0.3 (N)
29	4.3 (N)	2.1 (N)	1.78 (N)	0.27 (N)	0.02 (N)	0.12 (N)
43	7.14 (N)	3.7 (N)	2.85 (N)	0.42 (N)	0.03 (N)	0.13 (N)
75	7.99 (N)	3.48 (N)	3.82 (H)	0.49 (N)	0.06 (N)	0.14 (N)
-8*	7.99 (N)	3.48 (N)	3.82 (H)	0.49 (N)	0.06 (N)	0.14 (N)
22*	6.79 (N)	2.83 (N)	3.25 (H)	0.38 (N)	0.08 (N)	0.26 (N)
63*	5.48 (N)	2.54 (N)	2.33 (N)	0.35 (N)	0.07 (N)	0.18 (N)
102*	5.65 (N)	3.13 (N)	2.01 (N)	0.32 (N)	0.02 (N)	0.18 (N)
158*	3.75 (L)	1.65 (L)	1.76 (N)	0.22 (N)	0.02 (N)	0.1 (N)
214*	3.9 (N)	1.76 (L)	1.79 (N)	0.27 (N)	0.02 (N)	0.06 (N)
302*	4.93 (N)	2.39 (N)	1.97 (N)	0.38 (N)	0.03 (N)	0.16 (N)
325*	5.31 (N)	2.8 (N)	1.96 (N)	0.39 (N)	0.02 (N)	0.14 (N)
* denotes the Maintenance study day. 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)
-17	Yes	9 (N)	16 (N)	42 (N)	0.3 (N)	0.79 (N)
1	Yes	14 (N)	15 (N)	44 (N)	0.3 (N)	0.87 (N)
15	Yes	15 (N)	15 (N)	39 (N)	0.3 (N)	0.9 (N)
29	Yes	12 (N)	17 (N)	38 (N)	<0.2 (L)	0.88 (N)
43	Yes	14 (N)	18 (N)	39 (N)	0.3 (N)	0.97 (N)
75	Yes	18 (N)	16 (N)	41 (N)	0.2 (N)	0.94 (N)
-8*	Yes	18 (N)	16 (N)	41 (N)	0.2 (N)	0.94 (N)
22*	Yes	14 (N)	14 (N)	33 (L)	0.2 (N)	1.04 (N)
63*	Yes	15 (N)	19 (N)	39 (N)	0.3 (N)	0.9 (N)
102*	Yes	14 (N)	18 (N)	41 (N)	0.2 (N)	0.87 (N)
158*	Yes	15 (N)	20 (N)	44 (N)	0.2 (N)	1.03 (N)
214*	Yes	19 (N)	24 (N)	39 (N)	0.2 (N)	0.92 (N)
302*	Yes	11 (N)	18 (N)	41 (N)	0.3 (N)	0.87 (N)
325*	Yes	14 (N)	22 (N)	40 (N)	0.4 (N)	0.89 (N)
* denotes the Maintenance study day. 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)
-17	Yes	89.4 (N)	59 (N)	95 (N)	6.68 (N)
1	Yes	81 (N)	52 (N)	90 (N)	2.89 (N)
15	Yes	79.2 (N)	53 (N)	89 (N)	1.84 (N)
29	Yes	81 (N)	42 (N)	88 (N)	9.4 (N)
43	Yes	72.6 (L)	45 (N)	88 (N)	4.72 (N)
75	Yes	76.2 (N)	40 (N)	94 (N)	3.51 (N)
-8*	Yes	76.2 (N)	40 (N)	94 (N)	3.51 (N)
22*	Yes	70.8 (L)	39 (N)	86 (N)	1.08 (N)
63*	Yes	81.6 (N)	89 (N)	94 (N)	2.44 (N)
102*	Yes	84.6 (N)	94 (N)	89 (N)	4.16 (N)
158*	Yes	72 (L)	84 (N)	89 (N)	15.3 (H)
214*	Yes	81 (N)	92 (N)	100 (H)	1.85 (N)
302*	Yes	82.8 (N)	85 (N)	102 (H)	2.5 (N)
325*	Yes	79.8 (N)	96 (N)	105 (H)	2.11 (N)
* denotes the Maintenance study day. 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)
-17	Yes	325 (H)	63 (N)	230 (H)	183 (N)
1	Yes	323 (H)	73 (N)	222 (H)	149 (N)
15	Yes	335 (H)	99 (H)	223 (H)	107 (N)
29	Yes	347 (H)	102 (H)	215 (H)	153 (N)
43	Yes	382 (H)	121 (H)	231 (H)	160 (N)
75	Yes	377 (H)	108 (H)	229 (H)	239 (N)
-8*	Yes	377 (H)	108 (H)	229 (H)	239 (N)
22*	Yes	422 (H)	113 (H)	267 (H)	226 (N)
102*	Yes	338 (H)	88 (N)	224 (H)	213 (N)
325*	Yes	213 (N)	87 (N)	114 (N)	120 (N)
* denotes the Maintenance study day. H = High; L = Low; N = Normal.					

被験者識別番号：[redacted]

投与群：寛解導入試験－フィルゴチニブ 100 mg 群（コホート A）；寛解維持試験－フィルゴチニブ 100 mg 群

治験薬の投与状況：寛解導入試験－完了；寛解維持試験－完了

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、チェコからの参加であった。

一過性脳虚血発作（Day 313*～317*）（試験治療下の重篤な有害事象、試験治療下の注目すべき有害事象）（寛解維持試験）：
Day 313*、Grade 2 の重篤な一過性脳虚血発作が発現した。寛解導入治験薬に対する処置は非該当であった。寛解維持治験薬に対する処置は投与中断であった。本事象は治験薬と関連なしと判断された。Day 317*、Grade 2 の本事象は回復した。

その他の関連情報：被験者は、一過性構語障害及び左手の異常感覚のため入院した。コンピューター断層脳血管撮影検査の結果、異常は認められなかった。栓友病関連変異に関する検査結果は陰性であった。コレステロール値の上昇（5.93 mmol/L）及びトリグリセリド値の上昇（4.11 mmol/L）が認められた。治療薬としてアスピリン及びスタチンが投与された。症状は回復し、被験者は退院した。
*寛解維持試験における study day

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

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
mesalazine	ULCERATIVE COLITIS	ORAL	-628 days	Ongoing
azathioprine	ULCERATIVE COLITIS	ORAL	-166 days	Ongoing
escherichia coli	ULCERATIVE COLITIS	ORAL	-51 days	Ongoing
acetylsalicylic acid;glycine	CORONARY ARTERY DISEASE(SAE)	ORAL	391 days	Ongoing
pantoprazole	DISPEPSIA (SAE)	ORAL	391 days	Ongoing
rosuvastatin calcium	HYPERLIPIDEMIA (SAE)	ORAL	391 days	Ongoing
prednisone	ULCERATIVE COLITIS	ORAL	-223 days	-128 days
mesalazine	ULCERATIVE COLITIS	RECTAL	-411 days	-51 days
gabapentin	SPINAL RADICULOPATHY	ORAL	342 days	390 days
acetylsalicylate lysine	TRANSITORY ISCHEMIC ATTACK (SAE)	INTRAVENOUS	391 days	391 days
fenpiverinium bromide;metamizole sodium;pitofenone hydrochloride	TRANSITORY ISCHEMIC ATTACK (SAE)	ORAL	391 days	393 days
enoxaparin sodium	TRANSITORY ISCHEMIC ATTACK (SAE)	SUBCUTANEOUS	391 days	394 days

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
gluconate sodium;magnesium chloride hexahydrate;potassium chloride;sodium acetate trihydrate;sodium chloride	TRANSITORY ISCHEMIC ATTACK (SAE)	INTRAVENOUS	391 days	394 days
magnesium sulfate	TRANSITORY ISCHEMIC ATTACK (SAE)	INTRAVENOUS	391 days	394 days

All Adverse Events							
Preferred Term	**Onset Day**	**Resolution Day**	**Toxicity Grade**	**Causality**	**Action taken with Induction Drug**	**Action taken with Maintenance Drug**	**Action - Other**
Pyrexia	14*	20*	1	not related	not applicable	dose not changed	none
Coronary artery disease	313*	Ongoing	1	not related	not applicable	dose not changed	medication required
Dyspepsia	313*	Ongoing	1	not related	not applicable	dose not changed	medication required
Hyperlipidaemia	313*	Ongoing	1	not related	not applicable	dose not changed	medication required
Transient ischaemic attack	313*	317*	2	not related	not applicable	drug interrupted	medication required
* denotes the Maintenance study day.							

Hematology						
Study Day	Hemoglobin (g/dL)	Hematocrit (%)	Erythrocytes (x10^6/uL)	Platelets (x10^3/uL)	Reticulocytes (x10^6/uL)	Ery. Mean Corpuscular Volume (fL)
-21	16.1 (N)	47 (N)	5.1 (N)	312 (N)	0.12 (N)	92 (N)
1	16.3 (N)	48 (N)	5.2 (N)	289 (N)	0.105 (N)	93 (N)
15	16 (N)	46 (N)	5 (N)	288 (N)	0.101 (N)	92 (N)
44	16.2 (N)	48 (N)	5.1 (N)	336 (N)	0.084 (N)	94 (N)
71	16.5 (N)	47 (N)	5.1 (N)	276 (N)	0.079 (N)	92 (N)
-8*	16.5 (N)	47 (N)	5.1 (N)	276 (N)	0.079 (N)	92 (N)
21*	15.3 (N)	45 (N)	4.8 (N)	315 (N)	0.085 (N)	96 (N)
61*	15.4 (N)	46 (N)	4.5 (N)	276 (N)	0.091 (N)	101 (H)
98*	16.1 (N)	46 (N)	4.7 (N)	296 (N)	0.068 (N)	98 (H)
159*	16 (N)	48 (N)	4.8 (N)	285 (N)	0.111 (N)	101 (H)
215*	15.8 (N)	48 (N)	4.8 (N)	288 (N)	0.079 (N)	99 (H)
271*	16.5 (N)	48 (N)	4.9 (N)	290 (N)	0.079 (N)	98 (H)
328*	16.6 (N)	47 (N)	5 (N)	325 (N)	0.063 (N)	95 (N)
* denotes the Maintenance study day. 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)
-21	4.98 (N)	2.84 (N)	1.57 (N)	0.28 (N)	0.09 (N)	0.2 (N)
1	4.05 (N)	2.13 (N)	1.42 (N)	0.25 (N)	0.08 (N)	0.17 (N)
15	5.21 (N)	3.15 (N)	1.55 (N)	0.29 (N)	0.07 (N)	0.15 (N)
44	4.94 (N)	2.91 (N)	1.78 (N)	0.21 (N)	0.01 (N)	0.03 (N)
71	2.57 (L)	1.27 (L)	0.91 (N)	0.25 (N)	0.07 (N)	0.07 (N)
-8*	2.57 (L)	1.27 (L)	0.91 (N)	0.25 (N)	0.07 (N)	0.07 (N)
21*	3.89 (N)	2.15 (N)	1.5 (N)	0.19 (N)	0 (N)	0.05 (N)
61*	3.87 (N)	2.27 (N)	1.43 (N)	0.13 (N)	0.02 (N)	0.03 (N)
98*	5.21 (N)	3.39 (N)	1.44 (N)	0.3 (N)	0.04 (N)	0.05 (N)
159*	3.6 (L)	2.17 (N)	1.1 (N)	0.29 (N)	0.01 (N)	0.03 (N)
215*	4.51 (N)	2.78 (N)	1.47 (N)	0.19 (N)	0.01 (N)	0.05 (N)
271*	5.73 (N)	3.74 (N)	1.61 (N)	0.29 (N)	0.01 (N)	0.07 (N)
328*	5.31 (N)	3.58 (N)	1.4 (N)	0.25 (N)	0.02 (N)	0.06 (N)
* denotes the Maintenance study day. 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)
-21	Yes	27 (N)	25 (N)	49 (N)	0.8 (N)	0.84 (N)
1	Yes	28 (N)	28 (N)	48 (N)	0.9 (N)	0.86 (N)
15	Yes	26 (N)	22 (N)	46 (N)	0.6 (N)	0.92 (N)
31	Yes			48 (N)		0.85 (N)
44	Yes	28 (N)	20 (N)	47 (N)	1.1 (N)	0.9 (N)
71	Yes	27 (N)	23 (N)	44 (N)	0.6 (N)	0.85 (N)
-8*	Yes	27 (N)	23 (N)	44 (N)	0.6 (N)	0.85 (N)
21*	Yes	32 (N)	23 (N)	43 (N)	0.8 (N)	0.95 (N)
61*	Yes	21 (N)	16 (N)	41 (N)	0.8 (N)	0.81 (N)
98*	Yes	20 (N)	16 (N)	42 (N)	1 (N)	0.97 (N)
159*	Yes	22 (N)	15 (N)	42 (N)	0.5 (N)	0.93 (N)
215*	Yes	15 (N)	14 (N)	39 (N)	0.5 (N)	0.92 (N)
271*	Yes	24 (N)	17 (N)	39 (N)	0.5 (N)	0.93 (N)
328*	Yes	46 (H)	31 (N)	47 (N)	1.2 (N)	1.02 (N)

* denotes the Maintenance study day.
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)
-21	Yes	152.4 (H)	254 (N)	89 (N)	0.61 (N)
1	Yes	148.8 (H)	196 (N)	87 (N)	0.46 (N)
15	Yes	139.2 (H)	113 (N)	90 (N)	0.36 (N)
31	Yes	150.6 (H)			0.39 (N)
44	Yes	141 (H)	141 (N)	90 (N)	0.31 (N)
71	Yes	150.6 (H)	128 (N)	82 (N)	1.18 (N)
-8*	Yes	150.6 (H)	128 (N)	82 (N)	1.18 (N)
21*	Yes	134.4 (H)	149 (N)	88 (N)	0.62 (N)
61*	Yes	157.2 (H)	177 (N)	89 (N)	<0.20 (N)
98*	Yes	131.4 (H)	133 (N)	90 (N)	0.29 (N)
159*	Yes	136.2 (H)	144 (N)	102 (H)	0.36 (N)
215*	Yes	142.8 (H)	101 (N)	95 (N)	0.29 (N)
271*	Yes	136.2 (H)	111 (N)	92 (N)	0.45 (N)
328*	Yes	124.2 (N)	129 (N)	81 (N)	0.27 (N)

* denotes the Maintenance study day.
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)
-21	Yes	166 (N)	43 (N)	106 (N)	101 (N)
1	Yes	180 (N)	43 (N)	117 (N)	86 (N)
15	Yes	213 (N)	46 (N)	163 (H)	130 (N)
31	Yes	191 (N)	43 (N)	129 (N)	90 (N)
44	Yes	195 (N)	44 (N)	138 (H)	106 (N)
71	Yes	194 (N)	44 (N)	131 (H)	92 (N)
-8*	Yes	194 (N)	44 (N)	131 (H)	92 (N)
98*	Yes	181 (N)	42 (N)	123 (N)	111 (N)
328*	Yes	110 (L)	41 (N)	48 (N)	108 (N)
* denotes the Maintenance study day. H = High; L = Low; N = Normal.					

被験者識別番号：[redacted]

投与群：寛解導入試験－フィルゴチニブ 200 mg 群（コホート B）；寛解維持試験－フィルゴチニブ 200 mg 群

治験薬の投与状況：寛解導入試験－完了；寛解維持試験－治験実施計画書に規定された疾患の悪化により投与中止（Day 138*）

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、ベルギーからの参加であった。

上気道感染（Day 10～15）（試験治療下の注目すべき有害事象［TE-AEI］）（寛解導入試験）：
Day 10、Grade 2 の非重篤な上気道感染が発現した。寛解導入治験薬に対する処置は変更なし。寛解維持治験薬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 15、Grade 2 の本事象は回復した。

副鼻腔炎（Day 4*～8*）（TE-AEI）（寛解維持試験）：
Day 4*、Grade 2 の非重篤な副鼻腔炎が発現した。寛解導入治験薬に対する処置は非該当であった。寛解維持治験薬に対する処置は変更なし。本事象は治験薬と関連なしと判断された。Day 8*、Grade 2 の本事象は回復した。

腱断裂（Day 13*～15*）（試験治療下の重篤な有害事象）（寛解維持試験）：
Day 13*、Grade 3 の重篤な腱断裂が発現した。寛解導入治験薬に対する処置は非該当であった。寛解維持治験薬に対する処置は投与中断であった。本事象は治験薬と関連なしと判断された。Day 15*、Grade 3 の本事象は回復した。

副鼻腔炎（Day 50*～64*）（TE-AEI）（寛解維持試験）：
Day 50*、Grade 2 の非重篤な副鼻腔炎が発現した。寛解導入治験薬に対する処置は非該当であった。寛解維持治験薬に対する処置は変更なし。本事象は治験薬と関連なしと判断された。Day 64*、Grade 2 の本事象は回復した。

その他の関連情報：特になし。
*寛解維持試験における study day

Medical History	
Medical History	**Resolution**
colitis ulcerative	Ongoing
oesophagitis	Ongoing
sinusitis	-6 days

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
pantoprazole	OESOPHAGITIS	ORAL	-466 days	Ongoing
mesalazine	ULCERATIVE COLITIS	ORAL	-458 days	Ongoing
beclometasone dipropionate	ULCERATIVE COLITIS	ORAL	104 days	Ongoing
mesalazine	ULCERATIVE COLITIS	RECTAL	-458 days	-388 days
golimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	-283 days	-283 days
golimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	-269 days	-269 days

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
golimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	-241 days	-213 days
vedolizumab	ULCERATIVE COLITIS	INTRAVENOUS	-174 days	-174 days
vedolizumab	ULCERATIVE COLITIS	INTRAVENOUS	-153 days	-153 days
beclometasone dipropionate	ULCERATIVE COLITIS	ORAL	-416 days	-143 days
mesalazine	ULCERATIVE COLITIS	RECTAL	-143 days	-133 days
vedolizumab	ULCERATIVE COLITIS	INTRAVENOUS	-125 days	-97 days
acetylcysteine	SINUSITIS	RESPIRATORY (INHALATION)	-11 days	-6 days
budesonide	SINUSITIS	RESPIRATORY (INHALATION)	-11 days	-6 days
amoxicillin trihydrate	UPPER RESPIRATORY TRACT INFECTION	ORAL	12 days	17 days
clavulanic acid	UPPER RESPIRATORY TRACT INFECTION	ORAL	12 days	17 days
oxymetazoline	NASAL CONGESTION	NASAL	30 days	32 days
probiotics nos	PROPHYLAXIS	ORAL	30 days	44 days
doxycycline	SINUSITIS	ORAL	87 days	96 days
paracetamol	ACHILLES TENDON RUPTURE RELATED PAIN	ORAL	96 days	100 days
beclometasone dipropionate	ULCERATIVE COLITIS	ORAL	-142 days	103 days
enoxaparin sodium	DEEP VEIN THROMBOSIS PROPHYLAXIS	SUBCUTANEOUS	97 days	131 days
doxycycline	SINUSITIS	ORAL	134 days	143 days

All Adverse Events							
Preferred Term	Onset Day	Resolution Day	Toxicity Grade	Causality	Action taken with Induction Drug	Action taken with Maintenance Drug	Action - Other
Upper respiratory tract infection	10	15	2	not related	dose not changed	not applicable	medication required
Nasal congestion	26	32	2	not related	dose not changed	not applicable	medication required
Sinusitis	4*	8*	2	not related	not applicable	dose not changed	medication required
Tendon rupture	13*	15*	3	not related	not applicable	drug interrupted	medication required + other treatment required
Sinusitis	50*	64*	2	not related	not applicable	dose not changed	medication required
* denotes the Maintenance study day.							

Hematology						
Study Day	Hemoglobin (g/dL)	Hematocrit (%)	Erythrocytes (x10^6/uL)	Platelets (x10^3/uL)	Reticulocytes (x10^6/uL)	Ery. Mean Corpuscular Volume (fL)
-21	14 (N)	41 (N)	4.4 (L)	346 (N)	0.067 (N)	94 (N)
1	14.7 (N)	44 (N)	4.5 (N)	357 (N)	0.075 (N)	98 (H)
12	14.1 (N)	45 (N)	4.3 (L)	347 (N)	0.077 (N)	103 (H)
30	14.6 (N)	44 (N)	4.5 (N)	371 (N)	0.086 (N)	97 (H)
44	14.7 (N)	44 (N)	4.5 (N)	389 (N)	0.085 (N)	98 (H)
72	14.4 (N)	42 (N)	4.5 (N)	348 (N)	0.068 (N)	95 (N)
-11*	14.4 (N)	42 (N)	4.5 (N)	348 (N)	0.068 (N)	95 (N)
21*	14.6 (N)	43 (N)	4.4 (L)	379 (N)	0.051 (N)	97 (H)
59*	15.8 (N)	47 (N)	4.9 (N)	409 (H)	0.077 (N)	96 (N)
102*	14.9 (N)	45 (N)	4.6 (N)	398 (N)	0.049 (N)	97 (H)
* denotes the Maintenance study day. 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)
-21	8.65 (N)	4.8 (N)	3.2 (N)	0.57 (N)	0.01 (N)	0.07 (N)
1	8.05 (N)	4.12 (N)	3.18 (N)	0.62 (N)	0.04 (N)	0.09 (N)
12	10.48 (N)	6.73 (N)	2.67 (N)	0.98 (H)	0.03 (N)	0.07 (N)
30	7.99 (N)	4.12 (N)	3 (N)	0.75 (N)	0.03 (N)	0.08 (N)
44	8.23 (N)	4.33 (N)	2.93 (N)	0.87 (N)	0.02 (N)	0.07 (N)
72	6.87 (N)	4.38 (N)	1.95 (N)	0.49 (N)	0.01 (N)	0.04 (N)
-11*	6.87 (N)	4.38 (N)	1.95 (N)	0.49 (N)	0.01 (N)	0.04 (N)
21*	7.92 (N)	3.61 (N)	3.65 (N)	0.62 (N)	0.02 (N)	0.02 (N)
59*	13.98 (H)	8.57 (H)	4.48 (H)	0.89 (N)	0.02 (N)	0.04 (N)
102*	8.2 (N)	4.44 (N)	3 (N)	0.66 (N)	0.04 (N)	0.06 (N)
* denotes the Maintenance study day. 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)
-21	No	24 (N)	13 (N)	67 (N)	0.2 (N)	0.89 (N)
1	No	26 (N)	13 (N)	83 (N)	0.3 (N)	0.97 (N)
12	No	24 (N)	16 (N)	75 (N)	0.4 (N)	0.88 (N)
30	Yes	28 (N)	19 (N)	65 (N)	0.5 (N)	0.89 (N)
44	Yes	25 (N)	17 (N)	68 (N)	0.2 (N)	0.81 (N)
72	Yes	27 (N)	18 (N)	73 (N)	0.4 (N)	0.9 (N)
-11*	Yes	27 (N)	18 (N)	73 (N)	0.4 (N)	0.9 (N)
21*	Yes	30 (N)	17 (N)	71 (N)	0.4 (N)	0.93 (N)
59*	No	19 (N)	14 (N)	91 (N)	0.4 (N)	0.98 (N)
102*	No	19 (N)	14 (N)	78 (N)	0.2 (N)	0.94 (N)
* denotes the Maintenance study day. 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)
-21	No	107.4 (N)	37 (L)	131 (H)	0.63 (N)
1	No	98.4 (N)	55 (N)	101 (H)	0.72 (N)
12	No	109.2 (N)	64 (N)	83 (N)	0.39 (N)
30	Yes	106.8 (N)	72 (N)	81 (N)	0.45 (N)
44	Yes	118.2 (N)	47 (N)	82 (N)	0.97 (N)
72	Yes	106.2 (N)	69 (N)	78 (N)	0.25 (N)
-11*	Yes	106.2 (N)	69 (N)	78 (N)	0.25 (N)
21*	Yes	104.4 (N)	114 (N)	86 (N)	0.56 (N)
59*	No	95.4 (N)	71 (N)	55 (L)	14.6 (H)
102*	No	102.6 (N)	73 (N)	73 (N)	0.25 (N)
* denotes the Maintenance study day. 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	No	284 (H)	56 (N)	220 (H)	115 (N)
72	Yes	279 (N)	61 (N)	198 (H)	153 (N)
-11*	Yes	279 (N)	61 (N)	198 (H)	153 (N)

Lipid Panel					
Study Day	Fasting	Total Cholesterol (mg/dL)	HDL Cholesterol (mg/dL)	LDL Cholesterol (mg/dL)	Triglycerides (mg/dL)
102*	No	302 (H)	71 (H)	205 (H)	137 (N)
* denotes the Maintenance study day. H = High; L = Low; N = Normal.					

被験者識別番号：[redacted]

投与群：寛解導入試験－フィルゴチニブ 100 mg 群（コホート B）

治験薬の投与状況：寛解導入試験－有害事象により投与中止（Day 33）；寛解維持試験－不参加

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、ルーマニアからの参加であった。

潰瘍性大腸炎（Day 33～43）（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）（寛解導入試験）：
Day 33、Grade 3 の重篤な潰瘍性大腸炎が発現した。寛解導入治験薬に対する処置は投与中止であった。寛解維持治験薬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 43、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
iron deficiency anaemia	Ongoing
clostridium difficile infection	About -1488 days

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
ascorbic acid;ferric pyrophosphate	IRON DEFICIENCY ANEMIA	ORAL	5 days	Ongoing
mesalazine	ULCERATIVE COLITIS	ORAL	33 days	Ongoing
prednisone	ULCERATIVE COLITIS	ORAL	33 days	Ongoing
acetylsalicylic acid	PROPHYLAXIS OF THROMBOSIS	ORAL	44 days	Ongoing
pantoprazole	GASTRITIS	ORAL	44 days	Ongoing
mesalazine	ULCERATIVE COLITIS	RECTAL	About -2399 days	About -2003 days
azathioprine	ULCERATIVE COLITIS	ORAL	About -1760 days	About -1638 days
infliximab	ULCERATIVE COLITIS	INTRAVENOUS	About -1609 days	About -1488 days
adalimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	About -1091 days	About -1061 days
infliximab	ULCERATIVE COLITIS	INTRAVENOUS	About -1517 days	About -939 days
adalimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	About -1060 days	-767 days
prednisone	ULCERATIVE COLITIS	ORAL	About -2399 days	-148 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
adalimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	-766 days	-84 days
mesalazine	ULCERATIVE COLITIS	ORAL	About -2399 days	About -57 days
prednisone	ULCERATIVE COLITIS	ORAL	-147 days	About -57 days
citric acid;magnesium oxide;sodium picosulfate	COLONOSCOPY PREPARATION	ORAL	-3 days	-2 days
midazolam	COLONOSCOPY SEDATION	INTRAVENOUS	-2 days	-2 days
propofol	COLONOSCOPY SEDATION	INTRAVENOUS	-2 days	-2 days
alprazolam	UNKNOWN INDICATION FROM HOSPITAL DISCHARGE LETTER	ORAL	33 days	43 days
ciprofloxacin	UC FLARE	ORAL	33 days	43 days
fenpiverinium bromide;metamizole sodium;pitofenone hydrochloride	ABDOMINAL PAIN RELATED TO UC	INTRAVENOUS DRIP	33 days	43 days
fluconazole	MYCOSIS PROPHYLAXIS	INTRAVENOUS DRIP	33 days	43 days
glucose	NUTRITION	INTRAVENOUS	33 days	43 days
hydrocortisone acetate	ULCERATIVE COLITIS	INTRAVENOUS	33 days	43 days
loratadine	INDICATION UNK IN THE DISCHARGE LETTER AVAILABLE	INTRAVENOUS	33 days	43 days
magnesium aspartate;potassium aspartate	HYPOPOTASSEMIA	ORAL	33 days	43 days
metronidazole	ULCERATIVE COLITIS	UNKNOWN	33 days	43 days
nadroparin calcium	THROMBOSIS PROPHYLAXIS	SUBCUTANEOUS	33 days	43 days
ranitidine hydrochloride	GATRITIS	INTRAVENOUS DRIP	33 days	43 days
saccharated iron oxide	ANEMIA	INTRAVENOUS	33 days	43 days
sucralfate	GASTRITIS	ORAL	33 days	43 days
propofol	COLONOSCOPY SEDATION	INTRAVENOUS	43 days	43 days

All Adverse Events							
Preferred Term	Onset Day	Resolution Day	Toxicity Grade	Causality	Action taken with Induction Drug	Action taken with Maintenance Drug	Action - Other
Abdominal pain	22	Ongoing	1	not related	dose not changed	not applicable	none
Asthenia	22	Ongoing	1	not related	dose not changed	not applicable	none
Colitis ulcerative	33	43	3	not related	drug withdrawn	not applicable	medication required + permanent study discontinuation
Hypokalaemia	33	43	2	not related	not applicable	not applicable	medication required

All Adverse Events							
Preferred Term	Onset Day	Resolution Day	Toxicity Grade	Causality	Action taken with Induction Drug	Action taken with Maintenance Drug	Action - Other
Gastritis	43	Ongoing	2	not related	not applicable	not applicable	medication required
* denotes the Maintenance study day.							

Hematology						
Study Day	Hemoglobin (g/dL)	Hematocrit (%)	Erythrocytes (x10^6/uL)	Platelets (x10^3/uL)	Reticulocytes (x10^6/uL)	Ery. Mean Corpuscular Volume (fL)
-16	9.2 (L)	32 (L)	4.5 (N)	346 (N)	0.06 (N)	71 (L)
1	8.8 (L)	32 (L)	4.2 (L)	381 (N)	0.055 (N)	75 (L)
15	9.3 (L)	35 (L)	4.4 (L)	473 (H)	0.091 (N)	79 (N)
28	8.6 (L)	30 (L)	4.2 (L)	515 (H)	0.044 (N)	73 (L)
* denotes the Maintenance study day. 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)
-16	7.64 (N)	5.08 (N)	1.85 (N)	0.54 (N)	0.04 (N)	0.13 (N)
1	6.79 (N)	4.26 (N)	1.72 (N)	0.53 (N)	0.05 (N)	0.24 (N)
15	8.1 (N)	5.89 (N)	1.52 (N)	0.52 (N)	0.05 (N)	0.12 (N)
28	10.18 (N)	8.1 (H)	1.27 (N)	0.63 (N)	0.02 (N)	0.16 (N)
* denotes the Maintenance study day. 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)
-16	Yes	15 (N)	19 (N)	63 (N)	0.2 (N)	0.93 (N)
1	No	9 (N)	12 (N)	67 (N)	<0.2 (L)	0.92 (N)
15	Yes	12 (N)	18 (N)	77 (N)	0.3 (N)	1.06 (N)
28	Yes	11 (N)	14 (N)	60 (N)	<0.2 (L)	1.01 (N)
* denotes the Maintenance study day. 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)
-16	Yes	98.4 (N)	210 (N)	92 (N)	3.85 (N)
1	No	99.6 (N)	73 (N)	90 (N)	7.8 (N)
15	Yes	85.8 (N)	118 (N)		20.9 (H)
28	Yes	88.2 (N)	99 (N)	85 (N)	30.7 (H)
* denotes the Maintenance study day. 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	No	137 (L)	53 (N)	63 (N)	165 (N)
* denotes the Maintenance study day. H = High; L = Low; N = Normal.					

被験者識別番号：[redacted]

投与群：寛解導入試験－フィルゴチニブ 200 mg 群（コホート A）；寛解維持試験－フィルゴチニブ 200 mg 群

治験薬の投与状況：寛解導入試験－完了；寛解維持試験－完了

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、ロシアからの参加であった。

尿路結石（Day 99*～111*）（試験治療下の重篤な有害事象）（寛解維持試験）：
Day 99*、Grade 3 の重篤な尿路結石が発現した。寛解導入治験薬に対する処置は非該当であった。寛解維持治験薬に対する処置は変更なし。本事象は治験薬と関連なしと判断された。Day 111*、Grade 3 の本事象は回復した。

気管支炎（Day 212*～228*）（試験治療下の注目すべき有害事象）（寛解維持試験）：
Day 212*、Grade 2 の非重篤な気管支炎が発現した。寛解導入治験薬に対する処置は非該当であった。寛解維持治験薬に対する処置は変更なし。本事象は治験薬と関連なしと判断された。Day 228*、Grade 2 の本事象は回復した。

その他の関連情報：特になし。
*寛解維持試験における study day

Medical History	
Medical History	**Resolution**
calculus urinary	Ongoing
colitis ulcerative	Ongoing
hypertensive heart disease	Ongoing
pyelonephritis chronic	Ongoing

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
azathioprine	ULCERATIVE COLITIS	ORAL	About -3021 days	Ongoing
sulfasalazine	ULCERATIVE COLITIS	ORAL	About -1560 days	Ongoing
candesartan cilexetil	HEART HYPERTENSIVE DISEASE	ORAL	About -191 days	Ongoing
macrogol 4000;potassium chloride;sodium bicarbonate;sodium chloride;sodium sulfate anhydrous	PREPARATION FOR COLONOSKOPY	ORAL	-6 days	-6 days
ceftriaxone	ANTIBACTERIAL THERAPY. PREVENTION OF URINARY INFECTION.	INTRAMUSCULAR	177 days	186 days
achyranthes aspera;calcium silicate;cyperus scariosus;didymocarpus pedicellata;mineral wax;onosma bracteata;rubia cordifolia;saxifraga stolonifera;vernonia cinerea	'UROLITHIASIS KIDNEY STONE	ORAL	189 days	219 days
azithromycin	ACUTE BRONCHITIS	ORAL	290 days	292 days

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
diclofenac	VERTEBRATION LUMBALGIA	INTRAMUSCULAR	395 days	395 days
macrogol	PREPARATION FOR ENDOSCOPY	ORAL	406 days	406 days

All Adverse Events							
Preferred Term	**Onset Day**	**Resolution Day**	**Toxicity Grade**	**Causality**	**Action taken with Induction Drug**	**Action taken with Maintenance Drug**	**Action - Other**
Calculus urinary	99*	111*	3	not related	not applicable	dose not changed	medication required
Bronchitis	212*	228*	2	not related	not applicable	dose not changed	medication required
Back pain	317*	Ongoing	1	not related	not applicable	dose not changed	medication required
Blood cholesterol increased	329*	505*	1	related	not applicable	dose not changed	none
* denotes the Maintenance study day.							

Hematology						
Study Day	Hemoglobin (g/dL)	Hematocrit (%)	Erythrocytes (x10^6/uL)	Platelets (x10^3/uL)	Reticulocytes (x10^6/uL)	Ery. Mean Corpuscular Volume (fL)
-29	13.1 (N)	42 (N)	4.7 (N)	294 (N)	0.09 (N)	89 (N)
1	13.1 (N)	42 (N)	4.7 (N)	336 (N)	0.091 (N)	89 (N)
14	13.4 (N)	44 (N)	4.8 (N)	266 (N)	0.066 (N)	90 (N)
31	12.8 (N)	40 (N)	4.6 (N)	279 (N)	0.074 (N)	87 (N)
44	13 (N)	42 (N)	4.6 (N)	256 (N)	0.074 (N)	89 (N)
73	13.9 (N)	46 (N)	5 (N)	284 (N)	0.064 (N)	91 (N)
-6*	13.9 (N)	46 (N)	5 (N)	284 (N)	0.064 (N)	91 (N)
23*	12.6 (N)	42 (N)	4.6 (N)	255 (N)	0.073 (N)	91 (N)
63*	12.7 (N)	41 (N)	4.6 (N)	281 (N)	0.068 (N)	90 (N)
112*	13.3 (N)	42 (N)	4.9 (N)	288 (N)	0.063 (N)	86 (N)
160*	13.5 (N)	41 (N)	5 (N)	269 (N)	0.067 (N)	82 (N)
219*	14.5 (N)	43 (N)	5.2 (N)	214 (N)	0.03 (N)	83 (N)
274*	13.7 (N)	43 (N)	5.1 (N)	267 (N)	0.044 (N)	86 (N)
329*	14.9 (N)	48 (N)	5.4 (N)	273 (N)	0.033 (N)	89 (N)
* denotes the Maintenance study day. 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)
-29	6.65 (N)	3.95 (N)	1.93 (N)	0.53 (N)	0.05 (N)	0.2 (N)
1	6.16 (N)	3.59 (N)	1.89 (N)	0.51 (N)	0.04 (N)	0.12 (N)
14	3.98 (N)	1.52 (L)	1.9 (N)	0.48 (N)	0.05 (N)	0.04 (N)
31	5.39 (N)	2.9 (N)	1.8 (N)	0.52 (N)	0.04 (N)	0.12 (N)
44	7.13 (N)	4.48 (N)	2.09 (N)	0.41 (N)	0.05 (N)	0.1 (N)
73	7.17 (N)	4.91 (N)	1.76 (N)	0.35 (N)	0.07 (N)	0.08 (N)
-6*	7.17 (N)	4.91 (N)	1.76 (N)	0.35 (N)	0.07 (N)	0.08 (N)
23*	7.07 (N)	4.22 (N)	2.14 (N)	0.54 (N)	0.04 (N)	0.13 (N)
63*	6.6 (N)	4.23 (N)	1.8 (N)	0.43 (N)	0.05 (N)	0.08 (N)
112*	7 (N)	3.92 (N)	2.35 (N)	0.56 (N)	0.03 (N)	0.14 (N)
160*	6.06 (N)	3.43 (N)	1.74 (N)	0.54 (N)	0.1 (N)	0.26 (N)
219*	4.75 (N)	2.57 (N)	1.39 (N)	0.54 (N)	0.09 (N)	0.16 (N)
274*	6.82 (N)	4.35 (N)	1.74 (N)	0.58 (N)	0.02 (N)	0.12 (N)
329*	4.19 (N)	2.28 (N)	1.41 (N)	0.38 (N)	0.06 (N)	0.08 (N)
* denotes the Maintenance study day. 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)
-29	Yes	23 (N)	19 (N)	83 (N)	0.2 (N)	0.74 (N)
1	No	15 (N)	17 (N)	84 (N)	0.3 (N)	0.69 (N)
14	Yes	17 (N)	19 (N)	76 (N)	0.2 (N)	0.74 (N)
31	Yes	14 (N)	19 (N)	87 (N)	0.2 (N)	0.69 (N)
44	Yes	14 (N)	16 (N)	89 (N)	<0.2 (L)	0.76 (N)
73	Yes	16 (N)	21 (N)	81 (N)	0.3 (N)	0.79 (N)
-6*	Yes	16 (N)	21 (N)	81 (N)	0.3 (N)	0.79 (N)
23*	Yes	16 (N)	18 (N)	82 (N)	<0.2 (L)	0.79 (N)
63*	Yes	20 (N)	21 (N)	83 (N)	0.2 (N)	0.7 (N)
112*	Yes	25 (N)	21 (N)	90 (N)	<0.2 (L)	0.77 (N)
160*	Yes	18 (N)	19 (N)	89 (N)	<0.2 (L)	0.68 (N)
219*	Yes	31 (N)	28 (N)	80 (N)	0.2 (N)	0.84 (N)
274*	Yes	21 (N)	21 (N)	78 (N)	0.2 (N)	0.8 (N)
329*	Yes	21 (N)	23 (N)	82 (N)	0.3 (N)	0.84 (N)
* denotes the Maintenance study day. 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)
-29	Yes	89.4 (N)	67 (N)	104 (H)	9.69 (N)
1	No	95.4 (N)	78 (N)	97 (N)	7.78 (N)
14	Yes	88.8 (N)	94 (N)	90 (N)	1.36 (N)
31	Yes	94.2 (N)	132 (N)	90 (N)	2 (N)
44	Yes	87 (N)	122 (N)	97 (N)	2.39 (N)
73	Yes	82.2 (N)	136 (N)	93 (N)	1.41 (N)
-6*	Yes	82.2 (N)	136 (N)	93 (N)	1.41 (N)
23*	Yes	84.6 (N)	142 (N)	94 (N)	1.74 (N)
63*	Yes	94.2 (N)	136 (N)	91 (N)	3.23 (N)
112*	Yes	87 (N)	99 (N)	86 (N)	5.1 (N)
160*	Yes	99 (N)	96 (N)	106 (H)	4.83 (N)
219*	Yes	81.6 (N)	99 (N)	111 (H)	8.9 (N)
274*	Yes	87 (N)	104 (N)	102 (H)	4.13 (N)
329*	Yes	81.6 (N)	105 (N)	105 (H)	7 (N)
* denotes the Maintenance study day. 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	No	272 (N)	45 (N)	183 (H)	190 (N)
73	Yes	326 (H)	64 (N)	214 (H)	213 (N)
-6*	Yes	326 (H)	64 (N)	214 (H)	213 (N)
112*	Yes	258 (N)	42 (N)	163 (H)	349 (H)
329*	Yes	303 (N)	55 (N)	212 (H)	151 (N)
* denotes the Maintenance study day. H = High; L = Low; N = Normal.					

被験者識別番号：[redacted]

投与群：寛解導入試験－フィルゴチニブ 200 mg 群（コホート B）

治験薬の投与状況：寛解導入試験－有害事象により投与中止（Day 15）；寛解維持試験－不参加

ベースライン特性：本被験者は 2[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、ドイツからの参加であった。

肺塞栓症（Day 19～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、試験治療下の注目すべき有害事象）（寛解導入試験）：
Day 19、Grade 3 の重篤な肺塞栓症が発現した。寛解導入治験薬に対する処置は投与中止であった。寛解維持治験薬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。試験終了時点で本事象は未回復であった。

その他の関連情報：治験責任医師によると、被験者は肺症状（原因不明）の病歴を有していた。また、Week 2 に被験者からの咳の状態変化及び嚥下困難の訴えがあった。胸部 X 線検査の結果、円形の肺病変が認められた。続いて実施された胸部のコンピューター断層撮影検査により肺中央近傍の区域性肺塞栓症が認められ、被験者は入院した。心エコー検査の結果、右心負荷の所見は認められなかった。同日に測定された血小板数は 867 と報告されているが、単位の記載はなかった。凝固パラメータの値は正常であった。治療薬としてエノキサパリンが投与された。症状は回復し、被験者は退院して自宅でエノキサパリンによる治療を継続した。

Medical History	
Medical History	**Resolution**
colitis ulcerative	Ongoing
hypothyroidism	Ongoing
lung disorder	Ongoing

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
levothyroxine	HYPOTHYREOSE	ORAL	About -4970 days	Ongoing
colecalciferol	VITAMIN D DEFICIENCY PROPHYLAXIS	ORAL	-15 days	Ongoing
prednisolone	ULCERATIVE COLITIS	ORAL	-14 days	Ongoing
enoxaparin sodium	PULMONARY EMBOLISM	SUBCUTANEOUS	19 days	Ongoing
mesalazine	ULCERATIVE COLITIS	ORAL	-3236 days	-3055 days
mesalazine	ULCERATIVE COLITIS	ORAL	-3053 days	About -2963 days
azathioprine	ULCERATIVE COLITIS	ORAL	About -2778 days	About -1349 days
azathioprine	ULCERATIVE COLITIS	ORAL	About -1136 days	About -772 days
adalimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	About -801 days	About -680 days
vedolizumab	ULCERATIVE COLITIS	INTRAVENOUS	About -466 days	About -344 days
azathioprine	ULCERATIVE COLITIS	ORAL	About -709 days	About -222 days
infliximab	ULCERATIVE COLITIS	INTRAVENOUS	About -709 days	About -222 days

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
coffee coal;commiphora myrrha;matricaria recutita	ULCERATIVE COLITIS	ORAL	Unknown	-35 days
prednisolone	ULCERATIVE COLITIS	ORAL	About -162 days	-15 days

All Adverse Events							
Preferred Term	**Onset Day**	**Resolution Day**	**Toxicity Grade**	**Causality**	**Action taken with Induction Drug**	**Action taken with Maintenance Drug**	**Action - Other**
Secretion discharge	2	16	2	not related	dose not changed	not applicable	none
Cough	6	29	2	not related	drug interrupted	not applicable	none
Dysphagia	10	16	2	not related	drug interrupted	not applicable	none
Platelet count increased	16	Ongoing	3	not related	not applicable	not applicable	none
Pulmonary embolism	19	Ongoing	3	related	drug withdrawn	not applicable	medication required + permanent study discontinuation
* denotes the Maintenance study day.							

Hematology						
Study Day	Hemoglobin (g/dL)	Hematocrit (%)	Erythrocytes (x10^6/uL)	Platelets (x10^3/uL)	Reticulocytes (x10^6/uL)	Ery. Mean Corpuscular Volume (fL)
-14	11.6 (L)	41 (N)	5.5 (N)	564 (H)	0.185 (H)	74 (L)
1	11.3 (L)	39 (N)	5.4 (N)	524 (H)	0.162 (H)	73 (L)
15	10.2 (L)	37 (L)	4.8 (N)	800 (H)	0.128 (N)	77 (L)
29	10.9 (L)	37 (L)	5 (N)	601 (H)	0.15 (H)	73 (L)
43	11.1 (L)	40 (N)	5.1 (N)	692 (H)	0.153 (H)	80 (N)
* denotes the Maintenance study day. 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)
-14	9.48 (N)	8.3 (H)	0.97 (N)	0.18 (N)	0.01 (N)	0.02 (N)
1	12.82 (H)	11.41 (H)	0.59 (L)	0.74 (N)	0.04 (N)	0.05 (N)
15	15.73 (H)	14.16 (H)	1.06 (N)	0.39 (N)	0.04 (N)	0.08 (N)
29	6.51 (N)	5.73 (N)	0.65 (L)	0.13 (N)	0 (N)	0 (N)
43	6.92 (N)	5.2 (N)	1.32 (N)	0.33 (N)	0.03 (N)	0.04 (N)
* denotes the Maintenance study day. 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)
-14	No	19 (N)	14 (N)	63 (N)	<0.2 (L)	0.89 (N)
1	No	14 (N)	12 (N)	49 (N)	0.2 (N)	0.92 (N)
15	No	30 (N)	15 (N)	65 (N)	0.2 (N)	0.87 (N)
29	No	61 (H)	29 (N)	57 (N)	0.2 (N)	0.86 (N)
43	No	31 (N)	21 (N)	55 (N)	0.2 (N)	0.92 (N)
* denotes the Maintenance study day. 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)
-14	No	127.2 (H)	81 (N)	140 (H)	14.9 (H)
1	No	123 (N)	57 (N)	124 (H)	78.8 (H)
15	No	129.6 (H)	143 (N)	128 (H)	64.9 (H)
29	No	133.2 (H)	108 (N)	126 (H)	5.01 (N)
43	No	123 (N)	97 (N)	151 (H)	5.31 (N)
* denotes the Maintenance study day. 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)
-14	No	157 (N)	51 (N)	86 (N)	81 (N)
1	No	140 (N)	53 (N)	74 (N)	62 (N)
15	No	128 (L)	48 (N)	68 (N)	50 (N)
29	No	194 (N)	66 (H)	113 (N)	94 (N)
43	No	197 (N)	63 (N)	110 (N)	92 (N)
* denotes the Maintenance study day. H = High; L = Low; N = Normal.					

被験者識別番号：[redacted]

投与群：寛解導入試験－フィルゴチニブ 100 mg 群（コホート A）；寛解維持試験－プラセボ群

治験薬の投与状況：寛解導入試験－完了；寛解維持試験－治験実施計画書に規定された疾患の悪化により投与中止（Day 34*）

ベースライン特性：本被験者は 4[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、ポーランドからの参加であった。

鉄欠乏性貧血（Day 7*～7*）（試験治療下の重篤な有害事象）（寛解維持試験）：
Day 7*、Grade 3 の重篤な鉄欠乏性貧血が発現した。寛解導入治験薬に対する処置は非該当であった。寛解維持治験薬に対する処置は変更なし。本事象は治験薬と関連なしと判断された。Day 7*、Grade 3 の本事象は回復した。

その他の関連情報：特になし。
*寛解維持試験における study day

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

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
paroxetine hydrochloride	DEPRESION	ORAL	About -3545 days	Ongoing
mesalazine	ULCERATIVE COLITIS	ORAL	About -1779 days	Ongoing
methylprednisolone	ULCERATIVE COLITIS	ORAL	About -1049 days	About -655 days
budesonide	ULCERATIVE COLITIS	ORAL	About -137 days	About -46 days
diosmin	THROMBOSIS OF THE HEMORRHOIDS	ORAL	25 days	43 days
escherichia coli	HEMORRHOID THROMBOSIS	RECTAL	25 days	43 days
iron isomaltoside 1000	IRON DEFICIENCY ANEMIA	INTRAVENOUS	85 days	85 days

All Adverse Events							
Preferred Term	**Onset Day**	**Resolution Day**	**Toxicity Grade**	**Causality**	**Action taken with Induction Drug**	**Action taken with Maintenance Drug**	**Action - Other**
Haemorrhoids thrombosed	25	43	2	not related	dose not changed	not applicable	medication required
Iron deficiency anaemia	7*	7*	3	not related	not applicable	dose not changed	medication required
* denotes the Maintenance study day.							

Hematology						
Study Day	Hemoglobin (g/dL)	Hematocrit (%)	Erythrocytes (x10^6/uL)	Platelets (x10^3/uL)	Reticulocytes (x10^6/uL)	Ery. Mean Corpuscular Volume (fL)
-21	10.8 (L)	34 (N)	4.2 (N)	166 (N)	0.041 (N)	80 (N)
1	10.9 (L)	34 (N)	4.3 (N)	188 (N)	0.049 (N)	78 (L)
22	10.5 (L)	32 (L)	4.2 (N)	159 (N)	0.033 (N)	78 (L)
29	10 (L)	30 (L)	4 (L)	173 (N)	0.041 (N)	77 (L)
43	10.2 (L)	31 (L)	4 (L)	172 (N)	0.049 (N)	78 (L)
71	9.1 (L)	29 (L)	3.7 (L)	182 (N)	0.043 (N)	79 (N)
-8*	9.1 (L)	29 (L)	3.7 (L)	182 (N)	0.043 (N)	79 (N)
21*	11.4 (L)	35 (N)	4.2 (N)	182 (N)	0.13 (H)	82 (N)
35*	11.8 (N)	36 (N)	4.3 (N)	162 (N)	0.062 (N)	83 (N)
* denotes the Maintenance study day. 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)
-21	3.91 (N)	2.16 (N)	1.33 (N)	0.23 (N)	0.03 (N)	0.17 (N)
1	4.09 (N)	2.4 (N)	1.27 (N)	0.24 (N)	0.05 (N)	0.12 (N)
22	4.16 (N)	2.21 (N)	1.43 (N)	0.33 (N)	0.04 (N)	0.15 (N)
29	4.96 (N)	2.61 (N)	1.72 (N)	0.39 (N)	0.06 (N)	0.18 (N)
43	4.58 (N)	2.43 (N)	1.64 (N)	0.35 (N)	0.03 (N)	0.14 (N)
71	7.56 (N)	5.28 (N)	1.68 (N)	0.49 (N)	0.04 (N)	0.06 (N)
-8*	7.56 (N)	5.28 (N)	1.68 (N)	0.49 (N)	0.04 (N)	0.06 (N)
21*	4.8 (N)	2.68 (N)	1.64 (N)	0.31 (N)	0.03 (N)	0.14 (N)
35*	3.99 (N)	2.3 (N)	1.3 (N)	0.26 (N)	0.04 (N)	0.09 (N)
* denotes the Maintenance study day. 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)
-21	Yes	14 (N)	22 (N)	49 (N)	0.2 (N)	0.75 (N)
1	Yes	13 (N)	20 (N)	49 (N)	0.2 (N)	0.89 (N)
15	Yes			41 (N)		0.8 (N)
22	Yes	11 (N)	21 (N)	40 (N)	0.3 (N)	0.95 (N)
29	Yes	13 (N)	22 (N)	50 (N)	0.3 (N)	0.83 (N)
43	Yes	17 (N)	30 (N)	47 (N)	0.2 (N)	0.93 (N)
71	Yes	11 (N)	24 (N)	45 (N)	0.3 (N)	0.8 (N)
-8*	Yes	11 (N)	24 (N)	45 (N)	0.3 (N)	0.8 (N)
21*	Yes	21 (N)	28 (N)	52 (N)	0.3 (N)	0.76 (N)
35*	Yes	13 (N)	20 (N)	45 (N)	0.4 (N)	0.88 (N)
* denotes the Maintenance study day. 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)
-21	Yes	87.6 (N)	73 (N)	84 (N)	0.87 (N)
1	Yes	71.4 (L)	73 (N)	83 (N)	0.87 (N)
15	Yes	80.4 (N)			0.29 (N)
22	Yes	68.4 (L)	93 (N)	92 (N)	0.29 (N)
29	Yes	78 (N)	93 (N)	83 (N)	0.43 (N)
43	Yes	68.4 (L)	185 (N)	84 (N)	0.35 (N)
71	Yes	79.8 (N)	150 (N)	62 (L)	2.23 (N)
-8*	Yes	79.8 (N)	150 (N)	62 (L)	2.23 (N)
21*	Yes	84.6 (N)	73 (N)	78 (N)	0.44 (N)
35*	Yes	72.6 (L)	112 (N)	80 (N)	0.52 (N)
* denotes the Maintenance study day. 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)
-21	Yes	256 (N)	101 (H)	150 (H)	45 (N)
1	Yes	258 (N)	80 (N)	165 (H)	50 (N)
15	Yes	254 (N)	87 (N)	148 (H)	61 (N)
22	Yes	266 (H)	90 (H)	164 (H)	70 (N)

Lipid Panel					
Study Day	Fasting	Total Cholesterol (mg/dL)	HDL Cholesterol (mg/dL)	LDL Cholesterol (mg/dL)	Triglycerides (mg/dL)
29	Yes	267 (H)	95 (H)	159 (H)	66 (N)
43	Yes	262 (N)	104 (H)	149 (H)	48 (N)
71	Yes	245 (N)	97 (H)	142 (H)	72 (N)
-8*	Yes	245 (N)	97 (H)	142 (H)	72 (N)
21*	Yes	240 (N)	87 (N)	131 (H)	64 (N)
35*	Yes	259 (N)	102 (H)	148 (H)	64 (N)
* denotes the Maintenance study day. H = High; L = Low; N = Normal.					

被験者識別番号：[redacted]

投与群：寛解導入試験－フィルゴチニブ 100 mg 群（コホート A）；寛解維持試験－プラセボ群

治験薬の投与状況：寛解導入試験－完了；寛解維持試験－完了

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、民族は非ヒスパニック／ラテン系、ポーランドからの参加であった。

鉄欠乏性貧血（Day 65～65）（試験治療下の重篤な有害事象）（寛解導入試験）：
Day 65、Grade 2 の重篤な鉄欠乏性貧血が発現した。寛解導入治験薬に対する処置は変更なし。寛解維持治験薬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 65、Grade 2 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
hypothyroidism	Ongoing

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
levothyroxine sodium	HYPOTYROIDISM	ORAL	Unknown	Ongoing
azathioprine	ULCERATIVE COLITIS	ORAL	About -172 days	Ongoing
mebeverine	ULCERATIVE COLITIS	ORAL	About -172 days	Ongoing
desogestrel;ethinylestradiol	CONTYRACEPTION	ORAL	32 days	Ongoing
mesalazine	ULCERATIVE COLITIS	ORAL	209 days	Ongoing
iron isomaltoside 1000	IRON DEFICIENCY ANEMIA	INTRAVENOUS	65 days	65 days
mesalazine	ULCERATIVE COLITIS	ORAL	About -325 days	208 days

All Adverse Events							
Preferred Term	**Onset Day**	**Resolution Day**	**Toxicity Grade**	**Causality**	**Action taken with Induction Drug**	**Action taken with Maintenance Drug**	**Action - Other**
Iron deficiency anaemia	65	65	2	not related	dose not changed	not applicable	medication required
* denotes the Maintenance study day.							

Hematology						
Study Day	Hemoglobin (g/dL)	Hematocrit (%)	Erythrocytes (x10^6/uL)	Platelets (x10^3/uL)	Reticulocytes (x10^6/uL)	Ery. Mean Corpuscular Volume (fL)
-28	10.7 (L)	36 (N)	4.5 (N)	298 (N)	0.073 (N)	80 (N)
1	9.3 (L)	29 (L)	3.8 (L)	310 (N)	0.039 (N)	77 (L)
15	9.1 (L)	30 (L)	3.9 (L)	246 (N)	0.049 (N)	78 (L)
29	9.1 (L)	29 (L)	3.8 (L)	287 (N)	0.048 (N)	75 (L)
43	8.3 (L)	27 (L)	3.5 (L)	279 (N)	0.055 (N)	76 (L)
71	9.4 (L)	30 (L)	3.9 (L)	301 (N)	0.291 (H)	77 (L)
-7*	9.4 (L)	30 (L)	3.9 (L)	301 (N)	0.291 (H)	77 (L)
22*	11.3 (L)	36 (N)	4.3 (N)	257 (N)	0.048 (N)	84 (N)
69*	12.3 (N)	37 (N)	4.4 (N)	279 (N)	0.044 (N)	85 (N)
106*	11.7 (N)	35 (N)	4 (L)	257 (N)	0.046 (N)	87 (N)
162*	11.8 (N)	34 (N)	4 (L)	238 (N)	0.033 (N)	86 (N)
218*	11 (L)	35 (N)	4.2 (N)	241 (N)	0.037 (N)	83 (N)
274*	10.4 (L)	34 (N)	4.2 (N)	255 (N)	0.04 (N)	81 (N)
330*	9.6 (L)	30 (L)	3.9 (L)	242 (N)	0.059 (N)	78 (L)
* denotes the Maintenance study day. 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)
-28	3.73 (L)	1.83 (L)	1.66 (N)	0.21 (N)	0.02 (N)	0.01 (N)
1	4.26 (N)	2.54 (N)	1.37 (N)	0.32 (N)	0.02 (N)	0.02 (N)
15	3.39 (L)	1.65 (L)	1.53 (N)	0.16 (N)	0.03 (N)	0.01 (N)
29	3.5 (L)	2.34 (N)	0.91 (N)	0.23 (N)	0.01 (N)	0.01 (N)
43	4.02 (N)	2.72 (N)	1.03 (N)	0.25 (N)	0.01 (N)	0.02 (N)
71	5.67 (N)	4.27 (N)	1.08 (N)	0.3 (N)	0.01 (N)	0.01 (N)
-7*	5.67 (N)	4.27 (N)	1.08 (N)	0.3 (N)	0.01 (N)	0.01 (N)
22*	5.87 (N)	4.12 (N)	1.45 (N)	0.25 (N)	0.03 (N)	0.02 (N)
69*	5.24 (N)	3.56 (N)	1.35 (N)	0.29 (N)	0.02 (N)	0.02 (N)
106*	5.52 (N)	3.46 (N)	1.73 (N)	0.28 (N)	0.02 (N)	0.02 (N)
162*	4.38 (N)	2.43 (N)	1.55 (N)	0.35 (N)	0.02 (N)	0.03 (N)
218*	7.7 (N)	5.73 (N)	1.61 (N)	0.33 (N)	0.01 (N)	0.02 (N)
274*	6.78 (N)	4.95 (N)	1.4 (N)	0.38 (N)	0.02 (N)	0.04 (N)
330*	3.21 (L)	1.88 (L)	1.08 (N)	0.22 (N)	0.01 (N)	0.03 (N)
* denotes the Maintenance study day. 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)
-28	Yes	11 (N)	10 (N)	43 (N)	0.9 (N)	0.76 (N)
1	Yes	8 (N)	12 (N)	53 (N)	0.8 (N)	0.67 (N)
15	Yes	8 (N)	15 (N)	45 (N)	0.7 (N)	0.72 (N)
29	Yes	10 (N)	11 (N)	51 (N)	0.9 (N)	0.67 (N)
43	Yes	9 (N)	11 (N)	36 (N)	1.3 (H)	0.76 (N)
71	Yes	17 (N)	20 (N)	41 (N)	1.6 (H)	0.79 (N)
-7*	Yes	17 (N)	20 (N)	41 (N)	1.6 (H)	0.79 (N)
22*	Yes	11 (N)	13 (N)	25 (L)	0.8 (N)	0.69 (N)
69*	Yes	12 (N)	16 (N)	43 (N)	1 (N)	0.68 (N)
106*	No	10 (N)	16 (N)	41 (N)	0.9 (N)	0.68 (N)
162*	Yes	8 (N)	13 (N)	36 (N)	0.9 (N)	0.72 (N)
218*	No	20 (N)	19 (N)	34 (N)	0.9 (N)	0.63 (N)
274*	Yes	10 (N)	14 (N)	33 (N)	0.8 (N)	0.57 (N)
330*	Yes	9 (N)	12 (N)	30 (L)	1.1 (N)	0.66 (N)
* denotes the Maintenance study day. 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)
-28	Yes	102 (N)	304 (H)	83 (N)	<0.20 (N)
1	Yes	118.8 (H)	337 (H)	86 (N)	0.38 (N)
15	Yes	110.4 (N)	400 (H)	95 (N)	0.26 (N)
29	Yes	117.6 (H)	367 (H)	94 (N)	0.78 (N)
43	Yes	105.6 (N)	414 (H)	91 (N)	<0.20 (N)
71	Yes	104.4 (N)	388 (H)	80 (N)	<0.20 (N)
-7*	Yes	104.4 (N)	388 (H)	80 (N)	<0.20 (N)
22*	Yes	123.6 (H)	388 (H)	89 (N)	1.85 (N)
69*	Yes	129.6 (H)	400 (H)	95 (N)	0.77 (N)
106*	No	129.6 (H)	402 (H)	84 (N)	0.22 (N)
162*	Yes	119.4 (H)	398 (H)	84 (N)	0.29 (N)
218*	No	136.2 (H)	406 (H)	85 (N)	0.23 (N)
274*	Yes	156 (H)	499 (H)	91 (N)	0.36 (N)
330*	Yes	136.8 (H)	577 (H)	90 (N)	0.38 (N)
* denotes the Maintenance study day. 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	176 (N)	52 (N)	116 (N)	57 (N)
71	Yes	170 (N)	65 (N)	93 (N)	85 (N)
-7*	Yes	170 (N)	65 (N)	93 (N)	85 (N)
106*	No	189 (N)	66 (N)	128 (N)	63 (N)
162*	Yes	172 (N)	60 (N)	104 (N)	62 (N)
218*	No	174 (N)	60 (N)	108 (N)	51 (N)
274*	Yes	177 (N)	65 (N)	113 (N)	60 (N)
330*	Yes	166 (N)	62 (N)	101 (N)	39 (N)
* denotes the Maintenance study day. H = High; L = Low; N = Normal.					

被験者識別番号：[redacted]

投与群：寛解導入試験－フィルゴチニブ 100 mg 群（コホート A）；寛解維持試験－フィルゴチニブ 100 mg 群

治験薬の投与状況：寛解導入試験－完了；寛解維持試験－治験実施計画書に規定された疾患の悪化により投与中止（Day 21*）

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、民族は非ヒスパニック／ラテン系、ポーランドからの参加であった。

貧血（Day 6～6）（試験治療下の重篤な有害事象）（寛解導入試験）：
Day 6、Grade 3 の重篤な貧血が発現した。寛解導入治験薬に対する処置は変更なし。寛解維持治験薬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 6、Grade 3 の本事象は回復した。

その他の関連情報：特になし。
*寛解維持試験における study day

Medical History	
Medical History	Resolution
colitis ulcerative	Ongoing
anxiety	-16 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
mesalazine	ULCERATIVE COLITIS	ORAL	About -182 days	Ongoing
prednisone	ULCERATIVE COLITIS	ORAL	About -182 days	Ongoing
azathioprine	ULCERATIVE COLITIS	ORAL	6 days	Ongoing
diazepam	ANXIETY	ORAL	-28 days	-16 days
azathioprine	ULCERATIVE COLITIS	ORAL	About -182 days	5 days
iron isomaltoside 1000	ANEMIA	INTRAVENOUS	6 days	6 days

All Adverse Events							
Preferred Term	Onset Day	Resolution Day	Toxicity Grade	Causality	Action taken with Induction Drug	Action taken with Maintenance Drug	Action - Other
Lymphopenia	2	Ongoing	2	not related	dose not changed	not applicable	none
Anaemia	6	6	3	not related	dose not changed	not applicable	medication required
* denotes the Maintenance study day.							

Hematology						
Study Day	Hemoglobin (g/dL)	Hematocrit (%)	Erythrocytes (x10^6/uL)	Platelets (x10^3/uL)	Reticulocytes (x10^6/uL)	Ery. Mean Corpuscular Volume (fL)
-14	8.8 (L)	26 (L)	2.6 (L)	486 (H)	0.092 (N)	103 (H)
1	7 (L)	22 (L)	2.2 (L)	347 (N)	0.044 (N)	99 (H)
15	7.6 (L)	24 (L)	2.3 (L)	480 (H)	0.198 (H)	104 (H)
29	10.3 (L)	33 (L)	3 (L)	284 (N)	0.134 (H)	109 (H)
43	10.8 (L)	33 (L)	3.2 (L)	300 (N)	0.047 (N)	105 (H)
71	11 (L)	33 (L)	3.3 (L)	323 (N)	0.032 (N)	98 (N)
-7*	11 (L)	33 (L)	3.3 (L)	323 (N)	0.032 (N)	98 (N)
22*	11.2 (L)	34 (N)	3.5 (L)	294 (N)	0.024 (L)	98 (N)
* denotes the Maintenance study day. 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)
-14	10.94 (H)	7.88 (H)	2.12 (N)	0.48 (N)	0.04 (N)	0.42 (N)
1	4.13 (N)	3.54 (N)	0.46 (L)	0.04 (L)	0.01 (N)	0.07 (N)
15	4.05 (N)	3.17 (N)	0.66 (L)	0.13 (N)	0.01 (N)	0.08 (N)
29	5.38 (N)	4.49 (N)	0.62 (L)	0.2 (N)	0.01 (N)	0.06 (N)
43	7.32 (N)	5.98 (N)	0.89 (L)	0.3 (N)	0.03 (N)	0.12 (N)
71	4.77 (N)	3.21 (N)	1.16 (N)	0.24 (N)	0.02 (N)	0.14 (N)
-7*	4.77 (N)	3.21 (N)	1.16 (N)	0.24 (N)	0.02 (N)	0.14 (N)
22*	5.62 (N)	3.96 (N)	1.13 (N)	0.29 (N)	0.03 (N)	0.2 (N)
* denotes the Maintenance study day. 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)
-14	Yes	10 (N)	14 (N)	93 (N)	0.2 (N)	0.66 (N)
1	No	5 (L)	8 (L)	79 (N)	<0.2 (L)	0.52 (N)
15	Yes	8 (N)	11 (N)	74 (N)	<0.2 (L)	0.51 (N)
29	Yes	14 (N)	15 (N)	69 (N)	<0.2 (L)	0.6 (N)
43	Yes	11 (N)	14 (N)	62 (N)	<0.2 (L)	0.6 (N)
71	Yes	11 (N)	15 (N)	71 (N)	0.3 (N)	0.57 (N)
-7*	Yes	11 (N)	15 (N)	71 (N)	0.3 (N)	0.57 (N)
22*	Yes	8 (N)	13 (N)	68 (N)	0.3 (N)	0.59 (N)
* denotes the Maintenance study day. 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)
-14	Yes	87 (N)	<18 (L)	94 (N)	5.23 (N)
1	No	110.4 (N)	<18 (L)	129 (H)	13.8 (H)
15	Yes	112.8 (N)	<18 (L)	110 (H)	0.64 (N)
29	Yes	100.2 (N)	<18 (L)	95 (N)	<0.20 (N)
43	Yes	103.2 (N)	23 (L)	100 (N)	1.42 (N)
71	Yes	109.8 (N)	41 (N)	91 (N)	0.23 (N)
-7*	Yes	109.8 (N)	41 (N)	91 (N)	0.23 (N)
22*	Yes	103.2 (N)	47 (N)	91 (N)	<0.20 (N)
* denotes the Maintenance study day. 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)
-14	Yes	197 (N)	62 (N)	108 (N)	174 (N)
1	No	133 (L)	52 (N)	66 (N)	105 (N)
15	Yes	170 (N)	77 (N)	77 (N)	145 (N)
29	Yes	193 (N)	86 (H)	87 (N)	200 (H)
43	Yes	181 (N)	72 (N)	95 (N)	116 (N)
71	Yes	166 (N)	60 (N)	93 (N)	91 (N)
-7*	Yes	166 (N)	60 (N)	93 (N)	91 (N)
* denotes the Maintenance study day. H = High; L = Low; N = Normal.					

被験者識別番号：[redacted]

投与群：寛解導入試験－フィルゴチニブ 100 mg 群（コホート A）

治験薬の投与状況：寛解導入試験－完了；寛解維持試験－不参加

ベースライン特性：本被験者は 5[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、ウクライナからの参加であった。

高血圧（Day 69～71）（試験治療下の重篤な有害事象［TE-SAE］）（寛解導入試験）：
Day 69、Grade 3 の重篤な高血圧が発現した。寛解導入治験薬に対する処置は変更なし。寛解維持治験薬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 71、Grade 3 の本事象は回復した。

高血圧（Day 74～80）（TE-SAE）（寛解導入試験）：
Day 74、Grade 3 の重篤な高血圧が発現した。寛解導入治験薬に対する処置は投与中断であった。寛解維持治験薬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 80、Grade 3 の本事象は回復した。

上咽頭炎（Day 74～79）（試験治療下の注目すべき有害事象）（寛解導入試験）：
Day 74、Grade 2 の非重篤な上咽頭炎が発現した。寛解導入治験薬に対する処置は変更なし。寛解維持治験薬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 79、Grade 2 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**
cholecystitis chronic	Ongoing
colitis ulcerative	Ongoing
hypertension	Ongoing
pyelonephritis chronic	Ongoing
anaemia	About -4735 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
losartan potassium	ARTERIAL HYPERTENSION AND RETINAL ANGIOPATHY	ORAL	About -716 days	Ongoing
sulfasalazine	ULCERATIVE COLITIS	ORAL	About -108 days	Ongoing
bifidobacterium nos	ULCERATIVE COLITIS	ORAL	About -78 days	Ongoing
nimodipine	PROPHYLAXY OF ARTERIAL HYPERTENSION	ORAL	70 days	Ongoing
phenibut	WORSENING OF ARTERIAL HYPERTENSION	ORAL	70 days	Ongoing
methylprednisolone	ULCERATIVE COLITIS	ORAL	-495 days	-487 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
sodium phosphate	OSMOTIC LAXATIVES. PREPARATION FOR COLONOSCOPY	ORAL	-14 days	-14 days
captopril	ARTERIAL HYPERTENSION	ORAL	13 days	13 days
enalapril maleate	WORSENING OF ARTERIAL HYPERTENSION	ORAL	70 days	71 days
meldonium	ARTERIAL HYPERTENSION	INTRAVENOUS	70 days	71 days
quercetin	ARTERIAL HYPERTENSION	INTRAVENOUS	70 days	71 days
paracetamol	COLD	ORAL	74 days	76 days
ascorbic acid	COLD	ORAL	74 days	79 days
eucalyptus globulus oil;glycerol;mentha x piperita oil;sulfanilamide;sulfathiazole;thymol	COLD	OROPHARYNGEAL	74 days	79 days

All Adverse Events							
Preferred Term	Onset Day	Resolution Day	Toxicity Grade	Causality	Action taken with Induction Drug	Action taken with Maintenance Drug	Action - Other
Hypertension	13	19	2	related	dose not changed	not applicable	medication required
Hypertension	69	71	3	not related	dose not changed	not applicable	medication required
Retinal vascular disorder	70	80	2	not related	dose not changed	not applicable	medication required + other treatment required
Hypertension	74	80	3	not related	drug interrupted	not applicable	medication required
Nasopharyngitis	74	79	2	not related	dose not changed	not applicable	medication required
* denotes the Maintenance study day.							

Hematology						
Study Day	Hemoglobin (g/dL)	Hematocrit (%)	Erythrocytes (x10^6/uL)	Platelets (x10^3/uL)	Reticulocytes (x10^6/uL)	Ery. Mean Corpuscular Volume (fL)
-34	12.5 (N)	38 (N)	4.3 (N)	291 (N)	0.084 (N)	87 (N)
1	13.1 (N)	38 (N)	4.5 (N)	282 (N)	0.052 (N)	85 (N)
17	13.7 (N)	42 (N)	4.8 (N)	281 (N)	0.063 (N)	88 (N)
29	13.7 (N)	40 (N)	4.6 (N)	292 (N)	0.071 (N)	85 (N)
57	13.3 (N)	41 (N)	4.5 (N)	278 (N)	0.051 (N)	90 (N)
94	12.1 (N)	37 (N)	4.1 (N)	340 (N)	0.055 (N)	90 (N)
* denotes the Maintenance study day. 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)
-34	4.6 (N)	2.54 (N)	1.65 (N)	0.27 (N)	0.02 (N)	0.12 (N)
1	3.29 (L)	1.1 (L)	1.66 (N)	0.35 (N)	0.05 (N)	0.13 (N)
17	5.2 (N)	2.14 (N)	2.5 (N)	0.33 (N)	0.03 (N)	0.2 (N)
29	4.6 (N)	1.72 (L)	2.21 (N)	0.41 (N)	0.1 (N)	0.17 (N)
57	4.73 (N)	2.7 (N)	1.56 (N)	0.34 (N)	0.07 (N)	0.06 (N)
94	4.03 (N)	2.28 (N)	1.45 (N)	0.23 (N)	0.01 (N)	0.06 (N)
* denotes the Maintenance study day. 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)
-34	Yes	20 (N)	19 (N)	96 (N)	0.4 (N)	0.83 (N)
1	Yes	13 (N)	16 (N)	84 (N)	0.5 (N)	0.86 (N)
17	Yes	15 (N)	18 (N)	86 (N)	0.4 (N)	0.9 (N)
29	Yes	14 (N)	16 (N)	81 (N)	0.4 (N)	1.03 (N)
57	Yes	13 (N)	15 (N)	88 (N)	0.4 (N)	0.77 (N)
94	Yes	13 (N)	15 (N)	77 (N)	0.4 (N)	0.85 (N)
* denotes the Maintenance study day. 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)
-34	Yes	90.6 (N)	70 (N)	95 (N)	8.18 (N)
1	Yes	86.4 (N)	65 (N)	89 (N)	3.94 (N)
17	Yes	82.2 (N)	70 (N)	104 (H)	0.87 (N)
29	Yes	72 (L)	103 (N)	82 (N)	1.72 (N)
57	Yes	96.6 (N)	83 (N)	89 (N)	
94	Yes	87.6 (N)	109 (N)	90 (N)	1.08 (N)
* denotes the Maintenance study day. 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	275 (N)	42 (N)	205 (H)	205 (N)
94	Yes	258 (N)	51 (N)	193 (H)	120 (N)
* denotes the Maintenance study day. H = High; L = Low; N = Normal.					

被験者識別番号：[redacted]

投与群：寛解導入試験－フィルゴチニブ 200 mg 群（コホート A）

治験薬の投与状況：寛解導入試験－有害事象により投与中止（Day 75）；寛解維持試験－不参加

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、ウクライナからの参加であった。

結腸異形成（Day −12～継続）（投与中止に至った有害事象）（寛解導入試験）：
Day −12、Grade 3 の非重篤な結腸異形成が発現した。寛解導入治験薬に対する処置は投与中止であった。寛解維持治験薬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。試験終了時点で本事象は未回復であった。

上咽頭炎（Day 39～47）（試験治療下の注目すべき有害事象）（寛解導入試験）：
Day 39、Grade 2 の非重篤な上咽頭炎が発現した。寛解導入治験薬に対する処置は変更なし。寛解維持治験薬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 47、Grade 2 の本事象は回復した。

心膜炎（Day 63～67）（試験治療下の重篤な有害事象）（寛解導入試験）：
Day 63、Grade 3 の重篤な心膜炎が発現した。寛解導入治験薬に対する処置は投与中断であった。寛解維持治験薬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 67、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**
anaemia	Ongoing
chronic gastritis	Ongoing
colitis ulcerative	Ongoing
intellectual disability	Ongoing
peptic ulcer	Ongoing

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
sulfasalazine	ULCERATIVE COLITIS	ORAL	About -108 days	Ongoing
ascorbic acid;ferrous sulfate;folic acid;protease	ANEMIA	ORAL	1 day	Ongoing
methylprednisolone	ULCERATIVE COLITIS	ORAL	-232 days	About -201 days
phosphoric acid sodium;sodium phosphate dibasic	PREPARATION FOR COLONOSCOPY	ORAL	-13 days	-13 days
midazolam	PREMEDICATION BEFORE COLONOSCOPY	INTRAMUSCULAR	-12 days	-12 days
amiodarone hydrochloride	EXUDATIVE PERICARDITIS	INTRAVENOUS	64 days	67 days
cefotaxime	EXUDATIVE PERICARDITIS	INTRAVENOUS	64 days	67 days
inosine	EXUDATIVE PERICARDITIS	INTRAVENOUS	64 days	67 days
pantoprazole sodium sesquihydrate	CHRONIC GASTRITIS	ORAL	64 days	67 days

All Adverse Events							
Preferred Term	Onset Day	Resolution Day	Toxicity Grade	Causality	Action taken with Induction Drug	Action taken with Maintenance Drug	Action - Other
Colon dysplasia	-12	Ongoing	3	not related	drug withdrawn	not applicable	permanent study discontinuation
Nasopharyngitis	39	47	2	not related	dose not changed	not applicable	none
Colitis ulcerative	43	50	2	related	dose not changed	not applicable	none
Pericarditis	63	67	3	not related	drug interrupted	not applicable	medication required
* denotes the Maintenance study day.							

Hematology						
Study Day	Hemoglobin (g/dL)	Hematocrit (%)	Erythrocytes (x10^6/uL)	Platelets (x10^3/uL)	Reticulocytes (x10^6/uL)	Ery. Mean Corpuscular Volume (fL)
-34	8.8 (L)	31 (L)	4.2 (L)	408 (H)	0.052 (N)	74 (L)
17	9.2 (L)	33 (L)	4.5 (N)	283 (N)	0.123 (N)	73 (L)
50	10 (L)	36 (L)	4.4 (L)	303 (N)	0.071 (N)	81 (N)
106	10.8 (L)	36 (L)	4.5 (N)	340 (N)	0.039 (N)	81 (N)
* denotes the Maintenance study day. 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)
-34	5.76 (N)	4.1 (N)	0.82 (L)	0.4 (N)	0.04 (N)	0.39 (N)
17	5.17 (N)	3.89 (N)	0.54 (L)	0.27 (N)	0.03 (N)	0.43 (N)
50	4.07 (N)	2.97 (N)	0.48 (L)	0.23 (N)	0.07 (N)	0.33 (N)
106	6.74 (N)	4.41 (N)	0.75 (L)	0.47 (N)	0.2 (N)	0.91 (H)
* denotes the Maintenance study day. 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)
-34	Yes	8 (N)	12 (N)	191 (H)	<0.2 (L)	0.66 (N)
1	Yes	21 (N)	35 (N)	188 (H)	<0.2 (L)	0.74 (N)
17	Yes	10 (N)	14 (N)	161 (H)	0.2 (N)	0.7 (N)
29	Yes	13 (N)	16 (N)	162 (H)	0.2 (N)	0.75 (N)
50	Yes	9 (N)	11 (N)	131 (H)	<0.2 (L)	0.61 (N)
86	Yes	20 (N)	29 (N)	194 (H)	<0.2 (L)	0.77 (N)
106	Yes	19 (N)	18 (N)	276 (H)	0.2 (N)	0.64 (N)
* denotes the Maintenance study day. 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)
-34	Yes	104.4 (N)	35 (L)	82 (N)	33.3 (H)
1	Yes	93.6 (N)	38 (L)	77 (N)	28.8 (H)
17	Yes	97.8 (N)	39 (N)	72 (N)	12.7 (H)
29	Yes	91.8 (N)	41 (N)	73 (N)	21.9 (H)
50	Yes	111.6 (N)	49 (N)	72 (N)	29 (H)
86	Yes	88.8 (N)	21 (L)	57 (L)	12.5 (H)
106	Yes	105.6 (N)	29 (L)	58 (L)	59.2 (H)
* denotes the Maintenance study day. 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)
-34	Yes	128 (L)	47 (N)	71 (N)	56 (N)
1	Yes	115 (L)	43 (N)	63 (N)	64 (N)
86	Yes	145 (L)	48 (N)	80 (N)	116 (N)
106	Yes	138 (L)	43 (N)	79 (N)	74 (N)
* denotes the Maintenance study day. H = High; L = Low; N = Normal.					

被験者識別番号：[redacted]

投与群：寛解導入試験－フィルゴチニブ 100 mg 群（コホート B）；寛解維持試験－プラセボ群

治験薬の投与状況：寛解導入試験－完了；寛解維持試験－妊娠により投与中止（Day 62*）

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、民族は非ヒスパニック／ラテン系、フランスからの参加であった。

頭痛（Day 42～44）（試験治療下の重篤な有害事象［TE-SAE］）（寛解導入試験）：
Day 42、Grade 3 の重篤な頭痛が発現した。寛解導入治験薬に対する処置は投与中断であった。寛解維持治験薬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 44、Grade 3 の本事象は回復した。

筋肉痛（Day 42～43）（TE-SAE）（寛解導入試験）：
Day 42、Grade 3 の重篤な筋肉痛が発現した。寛解導入治験薬に対する処置は投与中断であった。寛解維持治験薬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 43、Grade 3 の本事象は回復した。

悪心（Day 42～43）（TE-SAE）（寛解導入試験）：
Day 42、Grade 3 の重篤な悪心が発現した。寛解導入治験薬に対する処置は投与中断であった。寛解維持治験薬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 43、Grade 3 の本事象は回復した。

嘔吐（Day 42～43）（TE-SAE）（寛解導入試験）：
Day 42、Grade 3 の重篤な嘔吐が発現した。寛解導入治験薬に対する処置は投与中断であった。寛解維持治験薬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 43、Grade 3 の本事象は回復した。

その他の関連情報：特になし。
*寛解維持試験における study day

Medical History	
Medical History	**Resolution**
colitis ulcerative	Ongoing
polyarthritis	Ongoing
rosacea	Ongoing
seborrhoeic dermatitis	Ongoing

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
metronidazole	ROSACEA	CUTANEOUS	About -105 days	Ongoing
ethinylestradiol;levonorgestrel	CONTRACEPTION	ORAL	-1 day	Ongoing
prednisone	ULCERATIVE COLITIS	ORAL	1 day	Ongoing
doxycycline	SEBORRHEIC DERMATITIS	ORAL	29 days	Ongoing
golimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	-875 days	-875 days
mesalazine	ULCERATIVE COLITIS	ORAL	About -928 days	About -868 days
golimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	About -898 days	About -868 days
azathioprine	ULCERATIVE COLITIS	ORAL	-847 days	-832 days
aminosalicylate sodium	ULCERATIVE COLITIS	RECTAL	About -928 days	About -808 days
infliximab	ULCERATIVE COLITIS	INTRAVENOUS	-846 days	-794 days
mercaptopurine	ULCERATIVE COLITIS	ORAL	-813 days	-590 days
infliximab	ULCERATIVE COLITIS	INTRAVENOUS	-736 days	-85 days
methotrexate	ULCERATIVE COLITIS	ORAL	-331 days	-85 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
prednisone	ULCERATIVE COLITIS	ORAL	-23 days	-1 day
metoclopramide	NAUSEA AND VOMITING	INTRAVENOUS	42 days	43 days
tramadol	HEADACHE AND MYALGIA	INTRAVENOUS	-324 days	44 days
paracetamol	HEADACHE AND MYALGIA	INTRAVENOUS	42 days	44 days
paracetamol	HEADACHE AND MYALGIA	ORAL	43 days	44 days
tramadol	HEADACHE AND MYALGIA	ORAL	43 days	44 days
mifepristone	ABORTION	ORAL	146 days	146 days
misoprostol	ABORTION	ORAL	148 days	148 days

All Adverse Events							
Preferred Term	Onset Day	Resolution Day	Toxicity Grade	Causality	Action taken with Induction Drug	Action taken with Maintenance Drug	Action - Other
Headache	42	44	3	not related	drug interrupted	not applicable	medication required
Myalgia	42	43	3	not related	drug interrupted	not applicable	medication required
Nausea	42	43	3	not related	drug interrupted	not applicable	medication required
Vomiting	42	43	3	not related	drug interrupted	not applicable	medication required
* denotes the Maintenance study day.							

Hematology						
Study Day	Hemoglobin (g/dL)	Hematocrit (%)	Erythrocytes (x10^6/uL)	Platelets (x10^3/uL)	Reticulocytes (x10^6/uL)	Ery. Mean Corpuscular Volume (fL)
-23	12.3 (N)	38 (N)	4.2 (N)		0.061 (N)	91 (N)
1	10.9 (L)	34 (N)	3.9 (L)	444 (H)	0.068 (N)	89 (N)
14	11 (L)	33 (L)	3.8 (L)	383 (N)	0.036 (N)	87 (N)
28	12.1 (N)	37 (N)	4.3 (N)	358 (N)	0.05 (N)	85 (N)
42	10.5 (L)	34 (N)	3.9 (L)	403 (H)	0.059 (N)	87 (N)
71	11.3 (L)	35 (N)	4.2 (N)	474 (H)	0.057 (N)	84 (N)
-8*	11.3 (L)	35 (N)	4.2 (N)	474 (H)	0.057 (N)	84 (N)
26*	11.8 (N)	38 (N)	4.4 (N)	389 (N)	0.054 (N)	86 (N)
61*	11.3 (L)	35 (N)	4.1 (N)	367 (N)	0.068 (N)	86 (N)
70*	11.5 (L)	37 (N)	4.3 (N)	397 (N)	0.061 (N)	86 (N)
103*	11.3 (L)	35 (N)	4.1 (N)	478 (H)	0.046 (N)	86 (N)

* denotes the Maintenance study day.
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)
-23	8.73 (N)	4.65 (N)	2.74 (N)	0.65 (N)	0.1 (N)	0.59 (H)
1	11.95 (H)	8.68 (H)	1.94 (N)	0.51 (N)	0.13 (N)	0.69 (H)
14	9.7 (N)	5.4 (N)	3.06 (N)	0.57 (N)	0.11 (N)	0.57 (N)
28	9.64 (N)	5.37 (N)	3.39 (N)	0.44 (N)	0.11 (N)	0.33 (N)
42	7.6 (N)	3.42 (N)	3.19 (N)	0.65 (N)	0.07 (N)	0.28 (N)
71	7.24 (N)	3.59 (N)	2.93 (N)	0.34 (N)	0.1 (N)	0.28 (N)
-8*	7.24 (N)	3.59 (N)	2.93 (N)	0.34 (N)	0.1 (N)	0.28 (N)
26*	7.39 (N)	4.02 (N)	2.3 (N)	0.65 (N)	0.08 (N)	0.34 (N)
61*	7.97 (N)	4.36 (N)	2.47 (N)	0.68 (N)	0.08 (N)	0.38 (N)
70*	8.3 (N)	4.53 (N)	2.52 (N)	0.74 (N)	0.07 (N)	0.45 (N)
103*	8.68 (N)	4.75 (N)	2.71 (N)	0.56 (N)	0.13 (N)	0.53 (N)

* denotes the Maintenance study day.
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)
-23	No	9 (N)	13 (N)	52 (N)	0.3 (N)	0.64 (N)
1	Yes	14 (N)	11 (N)	51 (N)	0.4 (N)	0.68 (N)
14	No	17 (N)	14 (N)	40 (N)	0.2 (N)	0.8 (N)
28	No	10 (N)	11 (N)	41 (N)	0.4 (N)	0.76 (N)
42	No	6 (N)	9 (N)	32 (N)	0.3 (N)	0.64 (N)
71	No	11 (N)	13 (N)	36 (N)	0.6 (N)	0.83 (N)
-8*	No	11 (N)	13 (N)	36 (N)	0.6 (N)	0.83 (N)
26*	No	8 (N)	15 (N)	37 (N)	0.7 (N)	0.67 (N)
61*	No	9 (N)	13 (N)	32 (N)	0.3 (N)	0.54 (N)
70*	No	15 (N)	20 (N)	27 (L)	0.2 (N)	0.48 (N)
103*	No	8 (N)	13 (N)	34 (N)	0.3 (N)	0.59 (N)
* denotes the Maintenance study day. 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)
-23	No	121.8 (H)	45 (N)	89 (N)	5.44 (N)
1	Yes	114 (N)	40 (N)	84 (N)	4.35 (N)
14	No	100.2 (N)	155 (N)	83 (N)	3.76 (N)
28	No	106.2 (N)	39 (N)	92 (N)	1.3 (N)
42	No	123.6 (H)	32 (N)	109 (H)	0.78 (N)
71	No	95.4 (N)	76 (N)	104 (H)	0.79 (N)
-8*	No	95.4 (N)	76 (N)	104 (H)	0.79 (N)
26*	No	119.4 (H)	105 (N)	76 (N)	1.26 (N)
61*	No	147 (H)	48 (N)	92 (N)	1.14 (N)
70*	No	168 (H)	27 (N)	82 (N)	8.37 (N)
103*	No	135.6 (H)	58 (N)	84 (N)	0.96 (N)
* denotes the Maintenance study day. 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	171 (N)	66 (N)	80 (N)	130 (N)
71	No	165 (N)	83 (H)	70 (N)	79 (N)
-8*	No	165 (N)	83 (H)	70 (N)	79 (N)
70*	No	126 (L)	60 (N)	51 (N)	77 (N)
* denotes the Maintenance study day. H = High; L = Low; N = Normal.					

被験者識別番号：[redacted]

投与群：寛解導入試験－フィルゴチニブ 100 mg 群（コホート B）

治験薬の投与状況：寛解導入試験－有害事象により投与中止（Day 58）；寛解維持試験－不参加

ベースライン特性：本被験者は 5[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、ギリシャからの参加であった。

ブドウ球菌感染（Day 57～141）（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）（寛解導入試験）：
Day 57、Grade 4 の重篤なブドウ球菌感染が発現した。寛解導入治験薬に対する処置は投与中止であった。寛解維持治験薬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 141、Grade 4 の本事象は回復した。

その他の関連情報：急性発症した右殿部痛及び発熱が認められた。磁気共鳴検査の結果、右殿部の筋肉間に液貯留が認められた。被験者は入院し、治療として抗生剤の静脈内投与が行われた。超音波ガイド下の貯留液ドレナージ術が実施された。貯留液の培養検査の結果、黄色ブドウ球菌が検出された。最終的に膿瘍の切開及びドレナージ術が実施され、陰圧閉鎖療法が行われた。排膿が無くなった時点で吸引器は外された。被験者は退院し、自宅で経口抗生剤による治療を継続した。

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

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
mesalazine	ULCERATIVE COLITIS	ORAL	-286 days	Ongoing
prednisolone	ULCERATIVE COLITIS	ORAL	-39 days	Ongoing
vedolizumab	ULCERATIVE COLITIS	INTRAVENOUS	-610 days	-518 days
infliximab	ULCERATIVE COLITIS	INTRAVENOUS	-475 days	-91 days
piperacillin sodium;tazobactam sodium	STAPHYLOCOCCUS AUREUN INFECTION	INTRAVENOUS	58 days	65 days
daptomycin	STAPHYLOCOCCUS AUREUN INFECTION	INTRAVENOUS	58 days	67 days
folic acid	PROPHYLAXIS FOR SULFA/TRIM AE	ORAL	72 days	113 days
rifampicin	STAPHYLOCOCCUS AUREUS INFECTION	ORAL	72 days	113 days
sulfamethoxazole;trimethoprim	STAPHYLOCOCCUS AYREUS INFECTION	ORAL	72 days	113 days

All Adverse Events							
Preferred Term	Onset Day	Resolution Day	Toxicity Grade	Causality	Action taken with Induction Drug	Action taken with Maintenance Drug	Action - Other
Arthralgia	8	57	1	not related	dose not changed	not applicable	none
Staphylococcal infection	57	141	4	related	drug withdrawn	not applicable	medication required + permanent study discontinuation
* denotes the Maintenance study day.							

Hematology						
Study Day	Hemoglobin (g/dL)	Hematocrit (%)	Erythrocytes (x10^6/uL)	Platelets (x10^3/uL)	Reticulocytes (x10^6/uL)	Ery. Mean Corpuscular Volume (fL)
-20	13.3 (N)	42 (N)	4.6 (N)	258 (N)	0.08 (N)	91 (N)
1	13.3 (N)	42 (N)	4.6 (N)	290 (N)	0.114 (N)	90 (N)
16	13.8 (N)	43 (N)	4.7 (N)	280 (N)	0.129 (H)	91 (N)
29	12.7 (N)	41 (N)	4.5 (N)	327 (N)	0.09 (N)	93 (N)
45	13.3 (N)	41 (N)	4.6 (N)	294 (N)	0.089 (N)	90 (N)
66	11.9 (N)	37 (N)	4.2 (N)	524 (H)	0.134 (H)	89 (N)
91	13.3 (N)	40 (N)	4.6 (N)	242 (N)	0.097 (N)	87 (N)
* denotes the Maintenance study day. 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)
-20	12.3 (H)	5.65 (N)	5.82 (H)	0.69 (N)	0.05 (N)	0.1 (N)
1	12.27 (H)	4.91 (N)	6.29 (H)	0.81 (N)	0.04 (N)	0.21 (N)
16	15.2 (H)	6.9 (N)	7.16 (H)	0.91 (N)	0.05 (N)	0.18 (N)
29	10.84 (H)	4.11 (N)	5.86 (H)	0.72 (N)	0.05 (N)	0.1 (N)
45	15.35 (H)	7.82 (H)	6.46 (H)	0.89 (N)	0.08 (N)	0.11 (N)
66	13.3 (H)	9.74 (H)	2.77 (N)	0.61 (N)	0.04 (N)	0.13 (N)
91	10.99 (H)	6.9 (N)	3.31 (N)	0.6 (N)	0.04 (N)	0.13 (N)
* denotes the Maintenance study day. 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)
-20	Yes	25 (N)	21 (N)	34 (L)	0.4 (N)	0.94 (N)
1	Yes	15 (N)	18 (N)	35 (N)	0.5 (N)	0.93 (N)
16	Yes	17 (N)	18 (N)	38 (N)	0.4 (N)	1.02 (N)
29	Yes	22 (N)	26 (N)	37 (N)	0.7 (N)	1.05 (N)
45	Yes	25 (N)	22 (N)	42 (N)	0.2 (N)	0.8 (N)
66	Yes	59 (H)	43 (H)	69 (N)	0.4 (N)	0.9 (N)
91	Yes	22 (N)	21 (N)	54 (N)	<0.2 (L)	1.24 (H)
* denotes the Maintenance study day. 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)
-20	Yes	80.4 (N)	92 (N)	83 (N)	1.33 (N)
1	Yes	81.6 (N)	74 (N)	81 (N)	1.84 (N)
16	Yes	73.2 (L)	63 (N)	82 (N)	1.01 (N)
29	Yes	69.6 (L)	178 (N)	75 (N)	7.54 (N)
45	Yes	92.4 (N)	98 (N)	83 (N)	8.39 (N)
66	Yes	81 (N)	134 (N)	94 (N)	47.6 (H)
91	Yes	58.8 (L)	66 (N)	67 (L)	4.62 (N)
* denotes the Maintenance study day. 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)
-20	Yes	288 (N)	76 (N)	188 (H)	202 (N)
1	Yes	290 (N)	78 (N)	187 (H)	198 (N)
16	Yes	323 (H)	88 (N)	208 (H)	203 (N)
29	Yes	294 (H)	94 (H)	189 (H)	131 (N)
45	Yes	305 (H)	82 (N)	188 (H)	205 (N)
66	Yes	221 (N)	36 (L)	128 (N)	338 (H)
* denotes the Maintenance study day. H = High; L = Low; N = Normal.					

被験者識別番号：[redacted]

投与群：寛解導入試験－プラセボ群（コホート A）

治験薬の投与状況：寛解導入試験－有害事象により投与中止（Day 32）；寛解維持試験－不参加

ベースライン特性：本被験者は 2[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、マレーシアからの参加であった。

貧血（Day 23～37）（試験治療下の重篤な有害事象［TE-SAE］、投与中止に至った有害事象）（寛解導入試験）：
Day 23、Grade 3 の重篤な貧血が発現した。寛解導入治験薬に対する処置は投与中止であった。寛解維持治験薬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 37、Grade 3 の本事象は回復した。

潰瘍性大腸炎（Day 23～継続）（TE-SAE、投与中止に至った有害事象）（寛解導入試験）：
Day 23、Grade 3 の重篤な潰瘍性大腸炎が発現した。寛解導入治験薬に対する処置は投与中止であった。寛解維持治験薬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。試験終了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**
colitis ulcerative	Ongoing

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
azathioprine	ULCERATIVE COLITIS	ORAL	-78 days	Ongoing
mesalazine	ULCERATIVE COLITIS	ORAL	-78 days	Ongoing
prednisolone	ULCERATIVE COLITIS	ORAL	32 days	Ongoing
red blood cells, concentrated	SYMTOMATIC ANAEMIA	INTRAVENOUS DRIP	27 days	27 days
hydrocortisone	ULCERATIVE COLITIS	INTRAVENOUS	27 days	31 days

All Adverse Events							
Preferred Term	**Onset Day**	**Resolution Day**	**Toxicity Grade**	**Causality**	**Action taken with Induction Drug**	**Action taken with Maintenance Drug**	**Action - Other**
Anaemia	23	37	3	related	drug withdrawn	not applicable	medication required + permanent study discontinuation
Colitis ulcerative	23	Ongoing	3	related	drug withdrawn	not applicable	other treatment required + permanent study discontinuation
* denotes the Maintenance study day.							

Hematology						
Study Day	Hemoglobin (g/dL)	Hematocrit (%)	Erythrocytes (x10^6/uL)	Platelets (x10^3/uL)	Reticulocytes (x10^6/uL)	Ery. Mean Corpuscular Volume (fL)
-22	9.5 (L)	34 (N)	4.6 (N)	433 (H)	0.088 (N)	74 (L)
1	8.5 (L)	30 (L)	4.1 (N)	479 (H)	0.057 (N)	72 (L)
13	7.5 (L)	26 (L)	3.8 (L)	448 (H)	0.051 (N)	70 (L)
19	7.7 (L)	27 (L)	3.9 (L)	462 (H)	0.067 (N)	70 (L)
50	9.4 (L)	33 (L)	4.2 (N)	442 (H)	0.128 (H)	77 (L)
56	9.6 (L)	33 (L)	4.2 (N)	345 (N)	0.081 (N)	78 (L)
* denotes the Maintenance study day. 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)
-22	6.43 (N)	3.6 (N)	1.63 (N)	0.54 (N)	0.09 (N)	0.58 (H)
1	7.34 (N)	5.28 (N)	1.07 (N)	0.33 (N)	0.06 (N)	0.59 (H)
13	5.27 (N)	2.87 (N)	1.39 (N)	0.39 (N)	0.05 (N)	0.57 (N)
19	7.74 (N)	4.94 (N)	1.53 (N)	0.68 (N)	0.06 (N)	0.54 (N)
50	12.75 (H)	9.97 (H)	1.88 (N)	0.66 (N)	0.03 (N)	0.21 (N)
56	8.97 (N)	6.83 (N)	1.38 (N)	0.57 (N)	0.02 (N)	0.16 (N)
* denotes the Maintenance study day. 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)
-22	No	5 (L)	10 (N)	62 (N)	0.2 (N)	0.77 (N)
1	Yes	6 (N)	10 (N)	54 (N)	0.2 (N)	0.8 (N)
13	Yes	4 (L)	9 (N)	53 (N)	<0.2 (L)	0.68 (N)
50	Yes	6 (N)	8 (L)	51 (N)	<0.2 (L)	0.67 (N)
56	Yes	5 (L)	6 (L)	50 (N)	0.2 (N)	0.66 (N)
* denotes the Maintenance study day. 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)
-22	No	83.4 (N)	29 (N)	86 (N)	14.7 (H)
1	Yes	77.4 (N)	33 (N)	68 (L)	12.5 (H)
13	Yes	93 (N)	29 (N)	79 (N)	4.54 (N)
50	Yes	94.2 (N)	<18 (L)	68 (L)	6.89 (N)
56	Yes	97.2 (N)	<18 (L)	67 (L)	12 (H)
* denotes the Maintenance study day. 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	142 (N)	39 (N)	95 (N)	87 (N)
50	Yes	145 (N)	57 (N)	92 (N)	65 (N)
* denotes the Maintenance study day. H = High; L = Low; N = Normal.					

被験者識別番号：[redacted]

投与群：寛解導入試験－フィルゴチニブ 100 mg 群（コホート A）；寛解維持試験－プラセボ群

治験薬の投与状況：寛解導入試験－完了；寛解維持試験－被験者の判断により投与中止（Day 75*）

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、ジョージアからの参加であった。

冠動脈狭窄（Day 97*～97*）（試験治療下の重篤な有害事象）（寛解維持試験）：
Day 97*、Grade 4 の重篤な冠動脈狭窄が発現した。寛解導入治験薬に対する処置は非該当であった。寛解維持治験薬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 97*、Grade 4 の本事象は回復した。

その他の関連情報：被験者は冠動脈狭窄のため入院した。冠動脈造影検査が実施され、ステント留置による血管内血管形成術が行われた。高血圧、安定狭心症、不整脈又は心筋梗塞の病歴はなかった。
*寛解維持試験における study day

Medical History	
Medical History	**Resolution**
colitis ulcerative	Ongoing
menopause	Ongoing
radical mastectomy	Ongoing

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
acetylsalicylic acid;magnesium hydroxide	ARTERIAL HYPERTENSION	ORAL	128 days	Ongoing
atorvastatin	ARTERIAL HYPERTENSION	ORAL	128 days	Ongoing
hydrochlorothiazide	ARTERIAL HYPERTENSION	ORAL	128 days	Ongoing
magnesium sulfate	ARTERIAL HYPERTENSION	ORAL	128 days	Ongoing
trimetazidine	ARTERIAL HYPERTENSION	ORAL	128 days	Ongoing
dexamethasone	ULCERATIVE COLITIS	ORAL	-63 days	100 days
dexamethasone	ULCERATIVE COLITIS	ORAL	101 days	107 days
dexamethasone	ULCERATIVE COLITIS	ORAL	108 days	114 days
dexamethasone	ULCERATIVE COLITIS	ORAL	115 days	121 days

All Adverse Events							
Preferred Term	Onset Day	Resolution Day	Toxicity Grade	Causality	Action taken with Induction Drug	Action taken with Maintenance Drug	Action - Other
Hypertension	46*	Ongoing	1	not related	not applicable	dose not changed	medication required
Insomnia	46*	Ongoing	1	not related	not applicable	dose not changed	none
Abdominal distension	66*	Ongoing	1	related	not applicable	drug interrupted	none
Abdominal pain upper	66*	Ongoing	1	related	not applicable	drug interrupted	none
Pruritus	66*	76*	1	related	not applicable	drug interrupted	none
Angina pectoris	75*	97*	1	not related	not applicable	drug interrupted	other treatment required

All Adverse Events							
Preferred Term	Onset Day	Resolution Day	Toxicity Grade	Causality	Action taken with Induction Drug	Action taken with Maintenance Drug	Action - Other
Coronary artery stenosis	97*	97*	4	not related	not applicable	not applicable	other treatment required
* denotes the Maintenance study day.							

Hematology						
Study Day	Hemoglobin (g/dL)	Hematocrit (%)	Erythrocytes (x10^6/uL)	Platelets (x10^3/uL)	Reticulocytes (x10^6/uL)	Ery. Mean Corpuscular Volume (fL)
-29	14.4 (N)	45 (N)	4.9 (N)	203 (N)	0.045 (N)	91 (N)
1	13.8 (N)	42 (N)	4.6 (N)	204 (N)	0.082 (N)	91 (N)
15	14.4 (N)	44 (N)	4.9 (N)	209 (N)	0.083 (N)	90 (N)
29	14 (N)	42 (N)	4.7 (N)	199 (N)	0.083 (N)	91 (N)
43	14.2 (N)	42 (N)	4.8 (N)	188 (N)	0.066 (N)	87 (N)
72	14.6 (N)	42 (N)	4.9 (N)	206 (N)	0.07 (N)	86 (N)
-8*	14.6 (N)	42 (N)	4.9 (N)	206 (N)	0.07 (N)	86 (N)
21*	14.3 (N)	42 (N)	4.8 (N)	208 (N)	0.069 (N)	88 (N)
63*	13.9 (N)	41 (N)	4.7 (N)	215 (N)	0.091 (N)	87 (N)
* denotes the Maintenance study day. 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)
-29	6.33 (N)	4.12 (N)	1.75 (N)	0.31 (N)	0.05 (N)	0.09 (N)
1	5.51 (N)	3.84 (N)	1.24 (N)	0.29 (N)	0.05 (N)	0.09 (N)
15	6.3 (N)	4 (N)	1.79 (N)	0.36 (N)	0.05 (N)	0.11 (N)
29	4.49 (N)	2.87 (N)	1.17 (N)	0.29 (N)	0.03 (N)	0.13 (N)
43	5.16 (N)	3.28 (N)	1.48 (N)	0.26 (N)	0.03 (N)	0.12 (N)
72	5.29 (N)	3.42 (N)	1.37 (N)	0.3 (N)	0.03 (N)	0.17 (N)
-8*	5.29 (N)	3.42 (N)	1.37 (N)	0.3 (N)	0.03 (N)	0.17 (N)
21*	6.41 (N)	3.81 (N)	1.91 (N)	0.5 (N)	0.04 (N)	0.14 (N)
63*	6.84 (N)	4.02 (N)	2.07 (N)	0.52 (N)	0.04 (N)	0.18 (N)
* denotes the Maintenance study day. 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)
-29	Yes	17 (N)	19 (N)	100 (N)	0.4 (N)	0.71 (N)
1	Yes	20 (N)	19 (N)	94 (N)	0.4 (N)	0.8 (N)
15	Yes	20 (N)	22 (N)	91 (N)	0.5 (N)	0.81 (N)
29	Yes	17 (N)	19 (N)	88 (N)	0.5 (N)	0.72 (N)
43	Yes	20 (N)	21 (N)	87 (N)	0.5 (N)	0.75 (N)
72	Yes	16 (N)	18 (N)	85 (N)	0.5 (N)	0.74 (N)
-8*	Yes	16 (N)	18 (N)	85 (N)	0.5 (N)	0.74 (N)
21*	Yes	17 (N)	15 (N)	89 (N)	0.3 (N)	0.8 (N)
63*	Yes	27 (N)	20 (N)	93 (N)	0.2 (N)	0.95 (N)
* denotes the Maintenance study day. 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)
-29	Yes	91.8 (N)	83 (N)	91 (N)	1.43 (N)
1	Yes	81 (N)	116 (N)	100 (H)	1.7 (N)
15	Yes	79.8 (N)	114 (N)	101 (H)	0.8 (N)
29	Yes	90 (N)	129 (N)	100 (N)	1.04 (N)
43	Yes	87.6 (N)	222 (H)	97 (N)	0.79 (N)
72	Yes	88.2 (N)	123 (N)	90 (N)	1.62 (N)
-8*	Yes	88.2 (N)	123 (N)	90 (N)	1.62 (N)
21*	Yes	81 (N)	75 (N)	66 (L)	0.65 (N)
63*	Yes	69 (L)	54 (N)	82 (N)	1.25 (N)
* denotes the Maintenance study day. 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)
-29	Yes	287 (N)	43 (N)	210 (H)	224 (N)
1	Yes	283 (N)	55 (N)	229 (H)	104 (N)
15	Yes	306 (N)	64 (N)	226 (H)	130 (N)
29	Yes	310 (N)	54 (N)	235 (H)	128 (N)
43	Yes	295 (N)	53 (N)	224 (H)	107 (N)
72	Yes	270 (N)	54 (N)	205 (H)	149 (N)

Lipid Panel					
Study Day	Fasting	Total Cholesterol (mg/dL)	HDL Cholesterol (mg/dL)	LDL Cholesterol (mg/dL)	Triglycerides (mg/dL)
-8*	Yes	270 (N)	54 (N)	205 (H)	149 (N)
21*	Yes	270 (N)	43 (N)	204 (H)	174 (N)
63*	Yes	160 (L)	49 (N)	93 (N)	156 (N)
* denotes the Maintenance study day. H = High; L = Low; N = Normal.					

被験者識別番号：[redacted]

投与群：寛解導入試験－プラセボ群（コホート B）

治験薬の投与状況：寛解導入試験－有害事象により投与中止（Day 14）；寛解維持試験－不参加

ベースライン特性：本被験者は 2[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、ドイツからの参加であった。

体重減少（Day 1～44）（投与中止に至った有害事象）（寛解導入試験）：
Day 1、Grade 2 の非重篤な体重減少が発現した。寛解導入治験薬に対する処置は投与中止であった。寛解維持治験薬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 44、Grade 2 の本事象は回復した。

腹痛（Day 13～24）（投与中止に至った有害事象）（寛解導入試験）：
Day 13、Grade 2 の非重篤な腹痛が発現した。寛解導入治験薬に対する処置は投与中止であった。寛解維持治験薬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 24、Grade 2 の本事象は回復した。

潰瘍性大腸炎（Day 13～24）（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）（寛解導入試験）：
Day 13、Grade 3 の重篤な潰瘍性大腸炎が発現した。寛解導入治験薬に対する処置は投与中止であった。寛解維持治験薬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 24、Grade 3 の本事象は回復した。

発熱（Day 13～18）（投与中止に至った有害事象）（寛解導入試験）：
Day 13、Grade 2 の非重篤な発熱が発現した。寛解導入治験薬に対する処置は投与中止であった。寛解維持治験薬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 18、Grade 2 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
gastritis	Unknown
helicobacter infection	Unknown
intervertebral disc protrusion	Unknown
malnutrition	Unknown
vitamin d deficiency	Unknown
iron deficiency anaemia	About -620 days
erythema nodosum	About -436 days

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
azathioprine	ULCERATIVE COLITIS	ORAL	About -923 days	About -681 days
infliximab	ULCERATIVE COLITIS	INTRAVENOUS	-697 days	-679 days
adalimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	-669 days	About -558 days
mesalazine	ULCERATIVE COLITIS	ORAL	About -588 days	About -285 days

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
tacrolimus	ULCERATIVE COLITIS	ORAL	About -588 days	About -193 days
vedolizumab	ULCERATIVE COLITIS	INTRAVENOUS	-399 days	-91 days
prednisolone	ULCERATIVE COLITIS	ORAL	-54 days	-49 days
prednisolone	ULCERATIVE COLITIS	ORAL	-48 days	-40 days
prednisolone	ULCERATIVE COLITIS	ORAL	-39 days	-33 days
prednisolone	ULCERATIVE COLITIS	ORAL	-32 days	-26 days
prednisolone	ULCERATIVE COLITIS	ORAL	-25 days	-19 days
macrogol 3350;potassium chloride;sodium bicarbonate;sodium chloride	PREPARATION FOR COLONOSCOPY	ORAL	-6 days	-5 days
propofol	SEDATION DURING COLONOSCOPY	INTRAVENOUS	-5 days	-5 days
prednisolone	SAE DISEASE WORSENING ULCERATIVE COLITIS	INTRAVENOUS	15 days	21 days
ceftriaxone sodium	FEVER	ORAL	15 days	22 days
metronidazole	FEVER	INTRAVENOUS	15 days	22 days
solutions for parenteral nutrition	WEIGHT LOSS	INTRAVENOUS	15 days	23 days
prednisolone	SAE DISEASE WORSENING ULCERATIVE COLITIS	INTRAVENOUS	22 days	24 days
prednisolone	ULCERATIVE COLITIS	ORAL	25 days	32 days
calcium carbonate	CALCIUMCARBONAT DEFICIENT	ORAL	15 days	40 days
folic acid	FOLATE DEFICIENT	ORAL	15 days	40 days
pantoprazole sodium sesquihydrate	STOMACH PROTECTION	ORAL	15 days	40 days
prednisolone	ULCERATIVE COLITIS	ORAL	33 days	40 days
prednisolone	ULCERATIVE COLITIS	ORAL	41 days	52 days

All Adverse Events							
Preferred Term	Onset Day	Resolution Day	Toxicity Grade	Causality	Action taken with Induction Drug	Action taken with Maintenance Drug	Action - Other
Weight decreased	1	44	2	not related	drug withdrawn	not applicable	other treatment required + permanent study discontinuation
Abdominal pain	13	24	2	not related	drug withdrawn	not applicable	permanent study discontinuation
Colitis ulcerative	13	24	3	not related	drug withdrawn	not applicable	medication required + permanent study discontinuation
Pyrexia	13	18	2	not related	drug withdrawn	not applicable	medication required + permanent study discontinuation
Calcium deficiency	15	40	1	not related	not applicable	not applicable	medication required

All Adverse Events							
Preferred Term	Onset Day	Resolution Day	Toxicity Grade	Causality	Action taken with Induction Drug	Action taken with Maintenance Drug	Action - Other
Folate deficiency	15	40	1	not related	not applicable	not applicable	medication required
* denotes the Maintenance study day.							

Hematology						
Study Day	Hemoglobin (g/dL)	Hematocrit (%)	Erythrocytes (x10^6/uL)	Platelets (x10^3/uL)	Reticulocytes (x10^6/uL)	Ery. Mean Corpuscular Volume (fL)
-18	12.8 (N)	41 (N)	4.6 (N)	313 (N)	0.063 (N)	90 (N)
1	13.5 (N)	42 (N)	4.9 (N)	362 (N)	0.042 (N)	85 (N)
15	12.5 (L)	39 (N)	4.7 (N)	636 (H)	0.071 (N)	83 (N)
44	11.5 (L)	37 (L)	4.2 (L)	284 (N)	0.116 (N)	87 (N)
* denotes the Maintenance study day. 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)
-18	11.31 (H)	8.14 (H)	2.31 (N)	0.55 (N)	0.06 (N)	0.25 (N)
1	9.95 (N)	6.43 (N)	2.16 (N)	0.96 (H)	0.11 (N)	0.29 (N)
15	12.26 (H)	10.03 (H)	1.2 (N)	0.96 (H)	0.03 (N)	0.03 (N)
44	15.7 (H)	12.02 (H)	2.51 (N)	0.86 (N)	0.11 (N)	0.21 (N)
* denotes the Maintenance study day. 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)
-18	Yes	6 (N)	11 (N)	79 (N)	0.4 (N)	0.89 (N)
1	Yes	8 (N)	13 (N)	72 (N)	0.3 (N)	0.94 (N)
15	Yes	5 (L)	13 (N)	68 (N)	0.3 (N)	0.9 (N)
44	Yes	12 (N)	9 (L)	49 (N)	0.4 (N)	0.87 (N)
* denotes the Maintenance study day. 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)
-18	Yes	140.4 (H)	62 (N)	80 (N)	16 (H)
1	Yes	130.8 (H)	49 (N)	87 (N)	51.6 (H)
15	Yes	127.2 (H)	29 (L)	113 (H)	82.6 (H)
44	Yes	146.4 (H)	46 (N)	72 (N)	2.93 (N)
* denotes the Maintenance study day. 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)
-18	Yes	155 (N)	36 (N)	94 (N)	102 (N)
1	Yes	130 (N)	34 (N)	76 (N)	99 (N)
15	Yes	123 (L)	32 (N)	66 (N)	101 (N)
* denotes the Maintenance study day. H = High; L = Low; N = Normal.					

被験者識別番号：[redacted]

投与群：寛解導入試験－フィルゴチニブ 200 mg 群（コホート B）

治験薬の投与状況：寛解導入試験－有害事象により投与中止（Day 73）；寛解維持試験－不参加

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、民族は非ヒスパニック／ラテン系、ドイツからの参加であった。

潰瘍性大腸炎（Day 74～91）（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）（寛解導入試験）：
Day 74、Grade 3 の重篤な潰瘍性大腸炎が発現した。寛解導入治験薬に対する処置は投与中止であった。寛解維持治験薬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 91、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**
blood albumin decreased	Ongoing
colitis ulcerative	Ongoing
malnutrition	Ongoing
oedema peripheral	15 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
carbohydrates nos;fatty acids nos;minerals nos;proteins nos;vitamins nos	MALNUTRITION	ORAL	-116 days	Ongoing
chlormadinone acetate;ethinylestradiol	CONTRACEPTION	ORAL	-90 days	Ongoing
azathioprine	ULCERATIVE COLITIS	ORAL	About -2029 days	About -569 days
adalimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	About -782 days	About -538 days
vedolizumab	ULCERATIVE COLITIS	INTRAVENOUS	About -537 days	About -265 days
ciclosporin	ULCERATIVE COLITIS	ORAL	About -478 days	About -265 days
tacrolimus	ULCERATIVE COLITIS	ORAL	About -478 days	About -265 days
infliximab	ULCERATIVE COLITIS	INTRAVENOUS	About -264 days	-140 days
mesalazine	ULCERATIVE COLITIS	ORAL	About -2029 days	About -114 days
prednisolone	ULCERATIVE COLITIS	INTRAVENOUS	-117 days	-111 days
ascorbic acid;macrogol 3350;potassium chloride;sodium ascorbate;sodium chloride;sodium sulfate	PREPARATION FOR COLONOSCOPY	ORAL	-6 days	-5 days
propofol	SEDATION DURING COLONOSCOPY	INTRAVENOUS	-5 days	-5 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
ferric carboxymaltose	ANEMIA	INTRAVENOUS	51 days	51 days
ascorbic acid;macrogol 3350;potassium chloride;sodium ascorbate;sodium chloride;sodium sulfate	PREPARATION FOR COLONOSCOPY	ORAL	73 days	74 days
propofol	SEDATION DURING COLONOSCOPY	INTRAVENOUS	74 days	74 days

All Adverse Events							
Preferred Term	Onset Day	Resolution Day	Toxicity Grade	Causality	Action taken with Induction Drug	Action taken with Maintenance Drug	Action - Other
Anaemia	51	Ongoing	2	not related	dose not changed	not applicable	medication required
Colitis ulcerative	74	91	3	not related	drug withdrawn	not applicable	other treatment required + permanent study discontinuation
* denotes the Maintenance study day.							

Hematology						
Study Day	Hemoglobin (g/dL)	Hematocrit (%)	Erythrocytes (x10^6/uL)	Platelets (x10^3/uL)	Reticulocytes (x10^6/uL)	Ery. Mean Corpuscular Volume (fL)
-14	10 (L)	34 (N)	3.8 (L)	516 (H)	0.124 (H)	90 (N)
1	9.5 (L)	31 (L)	3.4 (L)	497 (H)	0.144 (H)	90 (N)
15	10 (L)	34 (N)	3.5 (L)	515 (H)	0.112 (N)	97 (N)
29	10.1 (L)	32 (L)	3.5 (L)	469 (H)	0.121 (H)	92 (N)
43	10.6 (L)	35 (N)	3.7 (L)	384 (N)	0.083 (N)	93 (N)
74	10.6 (L)	33 (L)	3.6 (L)	342 (N)	0.088 (N)	93 (N)
* denotes the Maintenance study day. 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)
-14	7.81 (N)	6.14 (N)	1.21 (N)	0.31 (N)	0.01 (N)	0.13 (N)
1	5.33 (N)	3.91 (N)	1 (N)	0.3 (N)	0.03 (N)	0.09 (N)
15	3.71 (L)	1.95 (L)	1.5 (N)	0.21 (N)	0.01 (N)	0.04 (N)
29	3.68 (L)	2.35 (N)	1.02 (N)	0.23 (N)	0.01 (N)	0.07 (N)
43	2.93 (L)	2.12 (N)	0.58 (L)	0.2 (N)	0.01 (N)	0.03 (N)
74	3.95 (N)	2.79 (N)	0.78 (L)	0.3 (N)	0.01 (N)	0.08 (N)
* denotes the Maintenance study day. 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)
-14	No	14 (N)	14 (N)	92 (N)	<0.2 (L)	0.55 (N)
1	No	10 (N)	11 (N)	65 (N)	<0.2 (L)	0.46 (N)
15	No	12 (N)	13 (N)	76 (N)	<0.2 (L)	0.54 (N)
29	Yes	17 (N)	19 (N)	73 (N)	<0.2 (L)	0.54 (N)
43	Yes	17 (N)	20 (N)	60 (N)	<0.2 (L)	0.57 (N)
74	Yes	15 (N)	17 (N)	54 (N)	<0.2 (L)	0.53 (N)
* denotes the Maintenance study day. 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)
-14	No	114.6 (N)	20 (L)	110 (H)	45 (H)
1	No	136.2 (H)	18 (L)	103 (H)	68.6 (H)
15	No	114 (N)	26 (N)	84 (N)	24.5 (H)
29	Yes	117.6 (H)	32 (N)	78 (N)	11.8 (H)
43	Yes	114.6 (N)	32 (N)	124 (H)	18.6 (H)
74	Yes	124.8 (H)	25 (L)	81 (N)	8.48 (N)
* denotes the Maintenance study day. 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	No	79 (L)	50 (N)	19 (N)	61 (N)
74	Yes	142 (N)	63 (N)	71 (N)	88 (N)
* denotes the Maintenance study day. H = High; L = Low; N = Normal.					

被験者識別番号：[redacted]

投与群：寛解導入試験－フィルゴチニブ 200 mg 群（コホート A）；寛解維持試験－フィルゴチニブ 200 mg 群

治験薬の投与状況：寛解導入試験－完了；寛解維持試験－死亡により投与中止（Day 81*）

死因：Day 81*に左室不全のため死亡した。

ベースライン特性：本被験者は 6[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、ロシアからの参加であった。

左室不全（Day 81*～継続）（死亡、試験治療下の重篤な有害事象）（寛解維持試験）：
Day 81*、Grade 5 の重篤な左室不全が発現した。寛解導入治験薬に対する処置は非該当であった。寛解維持治験薬に対する処置は変更なし。本事象は治験薬と関連なしと判断された。死亡時、本事象は未回復であった。

その他の関連情報：寛解維持試験 Day 34*頃より Grade 3 の緑内障がみられ始めた。治験責任医師によると、被験者はその後緑内障手術を受け、脱力のためそのまま一晩入院した。翌日の寛解維持試験 Day 81*に、被験者は病棟で死亡しているのが発見された。剖検所見に基づき、Grade 4 の冠動脈硬化症及び Grade 5 の左室不全と報告された。剖検報告書によると、主な死因は左室不全であった。
*寛解維持試験における study day

Medical History	
Medical History	**Resolution**
bronchitis chronic	Ongoing
chronic gastritis	Ongoing
colitis ulcerative	Ongoing
cystic lung disease	Ongoing
deep vein thrombosis	Ongoing
gastric ulcer	Ongoing
helicobacter gastritis	Ongoing
nonalcoholic fatty liver disease	Ongoing
gastric dysplasia	About -315 days
gastrointestinal endoscopic therapy	About -315 days
intestinal polypectomy	-99 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
mesalazine	ULCERATIVE COLITIS	ORAL	About -985 days	Ongoing
apixaban	THROMBOPHLEBITIS OF DEEP LEFT FEMORAL AND POPLITEAL VEINS	ORAL	-116 days	Ongoing
diosmin;hesperidin	THROMBOPHLEBITIS OF DEEP LEFT FEMORAL AND POPLITEAL VEINS	ORAL	-116 days	Ongoing
folic acid	PREVENTION OF FOLIC ACID DEFICIENCY DURING METHOTREXATE THERAPY	ORAL	-98 days	Ongoing
methotrexate	ULCERATIVE COLITIS	SUBCUTANEOUS	-98 days	Ongoing
sulfasalazine	ULCERATIVE COLITIS	ORAL	About -1351 days	About -1291 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
mesalazine	ULCERATIVE COLITIS	ORAL	About -1321 days	About -1261 days
mesalazine	ULCERATIVE COLITIS	RECTAL	About -1290 days	About -1261 days
mesalazine	ULCERATIVE COLITIS	ORAL	About -1290 days	About -956 days
mesalazine	ULCERATIVE COLITIS	RECTAL	About -985 days	About -956 days
mesalazine	ULCERATIVE COLITIS	RECTAL	About -832 days	About -803 days
budesonide	ULCERATIVE COLITIS	ORAL	About -832 days	About -711 days
methylprednisolone	ULCERATIVE COLITIS	ORAL	-641 days	-636 days
methylprednisolone	ULCERATIVE COLITIS	ORAL	-729 days	About -621 days
mesalazine	ULCERATIVE COLITIS	RECTAL	-729 days	About -591 days
methylprednisolone	ULCERATIVE COLITIS	ORAL	-635 days	-531 days
methylprednisolone	ULCERATIVE COLITIS	ORAL	-518 days	About -346 days
azathioprine	ULCERATIVE COLITIS	ORAL	-635 days	About -165 days
budesonide	ULCERATIVE COLITIS	RECTAL	About -194 days	About -165 days
budesonide	ULCERATIVE COLITIS	ORAL	About -194 days	About -134 days
azathioprine	ULCERATIVE COLITIS	ORAL	About -194 days	-99 days
budesonide	ULCERATIVE COLITIS	ORAL	-98 days	-41 days
mesalazine	ULCERATIVE COLITIS	RECTAL	-98 days	-41 days
sodium picosulfate	BOWEL PREPARATION TO COLONOSCOPY	ORAL	-8 days	-8 days

All Adverse Events							
Preferred Term	Onset Day	Resolution Day	Toxicity Grade	Causality	Action taken with Induction Drug	Action taken with Maintenance Drug	Action - Other
Leukopenia	1	14	1	not related	dose not changed	not applicable	none
Lymphopenia	1	14	2	not related	dose not changed	not applicable	none
Nausea	8	23	1	not related	dose not changed	not applicable	none
Leukopenia	43	64	1	not related	dose not changed	not applicable	none

All Adverse Events							
Preferred Term	Onset Day	Resolution Day	Toxicity Grade	Causality	Action taken with Induction Drug	Action taken with Maintenance Drug	Action - Other
Neutropenia	43	64	1	not related	dose not changed	not applicable	none
Glaucoma	About 34*	81*	3	not related	not applicable	dose not changed	other treatment required
Arteriosclerosis coronary artery	81*	Ongoing	4	not related	not applicable	not applicable	none
Left ventricular failure	81*	Ongoing	5	not related	not applicable	dose not changed	permanent study discontinuation
* denotes the Maintenance study day.							

Hematology						
Study Day	Hemoglobin (g/dL)	Hematocrit (%)	Erythrocytes (x10^6/uL)	Platelets (x10^3/uL)	Reticulocytes (x10^6/uL)	Ery. Mean Corpuscular Volume (fL)
-21	13.6 (N)	41 (N)	4.3 (N)	281 (N)	0.087 (N)	97 (N)
1	13 (N)	39 (N)	4.1 (N)	215 (N)	0.064 (N)	95 (N)
14	13.4 (N)	39 (N)	4.3 (N)	313 (N)	0.084 (N)	91 (N)
36	14 (N)	41 (N)	4.5 (N)	230 (N)	0.074 (N)	92 (N)
43	13.7 (N)	42 (N)	4.6 (N)	219 (N)	0.08 (N)	91 (N)
64	13.9 (N)	42 (N)	4.5 (N)	241 (N)	0.064 (N)	94 (N)
71	14.6 (N)	44 (N)	4.6 (N)	256 (N)	0.078 (N)	94 (N)
-7*	14.6 (N)	44 (N)	4.6 (N)	256 (N)	0.078 (N)	94 (N)
21*	14 (N)	43 (N)	4.6 (N)	205 (N)	0.079 (N)	94 (N)
62*	14.4 (N)	44 (N)	4.7 (N)	247 (N)	0.07 (N)	93 (N)
* denotes the Maintenance study day. 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)
-21	4.28 (N)	2.91 (N)	0.84 (N)	0.4 (N)	0.03 (N)	0.11 (N)
1	3.62 (L)	2.21 (N)	0.74 (L)	0.46 (N)	0.03 (N)	0.18 (N)
14	4.66 (N)	3.07 (N)	0.87 (N)	0.46 (N)	0.08 (N)	0.19 (N)
36	4.81 (N)	3.16 (N)	1.03 (N)	0.41 (N)	0.03 (N)	0.19 (N)
43	2.52 (L)	1.25 (L)	0.81 (N)	0.28 (N)	0.05 (N)	0.13 (N)
64	4.17 (N)	2.62 (N)	1.16 (N)	0.29 (N)	0.03 (N)	0.07 (N)
71	4.19 (N)	3.08 (N)	0.73 (L)	0.24 (N)	0.04 (N)	0.09 (N)
-7*	4.19 (N)	3.08 (N)	0.73 (L)	0.24 (N)	0.04 (N)	0.09 (N)
21*	4.47 (N)	3.23 (N)	0.92 (N)	0.27 (N)	0.01 (N)	0.05 (N)
62*	4.61 (N)	2.98 (N)	1.21 (N)	0.33 (N)	0.02 (N)	0.07 (N)
* denotes the Maintenance study day. 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)
-21	Yes	50 (H)	30 (N)	93 (N)	0.3 (N)	0.74 (N)
1	Yes	27 (N)	19 (N)	67 (N)	0.4 (N)	0.71 (N)
14	Yes	26 (N)	19 (N)	77 (N)	0.2 (N)	0.84 (N)
29	Yes	42 (N)	32 (N)	88 (N)	0.4 (N)	0.79 (N)
36	Yes	32 (N)	22 (N)	79 (N)	0.4 (N)	0.74 (N)
43	Yes	19 (N)	19 (N)	75 (N)	0.5 (N)	0.81 (N)
71	Yes	22 (N)	25 (N)	71 (N)	1.3 (H)	0.95 (N)
-7*	Yes	22 (N)	25 (N)	71 (N)	1.3 (H)	0.95 (N)
21*	Yes	19 (N)	24 (N)	47 (N)	0.8 (N)	0.77 (N)
62*	Yes	21 (N)	21 (N)	64 (N)	0.4 (N)	0.86 (N)
* denotes the Maintenance study day. 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)
-21	Yes	123 (N)	40 (N)	90 (N)	4.71 (N)
1	Yes	126 (H)	34 (L)	95 (N)	19.6 (H)
14	Yes	106.8 (N)	50 (N)	93 (N)	7.58 (N)
29	Yes	113.4 (N)	50 (N)	83 (N)	5.1 (N)
36	Yes		42 (N)	85 (N)	
43	Yes	109.8 (N)	47 (N)	87 (N)	2.96 (N)
71	Yes	93.6 (N)	77 (N)	66 (L)	2.25 (N)
-7*	Yes	93.6 (N)	77 (N)	66 (L)	2.25 (N)
21*	Yes	115.2 (N)	76 (N)	89 (N)	0.46 (N)
62*	Yes	103.2 (N)	85 (N)	97 (N)	1.28 (N)
* denotes the Maintenance study day. 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	208 (N)	43 (N)	150 (H)	87 (N)
14	Yes	227 (N)	48 (N)	169 (H)	86 (N)
29	Yes	235 (N)	48 (N)	169 (H)	87 (N)
43	Yes	232 (N)	50 (N)	175 (H)	93 (N)

Lipid Panel					
Study Day	Fasting	Total Cholesterol (mg/dL)	HDL Cholesterol (mg/dL)	LDL Cholesterol (mg/dL)	Triglycerides (mg/dL)
71	Yes	272 (N)	63 (N)	200 (H)	51 (L)
-7*	Yes	272 (N)	63 (N)	200 (H)	51 (L)
21*	Yes	254 (N)	55 (N)	184 (H)	66 (N)
62*	Yes	263 (N)	57 (N)	191 (H)	70 (N)
* denotes the Maintenance study day. H = High; L = Low; N = Normal.					

被験者識別番号：[redacted]

投与群：寛解導入試験－フィルゴチニブ 100 mg 群（コホート B）

治験薬の投与状況：寛解導入試験－有害事象により投与中止（Day 14）；寛解維持試験－不参加

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、民族は非ヒスパニック／ラテン系、ドイツからの参加であった。

潰瘍性大腸炎（Day 15～18）（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）（寛解導入試験）：
Day 15、Grade 3 の重篤な潰瘍性大腸炎が発現した。寛解導入治験薬に対する処置は投与中止であった。寛解維持治験薬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 18、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**
arthralgia	Ongoing
colitis ulcerative	Ongoing
drug intolerance	Ongoing
iron deficiency anaemia	Ongoing
osteoporosis	Ongoing

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
desogestrel;ethinylestradiol	CONTRACEPTIVA	ORAL	About -4433 days	Ongoing
calcium carbonate;colecalciferol	PROPHYLAXE VITAMIN DEFICIENCY	ORAL	About -415 days	Ongoing
prednisolone	ULCERATIVE COLITIS	ORAL	21 days	Ongoing
infliximab	ULCERATIVE COLITIS	INTRAVENOUS	About -2607 days	About -477 days
vedolizumab	ULCERATIVE COLITIS	INTRAVENOUS	-462 days	-120 days
budesonide	ULCERATIVE COLITIS	ORAL	About -111 days	-103 days
prednisolone	ULCERATIVE COLITIS	ORAL	-103 days	-100 days
vedolizumab	ULCERATIVE COLITIS	INTRAVENOUS	-119 days	-98 days
adalimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	-96 days	-96 days
prednisolone	ULCERATIVE COLITIS	ORAL	-99 days	-95 days
prednisolone	ULCERATIVE COLITIS	ORAL	-94 days	-89 days
prednisolone	ULCERATIVE COLITIS	ORAL	-88 days	-77 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
adalimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	-77 days	-77 days
mercaptopurine	ULCERATIVE COLITIS	ORAL	-70 days	-60 days
prednisolone	ULCERATIVE COLITIS	ORAL	-76 days	-49 days
prednisolone	ULCERATIVE COLITIS	ORAL	-48 days	-44 days
mesalazine	ULCERATIVE COLITIS	ORAL	-49 days	-42 days
citric acid;magnesium oxide;sodium picosulfate	COLONOSCOPY	ORAL	-8 days	-8 days
propofol	SEDATION DUING TO COLONOSCOPY	INTRAVENOUS	-7 days	-7 days
prednisolone	ULCERATIVE COLITIS	ORAL	-43 days	14 days
ciprofloxacin	ULCERATIVE COLITIS	INTRAVENOUS	15 days	15 days
metronidazole	ULCERATIVE COLITIS	INTRAVENOUS	15 days	15 days
metronidazole	ULCERATIVE COLITIS	INTRAVENOUS	16 days	16 days
midazolam	SEDATION DUING TO SIGMOIDOSCOPY	INTRAVENOUS	16 days	16 days
propofol	SEDATION DUING TO SIGMOIDOSCOPY	INTRAVENOUS	16 days	16 days
calcium acetate;magnesium acetate;potassium acetate;sodium acetate;sodium chloride	SAE - WORSENING OF ULCERATIVE COLITIS	INTRAVENOUS	15 days	17 days
ciprofloxacin	ULCERATIVE COLITIS	INTRAVENOUS	16 days	17 days
metronidazole	ULCERATIVE COLITIS	INTRAVENOUS	17 days	17 days
prednisolone	ULCERATIVE COLITIS	INTRAVENOUS	16 days	18 days
ciprofloxacin	ULCERATIVE COLITIS	INTRAVENOUS	18 days	18 days
metronidazole	ULCERATIVE COLITIS	INTRAVENOUS	18 days	18 days
prednisolone	ULCERATIVE COLITIS	ORAL	19 days	20 days
ferric carboxymaltose	IRON DEFICIENCY ANEMIA	INTRAVENOUS	22 days	22 days
certoparin sodium	THROMBOEMBOLISM PROPHYLAXIS BLOOD DILUTION AS A PROPHYLAXIS	SUBCUTANEOUS	16 days	25 days

All Adverse Events							
Preferred Term	Onset Day	Resolution Day	Toxicity Grade	Causality	Action taken with Induction Drug	Action taken with Maintenance Drug	Action - Other
Colitis ulcerative	7	14	3	not related	dose not changed	not applicable	none
Colitis ulcerative	15	18	3	not related	drug withdrawn	not applicable	medication required + permanent study discontinuation
Iron deficiency anaemia	15	22	2	not related	not applicable	not applicable	medication required
* denotes the Maintenance study day.							

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	12.7 (N)	40 (N)	4.6 (N)	511 (H)	0.098 (N)	87 (N)
28	12.1 (N)	38 (N)	4.5 (N)	492 (H)	0.203 (H)	84 (N)
* denotes the Maintenance study day. 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	21.51 (H)	17.42 (H)	2.15 (N)	0.65 (N)	0 (N)	0.43 (N)
28	21.36 (H)	19.01 (H)	1.28 (N)	0.43 (N)	0 (N)	0.21 (N)
* denotes the Maintenance study day. 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)
-19	No	7 (N)	7 (L)	44 (N)	0.2 (N)	0.8 (N)
1	No	13 (N)	12 (N)	48 (N)	<0.2 (L)	0.84 (N)
28	Yes	13 (N)	15 (N)	41 (N)	<0.2 (L)	0.77 (N)
43	Yes	14 (N)	15 (N)	44 (N)	<0.2 (L)	0.71 (N)
* denotes the Maintenance study day. 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)
-19	No	101.4 (N)	30 (N)	98 (N)	8.74 (N)
1	No	92.4 (N)	21 (L)	97 (N)	16.6 (H)
28	Yes	99 (N)	<18 (L)	144 (H)	5.96 (N)
43	Yes		21 (L)	117 (H)	
* denotes the Maintenance study day. 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)
-19	No	193 (N)	56 (N)	107 (N)	173 (H)
1	No	220 (H)	46 (N)	123 (N)	256 (H)
28	Yes	193 (N)		100 (N)	153 (H)
* denotes the Maintenance study day. H = High; L = Low; N = Normal.					

被験者識別番号：[redacted]

投与群：寛解導入試験－フィルゴチニブ 100 mg 群（コホート B）

治験薬の投与状況：寛解導入試験－有害事象により投与中止（Day 5）；寛解維持試験－不参加

ベースライン特性：本被験者は 2[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、韓国からの参加であった。

肛門膿瘍（Day 5～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、試験治療下の注目すべき有害事象）（寛解導入試験）：
Day 5、Grade 3 の重篤な肛門膿瘍が発現した。寛解導入治験薬に対する処置は投与中止であった。寛解維持治験薬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。試験終了時点で本事象は未回復であった。

その他の関連情報：被験者は、肛門周囲膿瘍による肛門痛及び出血のため入院した。被験者は切開及びドレナージ術を受け、術後急速に回復した。被験者は手術翌日に退院し自宅にて抗生剤治療を継続した。

Medical History	
Medical History	**Resolution**
colitis ulcerative	Ongoing
erosive duodenitis	Ongoing
iron deficiency anaemia	Ongoing

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
mesalazine	ULCERATIVE COLITIS	ORAL	-583 days	Ongoing
prednisolone	ULCERATIVE COLITIS	ORAL	19 days	Ongoing
balsalazide sodium	ULCERATIVE COLITIS	ORAL	-4207 days	-3358 days
azathioprine	ULCERATIVE COLITIS	ORAL	-3357 days	-3330 days
prednisolone	ULCERATIVE COLITIS	ORAL	-3357 days	-3330 days
prednisolone	ULCERATIVE COLITIS	ORAL	-3329 days	-3316 days
prednisolone	ULCERATIVE COLITIS	ORAL	-3315 days	-3302 days
prednisolone	ULCERATIVE COLITIS	ORAL	-3301 days	-3288 days
azathioprine	ULCERATIVE COLITIS	ORAL	-3329 days	-3274 days
prednisolone	ULCERATIVE COLITIS	ORAL	-3287 days	-3274 days
prednisolone	ULCERATIVE COLITIS	ORAL	-3273 days	-3260 days
prednisolone	ULCERATIVE COLITIS	ORAL	-3116 days	-3068 days
prednisolone	ULCERATIVE COLITIS	ORAL	-3067 days	-3008 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
azathioprine	ULCERATIVE COLITIS	ORAL	-3273 days	-2796 days
azathioprine	ULCERATIVE COLITIS	ORAL	-2795 days	-2770 days
prednisolone	ULCERATIVE COLITIS	ORAL	-2769 days	-2763 days
prednisolone	ULCERATIVE COLITIS	ORAL	-2762 days	-2756 days
prednisolone	ULCERATIVE COLITIS	ORAL	-2755 days	-2749 days
prednisolone	ULCERATIVE COLITIS	ORAL	-2748 days	-2742 days
prednisolone	ULCERATIVE COLITIS	ORAL	-2584 days	-2571 days
prednisolone	ULCERATIVE COLITIS	ORAL	-2397 days	-2382 days
prednisolone	ULCERATIVE COLITIS	ORAL	-2381 days	-2368 days
prednisolone	ULCERATIVE COLITIS	ORAL	-2367 days	-2355 days
prednisolone	ULCERATIVE COLITIS	ORAL	-2354 days	-2341 days
prednisolone	ULCERATIVE COLITIS	ORAL	-2340 days	-2327 days
prednisolone	ULCERATIVE COLITIS	ORAL	-2326 days	-2313 days
prednisolone	ULCERATIVE COLITIS	ORAL	-2312 days	-2299 days
prednisolone	ULCERATIVE COLITIS	ORAL	-2298 days	-2285 days
prednisolone	ULCERATIVE COLITIS	ORAL	-2284 days	-2271 days
azathioprine	ULCERATIVE COLITIS	ORAL	-2769 days	-2243 days
azathioprine	ULCERATIVE COLITIS	ORAL	-2242 days	-2187 days
prednisolone	ULCERATIVE COLITIS	ORAL	-2186 days	-2172 days
prednisolone	ULCERATIVE COLITIS	ORAL	-2151 days	-2138 days
prednisolone	ULCERATIVE COLITIS	ORAL	-2137 days	-2124 days
prednisolone	ULCERATIVE COLITIS	ORAL	-2123 days	-2109 days
azathioprine	ULCERATIVE COLITIS	ORAL	-2186 days	-2096 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
prednisolone	ULCERATIVE COLITIS	ORAL	-2108 days	-2095 days
balsalazide sodium	ULCERATIVE COLITIS	ORAL	-3357 days	-2030 days
prednisolone	ULCERATIVE COLITIS	ORAL	-2018 days	-2005 days
infliximab	ULCERATIVE COLITIS	INTRAVENOUS	-2284 days	-2004 days
prednisolone	ULCERATIVE COLITIS	ORAL	-2004 days	-1977 days
infliximab	ULCERATIVE COLITIS	INTRAVENOUS	-1948 days	-1887 days
infliximab	ULCERATIVE COLITIS	INTRAVENOUS	-1822 days	-1761 days
infliximab	ULCERATIVE COLITIS	INTRAVENOUS	-1716 days	-1716 days
infliximab	ULCERATIVE COLITIS	INTRAVENOUS	-1668 days	-1668 days
adalimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	-2298 days	-1612 days
adalimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	-1600 days	-1600 days
adalimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	-1576 days	-1548 days
prednisolone	ULCERATIVE COLITIS	ORAL	-1484 days	-1465 days
prednisolone	ULCERATIVE COLITIS	ORAL	-1353 days	-1340 days
sulfasalazine	ULCERATIVE COLITIS	ORAL	-4725 days	-592 days
prednisolone	ULCERATIVE COLITIS	ORAL	-254 days	-151 days
adalimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	-1492 days	-134 days
rebamipide	DUODENAL EROSION	ORAL	-66 days	-60 days
iron succinyl-protein complex	ANEMIA	ORAL	-519 days	-32 days
almagate	DUODENAL EROSION	ORAL	-66 days	-32 days
lafutidine	DUODENAL EROSION	ORAL	-66 days	-32 days
midazolam	PREMEDICATION FOR SIGMOIDOSCOPY	INTRAVENOUS	-17 days	-17 days
phosphoric acid sodium;sodium phosphate dibasic	BOWELPREP FOR SIGMOIDOSCOPY	RECTAL	-17 days	-17 days
propofol	PREMEDICATION FOR SIGMOIDOSCOPY	INTRAVENOUS	-17 days	-17 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
bupivacaine hydrochloride;glucose	ANESTHETIC FOR OPERATION	EPIDURAL	5 days	5 days
calcium chloride dihydrate;potassium chloride;sodium chloride;sodium lactate	ELECTROLYTE BALANCE	INTRAVENOUS	5 days	5 days
dexmedetomidine hydrochloride	PREMEDICATION FOR OPERATION	INTRAVENOUS	5 days	5 days
flomoxef sodium	PERIANAL ABSCESS	INTRAVENOUS	5 days	5 days
lidocaine	ANESTHETIC FOR OPERATION	EPIDURAL	5 days	5 days
phosphoric acid sodium;sodium phosphate dibasic	BOWELPREP FOR OPERATION	RECTAL	5 days	5 days
cefdinir	PERIANAL ABSCESS	ORAL	6 days	12 days
magnesium hydroxide	PROPHYLAXIS FOR INDIGETION	ORAL	6 days	12 days
metronidazole	PERIANAL ABSCESS	ORAL	6 days	25 days

All Adverse Events							
Preferred Term	Onset Day	Resolution Day	Toxicity Grade	Causality	Action taken with Induction Drug	Action taken with Maintenance Drug	Action - Other
Anal abscess	5	Ongoing	3	not related	drug withdrawn	not applicable	medication required + other treatment required + permanent study discontinuation
* denotes the Maintenance study day.							

Hematology						
Study Day	Hemoglobin (g/dL)	Hematocrit (%)	Erythrocytes (x10^6/uL)	Platelets (x10^3/uL)	Reticulocytes (x10^6/uL)	Ery. Mean Corpuscular Volume (fL)
-38	8.7 (L)	30 (L)	4 (L)	423 (H)	0.066 (N)	76 (L)
1	8.9 (L)	29 (L)	3.9 (L)	445 (H)	0.043 (N)	75 (L)
19	9.6 (L)	33 (L)	4.1 (N)	556 (H)	0.055 (N)	79 (N)
33	8.9 (L)	31 (L)	4 (L)	435 (H)	0.092 (N)	79 (N)
* denotes the Maintenance study day. 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)
-38	9.01 (N)	6.46 (N)	1.88 (N)	0.46 (N)	0.06 (N)	0.16 (N)
1	8.91 (N)	6.02 (N)	1.96 (N)	0.6 (N)	0.05 (N)	0.28 (N)
19	13.61 (H)	8.7 (H)	4.03 (N)	0.73 (N)	0.05 (N)	0.09 (N)
33	13.09 (H)	9.05 (H)	3.46 (N)	0.51 (N)	0.02 (N)	0.05 (N)
* denotes the Maintenance study day. 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)
-38	Yes	9 (N)	14 (N)	74 (N)	<0.2 (L)	0.63 (N)
1	Yes	8 (N)	14 (N)	78 (N)	0.3 (N)	0.62 (N)
19	Yes	22 (N)	15 (N)	57 (N)	0.4 (N)	0.86 (N)
33	Yes	10 (N)	11 (N)	42 (N)	0.3 (N)	0.66 (N)
* denotes the Maintenance study day. 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)
-38	Yes	94.8 (N)	95 (N)	94 (N)	4.57 (N)
1	Yes	99 (N)	73 (N)	96 (N)	3.24 (N)
19	Yes	67.8 (L)	32 (N)	92 (N)	0.72 (N)
33	Yes	94.2 (N)	46 (N)	82 (N)	1.1 (N)
* denotes the Maintenance study day. 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	188 (N)	77 (N)	109 (N)	64 (N)
19	Yes	186 (N)	76 (N)	94 (N)	120 (N)
* denotes the Maintenance study day. H = High; L = Low; N = Normal.					

被験者識別番号：[redacted]

投与群：寛解導入試験－フィルゴチニブ 100 mg 群（コホート A）

治験薬の投与状況：寛解導入試験－有害事象により投与中止（Day 21）；寛解維持試験－不参加

ベースライン特性：本被験者は 6[redacted] 歳のアジア系女性であった。その他の特性として、民族はヒスパニック／ラテン系、インドからの参加であった。

汎血球減少症（Day 16～30）（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）（寛解導入試験）：
Day 16、Grade 4 の重篤な汎血球減少症が発現した。寛解導入治験薬に対する処置は投与中止であった。寛解維持治験薬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 30、Grade 4 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**
anxiety	Ongoing
colitis ulcerative	Ongoing
gastritis	Ongoing

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
mesalazine	ULCERATIVE COLITIS	ORAL	-697 days	Ongoing
amitriptyline;chlordiazepoxide	PROPHYLAXIS FOR ANXIETY	ORAL	-637 days	Ongoing
prednisolone	ULCERATIVE COLITIS	ORAL	-637 days	Ongoing
clonazepam;escitalopram	PROPHYLAXIS FOR ANXIETY	ORAL	21 days	Ongoing
colecalciferol	NUTRITIONAL SUPPLEMENT	ORAL	21 days	Ongoing
folic acid	ULCERATIVE COLITIS	ORAL	21 days	Ongoing
magnesium hydroxide;paraffin, liquid;sodium picosulfate	PROPHYLAXIS FOR CONSTIPATION	ORAL	21 days	Ongoing
plantago ovata husk	PROPHYLAXIS FOR CONSTIPATION	ORAL	21 days	Ongoing
povidone-iodine	ORAL ULCER	ORAL	21 days	Ongoing
sucralfate	PROPHYLAXIS FOR GASTRITIS	ORAL	21 days	Ongoing
sulfasalazine	ULCERATIVE COLITIS	ORAL	21 days	Ongoing
mesalazine	ULCERATIVE COLITIS	RECTAL	30 days	Ongoing
azathioprine	ULCERATIVE COLITIS	ORAL	-846 days	21 days
domperidone;ranitidine	PROPHYLAXIS FOR GASTRITIS	ORAL	-697 days	21 days
epoetin alfa	ANEMIA	SUBCUTANEOUS	22 days	22 days
calcium chloride;glucose;potassium chloride;sodium chloride;sodium lactate	FLUID SUPPLEMENT	INTRAVENOUS	21 days	25 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
ondansetron	PROPHYLAXIS FOR NAUSEA AND VOMITING	INTRAVENOUS	23 days	25 days
clonazepam;escitalopram oxalate	PROPHYLAXIS FOR ANXIETY	ORAL	21 days	26 days
granulocyte colony stimulating factor	PANCYTOPENIA	SUBCUTANEOUS	22 days	26 days
ceftazidime	BACTERIAL INFECTION	INTRAVENOUS	23 days	28 days
aceclofenac;rabeprazole	PROPHYLAXIS FOR PAIN	ORAL	21 days	29 days
pantoprazole	PROPHYLAXIS FOR GASTRITIS	INTRAVENOUS	21 days	29 days
epoetin alfa	ANEMIA	SUBCUTANEOUS	29 days	29 days

All Adverse Events							
Preferred Term	Onset Day	Resolution Day	Toxicity Grade	Causality	Action taken with Induction Drug	Action taken with Maintenance Drug	Action - Other
Pancytopenia	16	30	4	related	drug withdrawn	not applicable	medication required + other treatment required + permanent study discontinuation
* denotes the Maintenance study day.							

Hematology						
Study Day	Hemoglobin (g/dL)	Hematocrit (%)	Erythrocytes (x10^6/uL)	Platelets (x10^3/uL)	Reticulocytes (x10^6/uL)	Ery. Mean Corpuscular Volume (fL)
-23	11 (L)	37 (N)	3.2 (L)	422 (H)	0.054 (N)	115 (H)
1	10.2 (L)	36 (N)	3.1 (L)	408 (H)	0.119 (N)	114 (H)
16	7.3 (L)	25 (L)	2.3 (L)	51 (L)	0.014 (L)	110 (H)
22	4.9 (L)	16 (L)	1.5 (L)	55 (L)	0.008 (L)	103 (H)
30	11 (L)	34 (N)	3.6 (L)	76 (L)	0.078 (N)	94 (N)
36	10.4 (L)	35 (N)	3.5 (L)	654 (H)		101 (H)
* denotes the Maintenance study day. 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)
-23	6.99 (N)	4.23 (N)	2.35 (N)	0.33 (N)	0.05 (N)	0.04 (N)
1	5.91 (N)	4.66 (N)	0.82 (N)	0.32 (N)	0.03 (N)	0.08 (N)
16	1.59 (L)	0.33 (L)	1.13 (N)	0.03 (L)	0.02 (N)	0.07 (N)
22	1.14 (L)	0.03 (L)	0.98 (N)	0.01 (L)	0 (N)	0.11 (N)
30	9.93 (N)	7.37 (H)	1.6 (N)	0.51 (N)	0.18 (N)	0.27 (N)
36	8.11 (N)	6.64 (N)	1.17 (N)	0.15 (N)	0.07 (N)	0.08 (N)
* denotes the Maintenance study day. 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)
-23	Yes	11 (N)	31 (N)	66 (N)	0.3 (N)	0.61 (N)
1	Yes	9 (N)	13 (N)	69 (N)	0.4 (N)	0.64 (N)
16	Yes	6 (N)	9 (N)	58 (N)	0.4 (N)	0.63 (N)
30	Yes	8 (N)	9 (N)	72 (N)	0.4 (N)	0.48 (N)
36	Yes	8 (N)	10 (N)	81 (N)	0.3 (N)	0.59 (N)
* denotes the Maintenance study day. 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)
-23	Yes	64.2 (L)	525 (H)	97 (N)	6.35 (N)
1	Yes	60.6 (L)	<18 (L)	154 (H)	18.4 (H)
16	Yes	61.8 (L)	<18 (L)	133 (H)	165 (H)
30	Yes	82.2 (N)	18 (L)	100 (N)	90.5 (H)
36	Yes	66 (L)	20 (L)	126 (H)	
* denotes the Maintenance study day. 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)
-23	Yes	225 (N)	67 (N)	134 (H)	143 (N)
1	Yes	212 (N)	71 (N)	117 (N)	145 (N)
16	Yes	205 (N)	71 (N)	113 (N)	120 (N)
30	Yes	137 (L)	44 (N)	72 (N)	109 (N)
36	Yes	176 (L)	66 (N)	91 (N)	104 (N)
* denotes the Maintenance study day. H = High; L = Low; N = Normal.					

被験者識別番号：[redacted]

投与群：寛解導入試験－フィルゴチニブ 100 mg 群（コホート A）

治験薬の投与状況：寛解導入試験－完了；寛解維持試験－不参加

ベースライン特性：本被験者は 2[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、インドからの参加であった。

1 型過敏症（Day 38～40）（試験治療下の重篤な有害事象）（寛解導入試験）：
Day 38、Grade 3 の重篤な 1 型過敏症が発現した。寛解導入治験薬に対する処置は変更なし。寛解維持治験薬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 40、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**
azathioprine	ULCERATIVE COLITIS	ORAL	-275 days	Ongoing
mesalazine	ULCERATIVE COLITIS	ORAL	-275 days	Ongoing
folic acid	ULCERATIVE COLITIS	ORAL	-198 days	Ongoing
amitriptyline	ANXITEY	ORAL	40 days	Ongoing
dexamethasone	ULCERATIVE COLITIS	INTRAVENOUS	31 days	31 days
mesalazine	ULCERATIVE COLITIS	RECTAL	38 days	39 days
domperidone	GASTRITIS	ORAL	38 days	40 days
furosemide	ODEMA	ORAL	38 days	40 days
pantoprazole	GASTRITIS	ORAL	38 days	40 days
spironolactone	ODEMA	ORAL	38 days	40 days
tramadol	PAIN RELIF	ORAL	38 days	40 days
clobetasol propionate	TYPE 1 HYPERSENSITIVITY	TOPICAL	40 days	40 days
hydroxyzine	TYPE 1 HYPERSENSITIVITY	ORAL	38 days	42 days

All Adverse Events							
Preferred Term	**Onset Day**	**Resolution Day**	**Toxicity Grade**	**Causality**	**Action taken with Induction Drug**	**Action taken with Maintenance Drug**	**Action - Other**
Type I hypersensitivity	38	40	3	not related	dose not changed	not applicable	medication required
* denotes the Maintenance study day.							

Hematology						
Study Day	Hemoglobin (g/dL)	Hematocrit (%)	Erythrocytes (x10^6/uL)	Platelets (x10^3/uL)	Reticulocytes (x10^6/uL)	Ery. Mean Corpuscular Volume (fL)
-171	11.6 (N)	34 (N)	3.2 (L)	269 (N)	0.053 (N)	105 (H)
-27	10.6 (L)	34 (N)	3.4 (L)	273 (N)	0.064 (N)	103 (H)
-7	10.7 (L)	36 (N)	3.5 (L)	233 (N)	0.051 (N)	101 (H)
1	11 (L)	37 (N)	3.7 (L)	310 (N)	0.046 (N)	101 (H)
12	10.6 (L)	35 (N)	3.5 (L)	293 (N)	0.05 (N)	102 (H)
29	10.2 (L)	34 (N)	3.4 (L)	319 (N)	0.034 (N)	101 (H)
41	12.4 (N)	42 (N)	4.2 (N)	405 (H)	0.085 (N)	101 (H)
71	9.9 (L)	33 (L)	3.4 (L)	300 (N)	0.059 (N)	99 (H)
* denotes the Maintenance study day. 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)
-171	4.02 (N)	2.46 (N)	1.22 (N)	0.21 (N)	0.03 (N)	0.1 (N)
-27	3.5 (L)	1.45 (L)	1.71 (N)	0.28 (N)	0.02 (N)	0.04 (N)
-7	5.66 (N)	2.8 (N)	2 (N)	0.56 (N)	0.05 (N)	0.25 (N)
1	6.7 (N)	3.01 (N)	2.94 (N)	0.46 (N)	0.06 (N)	0.24 (N)
12	4.29 (N)	1.97 (N)	1.91 (N)	0.17 (N)	0.04 (N)	0.19 (N)
29	6.63 (N)	3.93 (N)	2.24 (N)	0.36 (N)	0.01 (N)	0.09 (N)
41	4.83 (N)	2.54 (N)	1.79 (N)	0.38 (N)	0.02 (N)	0.11 (N)
71	4.72 (N)	2.47 (N)	1.85 (N)	0.33 (N)	0.02 (N)	0.06 (N)
* denotes the Maintenance study day. 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)
-171	Yes	7 (N)	14 (N)	56 (N)	0.4 (N)	0.6 (N)
-27	Yes	13 (N)	18 (N)	54 (N)	0.2 (N)	0.6 (N)
1	Yes	9 (N)	15 (N)	69 (N)	0.2 (N)	0.66 (N)
12	Yes	7 (N)	15 (N)	53 (N)	0.2 (N)	0.59 (N)
29	Yes	7 (N)	10 (N)	44 (N)	0.4 (N)	0.61 (N)
41	Yes	15 (N)	16 (N)	46 (N)	0.4 (N)	0.71 (N)
71	Yes	7 (N)	12 (N)	48 (N)	0.2 (N)	0.62 (N)
* denotes the Maintenance study day. 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)
-171	Yes	148.8 (H)	82 (N)	100 (H)	1.05 (N)
-27	Yes	147.6 (H)	55 (N)	89 (N)	3.22 (N)
1	Yes	132.6 (H)	57 (N)	88 (N)	1 (N)
12	Yes	143.4 (H)	73 (N)	94 (N)	0.38 (N)
29	Yes	138 (H)	59 (N)	101 (H)	<0.20 (N)
41	Yes	118.2 (H)	29 (N)	107 (H)	1.79 (N)
71	Yes	135 (H)	83 (N)	101 (H)	1.22 (N)
* denotes the Maintenance study day. 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)
-171	Yes	172 (N)	41 (N)	106 (N)	134 (N)
1	Yes	149 (N)	32 (L)	114 (N)	116 (N)
71	Yes	189 (N)	44 (N)	112 (N)	192 (H)
* denotes the Maintenance study day. H = High; L = Low; N = Normal.					

被験者識別番号：[redacted]

投与群：寛解導入試験－プラセボ群（コホート B）

治験薬の投与状況：寛解導入試験－有害事象により投与中止（Day 23）；寛解維持試験－不参加

ベースライン特性：本被験者は 2[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。

急性膵炎（Day 24～36）（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）（寛解導入試験）：
Day 24、Grade 3 の重篤な急性膵炎が発現した。寛解導入治験薬に対する処置は投与中止であった。寛解維持治験薬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 36、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**
abdominal pain upper	Ongoing
colitis ulcerative	Ongoing
dysmenorrhoea	Ongoing
gastrooesophageal reflux disease	Ongoing
pancreatitis	-1745 days
headache	-15 days
vomiting	-15 days

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
clostridium butyricum	ULCERATIVE COLITIS	ORAL	-1107 days	Ongoing
golimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	31 days	Ongoing
budesonide	ULCERATIVE COLITIS	RECTAL	34 days	Ongoing
white soft paraffin	LUBRICATION AT THE TIME OF ENEMA	TOPICAL	35 days	Ongoing
esomeprazole magnesium	REFLUX ESOPHAGITIS	ORAL	46 days	Ongoing
adalimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	-1538 days	-1419 days
infliximab	ULCERATIVE COLITIS	INTRAVENOUS	-1400 days	-1135 days
vedolizumab	ULCERATIVE COLITIS	INTRAVENOUS	-1079 days	-139 days
berberine hydrochloride	ULCERATIVE COLITIS	ORAL	-1479 days	-33 days
rabeprazole sodium	REFLUX ESOPHAGITIS	ORAL	-1766 days	-21 days
prednisolone	ULCERATIVE COLITIS	ORAL	-33 days	-16 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
diazepam	COLONOSCOPY	INTRAVENOUS	-16 days	-16 days
glycerol	COLONOSCOPY	OTHER	-16 days	-16 days
hyoscine butylbromide	COLONOSCOPY	INTRAMUSCULAR	-16 days	-16 days
lidocaine	COLONOSCOPY	TOPICAL	-16 days	-16 days
paracetamol	HEADACHES	ORAL	-16 days	-16 days
pentazocine	COLONOSCOPY	INTRAVENOUS	-16 days	-16 days
sodium chloride	COLONOSCOPY	INTRAVENOUS	-16 days	-16 days
ibuprofen	HEADACHES	ORAL	-15 days	-15 days
esomeprazole magnesium	REFLUX ESOPHAGITIS	ORAL	-20 days	-3 days
calcium chloride dihydrate;potassium chloride;sodium acetate trihydrate;sodium chloride	COLONOSCOPY	INTRAVENOUS	-2 days	-2 days
diazepam	COLONOSCOPY	INTRAVENOUS	-2 days	-2 days
glycerol	COLONOSCOPY	OTHER	-2 days	-2 days
hyoscine butylbromide	COLONOSCOPY	INTRAMUSCULAR	-2 days	-2 days
lidocaine	COLONOSCOPY	TOPICAL	-2 days	-2 days
prednisolone	ULCERATIVE COLITIS	ORAL	-15 days	7 days
mesalazine	ULCERATIVE COLITIS	ORAL	-54 days	23 days
sucralfate	EPIGASTRIC PAIN	ORAL	14 days	23 days
paracetamol	HEADACHES	ORAL	26 days	26 days
paracetamol	EPIGASTRIC PAIN	ORAL	28 days	28 days
ibuprofen	EPIGASTRIC PAIN	ORAL	7 days	29 days
buprenorphine hydrochloride	PANCREATITIS ACUTE	INTRAVENOUS	28 days	29 days
mesalazine	ULCERATIVE COLITIS	ORAL	28 days	29 days
dexchlorpheniramine maleate	PANCREATITIS ACUTE	INTRAVENOUS	29 days	29 days
metoclopramide hydrochloride	PANCREATITIS ACUTE	INTRAVENOUS	29 days	29 days
glucose	PANCREATITIS ACUTE	INTRAVENOUS	24 days	31 days
glucose;sodium chloride	PANCREATITIS ACUTE	INTRAVENOUS	24 days	31 days
nafamostat mesilate	PANCREATITIS ACUTE	INTRAVENOUS DRIP	24 days	31 days
prednisolone	ULCERATIVE COLITIS	ORAL	8 days	38 days
vonoprazan fumarate	REFLUX ESOPHAGITIS	ORAL	-2 days	45 days
prednisolone	ULCERATIVE COLITIS	ORAL	39 days	45 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
dimeticone	ULCERATIVE COLITIS	ORAL	-1009 days	56 days
prednisolone	ULCERATIVE COLITIS	ORAL	46 days	56 days

All Adverse Events							
Preferred Term	Onset Day	Resolution Day	Toxicity Grade	Causality	Action taken with Induction Drug	Action taken with Maintenance Drug	Action - Other
Colitis ulcerative	3	45	2	not related	dose not changed	not applicable	none
Pancreatitis acute	24	36	3	not related	drug withdrawn	not applicable	medication required + permanent study discontinuation
Headache	26	26	2	not related	not applicable	not applicable	medication required
* denotes the Maintenance study day.							

Hematology						
Study Day	Hemoglobin (g/dL)	Hematocrit (%)	Erythrocytes (x10^6/uL)	Platelets (x10^3/uL)	Reticulocytes (x10^6/uL)	Ery. Mean Corpuscular Volume (fL)
-15	12.9 (N)	39 (N)	4.8 (N)	616 (H)	0.079 (N)	81 (N)
1	12.2 (N)	37 (N)	4.6 (N)	483 (H)	0.089 (N)	81 (N)
14	12.3 (N)	39 (N)	4.7 (N)	779 (H)	0.099 (N)	82 (N)
24	11 (L)	36 (N)	4.4 (N)	644 (H)	0.108 (N)	83 (N)
56	10.9 (L)	35 (N)	4.3 (N)	519 (H)	0.127 (H)	80 (N)
* denotes the Maintenance study day. 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)
-15	9.41 (N)	5.61 (N)	2.82 (N)	0.56 (N)	0.06 (N)	0.35 (N)
1	10.03 (N)	5.3 (N)	3.7 (N)	0.63 (N)	0.06 (N)	0.34 (N)
14	14.8 (H)	11.57 (H)	2.52 (N)	0.41 (N)	0.12 (N)	0.17 (N)
24	15.01 (H)	8.54 (H)	5 (H)	0.87 (N)	0.11 (N)	0.49 (N)
56	12.15 (H)	4.96 (N)	6.04 (H)	0.7 (N)	0.11 (N)	0.34 (N)
* denotes the Maintenance study day. 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)
-15	No	10 (N)	14 (N)	58 (N)	0.2 (N)	0.51 (N)
1	Yes	7 (N)	12 (N)	56 (N)	<0.2 (L)	0.42 (N)
14	No	8 (N)	10 (N)	58 (N)	<0.2 (L)	0.59 (N)
24	Yes	7 (N)	9 (N)	50 (N)	<0.2 (L)	0.48 (N)
56	No	9 (N)	10 (N)	44 (N)	0.2 (N)	0.5 (N)
* denotes the Maintenance study day. 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)
-15	No	151.8 (H)	50 (N)	88 (N)	6.11 (N)
1	Yes	181.8 (H)	41 (N)	89 (N)	15.2 (H)
14	No	127.8 (H)	30 (N)	106 (H)	33.4 (H)
24	Yes	156.6 (H)	24 (L)	94 (N)	31.2 (H)
56	No	152.4 (H)	32 (N)	87 (N)	3.65 (N)
* denotes the Maintenance study day. 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)
-15	No	223 (H)	80 (N)	144 (H)	87 (N)
1	Yes	200 (N)	75 (N)	118 (N)	88 (N)
24	Yes	199 (N)	69 (N)	118 (N)	128 (N)
* denotes the Maintenance study day. H = High; L = Low; N = Normal.					

被験者識別番号：[redacted]

投与群：寛解導入試験－フィルゴチニブ 100 mg 群（コホート A）；寛解維持試験－フィルゴチニブ 100 mg 群

治験薬の投与状況：寛解導入試験－完了；寛解維持試験－有害事象により投与中止（Day 93*）

ベースライン特性：本被験者は 6[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。

結腸癌（Day 71～159）（試験治療下の注目すべき有害事象［TE-AEI］）（寛解導入試験）：
Day 71、Grade 2 の非重篤な結腸癌が発現した。寛解導入治験薬に対する処置は変更なし。寛解維持治験薬に対する処置は変更なし。本事象は治験薬と関連なしと判断された。Day 159、Grade 2 の本事象は回復した。

結腸癌（Day 82*～115*）（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）（寛解維持試験）：
Day 82*、Grade 3 の重篤な結腸癌が発現した。寛解導入治験薬に対する処置は非該当であった。寛解維持治験薬に対する処置は投与中止であった。本事象は治験薬と関連なしと判断された。Day 115*、Grade 3 の本事象は回復した。

その他の関連情報：2018 年 2 月 21 日（Week 10）に行われた結腸内視鏡検査により、S 状結腸に 2 cm の隆起が認められ、生検が行われた。病理報告書によると、高異型度管状腺腫が認められた。被験者は、2018 年 5 月 21 日*に内視鏡的粘膜下層剥離術を受けるため入院した。術中に non-lifting sign が認められ、悪性腫瘍の懸念があると診断された。2018 年 6 月 21 日*に結腸全摘術及び回腸嚢肛門管吻合術が実施された。外科病理報告書によると、S 状結腸に高分化型管状腺癌が認められた。寛解導入試験のスクリーニング時に、試験への適格性を判定するための軟性 S 状結腸鏡検査が実施されていた。治験責任医師により、S 状結腸の病変は便の下に隠れていた可能性が高く、スクリーニング時の内視鏡検査では確認できなかったとされた。
*寛解維持試験における study day

Medical History	
Medical History	**Resolution**
chronic gastritis	Ongoing
colitis ulcerative	Ongoing
intervertebral disc protrusion	Ongoing
migraine	Ongoing
proctalgia	Ongoing
spinal stenosis	Ongoing

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
rabeprazole sodium	CHRONIC GASTRITIS	ORAL	-1181 days	Ongoing
butyric acid	ULCERATIVE COLITIS	ORAL	-1027 days	Ongoing
calcium chloride dihydrate;potassium chloride;sodium chloride;sodium lactate	LARGE INTESTINE CARCINOMA	INTRAVENOUS DRIP	193 days	Ongoing
enoxaparin sodium	LARGE INTESTINE CARCINOMA	SUBCUTANEOUS	193 days	Ongoing
12662302001:acetylcysteine;alanine;arginine;ascorbic acid;aspartic acid;biotin;calcium chloride dihydrate;cyanocobalamin;folic acid;glucose;glutamic acid;glycine;histidine;isoleucine;leucine;lysine hy	LARGE INTESTINE CARCINOMA	INTRAVENOUS DRIP	194 days	Ongoing
mesalazine	ULCERATIVE COLITIS	RECTAL	-1531 days	-1504 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
betamethasone	ULCERATIVE COLITIS	RECTAL	-1223 days	-1181 days
azathioprine	ULCERATIVE COLITIS	ORAL	-775 days	-733 days
prednisolone sodium phosphate	ULCERATIVE COLITIS	RECTAL	-723 days	-706 days
mercaptopurine	ULCERATIVE COLITIS	ORAL	-705 days	-698 days
prednisolone	ULCERATIVE COLITIS	ORAL	-111 days	-20 days
prednisolone	ULCERATIVE COLITIS	ORAL	-19 days	-15 days
escherichia coli	ANAL PAIN	TOPICAL	-14 days	-12 days
glucagon	ENDOSCOPY	INTRAVENOUS	-7 days	-7 days
lidocaine	ENDOSCOPY	TOPICAL	-7 days	-7 days
thrombin	ENDOSCOPY	OTHER	-7 days	-7 days
prednisolone	ULCERATIVE COLITIS	ORAL	-14 days	14 days
glucagon	ENDOSCOPY	INTRAVENOUS	71 days	71 days
glycerol	ENDOSCOPY	RECTAL	71 days	71 days
lidocaine	ENDOSCOPY	TOPICAL	71 days	71 days
sodium chloride	ENDOSCOPY	INTRAVENOUS DRIP	71 days	71 days
thrombin	ENDOSCOPY	OTHER	71 days	71 days
ascorbic acid;macrogol 3350;potassium chloride;sodium ascorbate;sodium chloride;sodium sulfate	LARGE INTESTINE CARCINOMA	ORAL	86 days	86 days
glucagon	LARGE INTESTINE CARCINOMA	INTRAVENOUS	86 days	86 days
pethidine hydrochloride	LARGE INTESTINE CARCINOMA	INTRAVENOUS	86 days	86 days
sodium chloride	LARGE INTESTINE CARCINOMA	INTRAVENOUS DRIP	86 days	86 days
prednisolone	ULCERATIVE COLITIS	ORAL	15 days	94 days
prednisolone	ULCERATIVE COLITIS	ORAL	95 days	101 days
prednisolone	ULCERATIVE COLITIS	ORAL	102 days	108 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
prednisolone	ULCERATIVE COLITIS	ORAL	109 days	115 days
prednisolone	ULCERATIVE COLITIS	ORAL	116 days	122 days
prednisolone	ULCERATIVE COLITIS	ORAL	123 days	123 days
sennoside a+b calcium	LARGE INTESTINE CARCINOMA	ORAL	159 days	159 days
loxoprofen sodium dihydrate	MIGRAINE HEADACHES	ORAL	159 days	160 days
ascorbic acid;macrogol 3350;potassium chloride;sodium ascorbate;sodium chloride;sodium sulfate	LARGE INTESTINE CARCINOMA	ORAL	160 days	160 days
calcium chloride dihydrate;potassium chloride;sodium chloride;sodium lactate	LARGE INTESTINE CARCINOMA	INTRAVENOUS DRIP	160 days	160 days
diazepam	LARGE INTESTINE CARCINOMA	INTRAVENOUS	160 days	160 days
epinephrine	LARGE INTESTINE CARCINOMA	OTHER	160 days	160 days
fructose;glycerol	LARGE INTESTINE CARCINOMA	OTHER	160 days	160 days
glucagon	LARGE INTESTINE CARCINOMA	INTRAVENOUS	160 days	160 days
hyaluronate sodium	LARGE INTESTINE CARCINOMA	OTHER	160 days	160 days
lidocaine	LARGE INTESTINE CARCINOMA	TOPICAL	160 days	160 days
pethidine hydrochloride	LARGE INTESTINE CARCINOMA	INTRAVENOUS	160 days	160 days
pronase	LARGE INTESTINE CARCINOMA	ORAL	160 days	160 days
silicon dioxide	LARGE INTESTINE CARCINOMA	ORAL	160 days	160 days
sodium alginate	LARGE INTESTINE CARCINOMA	INTRAVENOUS	160 days	160 days
sodium bicarbonate	LARGE INTESTINE CARCINOMA	ORAL	160 days	160 days
cefotiam hydrochloride	LARGE INTESTINE CARCINOMA	INTRAVENOUS	160 days	161 days
oxygen	LARGE INTESTINE CARCINOMA	NASAL	160 days	161 days
calcium chloride;potassium chloride;sodium chloride;sodium lactate;sorbitol	LARGE INTESTINE CARCINOMA	INTRAVENOUS DRIP	160 days	162 days
carbazochrome sodium sulfonate	LARGE INTESTINE CARCINOMA	INTRAVENOUS	160 days	162 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	LARGE INTESTINE CARCINOMA	INTRAVENOUS DRIP	161 days	162 days
risedronate sodium	PREVENTION OF OSTEOPOROSIS	ORAL	-1069 days	171 days
mesalazine	ULCERATIVE COLITIS	ORAL	-370 days	189 days
budesonide	ULCERATIVE COLITIS	RECTAL	176 days	189 days
white soft paraffin	SMOOTH USE OF RECTABUL	TOPICAL	183 days	189 days
magnesium citrate	LARGE INTESTINE CARCINOMA	ORAL	190 days	190 days
sennoside a+b calcium	LARGE INTESTINE CARCINOMA	ORAL	190 days	190 days
sodium picosulfate	LARGE INTESTINE CARCINOMA	ORAL	190 days	190 days
calcium chloride dihydrate;magnesium chloride hexahydrate;potassium chloride;sodium bicarbonate;sodium chloride;sodium citrate dihydrate	LARGE INTESTINE CARCINOMA	INTRAVENOUS DRIP	191 days	191 days
calcium chloride;potassium chloride;sodium acetate	LARGE INTESTINE CARCINOMA	INTRAVENOUS DRIP	191 days	191 days
dopamine hydrochloride	LARGE INTESTINE CARCINOMA	INTRAVENOUS	191 days	191 days
ephedrine hydrochloride	LARGE INTESTINE CARCINOMA	INTRAVENOUS	191 days	191 days
flurbiprofen axetil	LARGE INTESTINE CARCINOMA	INTRAVENOUS	191 days	191 days
heparin sodium	LARGE INTESTINE CARCINOMA	INTRAVENOUS	191 days	191 days
hetastarch	LARGE INTESTINE CARCINOMA	INTRAVENOUS DRIP	191 days	191 days
lidocaine	LARGE INTESTINE CARCINOMA	TOPICAL	191 days	191 days
phenylephrine hydrochloride	LARGE INTESTINE CARCINOMA	INTRAVENOUS	191 days	191 days
propofol	LARGE INTESTINE CARCINOMA	INTRAVENOUS	191 days	191 days
remifentanil hydrochloride	LARGE INTESTINE CARCINOMA	INTRAVENOUS	191 days	191 days
rocuronium bromide	LARGE INTESTINE CARCINOMA	INTRAVENOUS	191 days	191 days
ropivacaine hydrochloride monohydrate	LARGE INTESTINE CARCINOMA	EPIDURAL	191 days	191 days
sugammadex sodium	LARGE INTESTINE CARCINOMA	INTRAVENOUS	191 days	191 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
cefmetazole sodium	LARGE INTESTINE CARCINOMA	INTRAVENOUS	191 days	192 days
fentanyl citrate	LARGE INTESTINE CARCINOMA	INTRAVENOUS	191 days	192 days
sodium chloride	LARGE INTESTINE CARCINOMA	INTRAVENOUS	191 days	192 days
amino acids nos;electrolytes nos;glucose;thiamine hydrochloride	LARGE INTESTINE CARCINOMA	INTRAVENOUS DRIP	191 days	193 days
oxygen	LARGE INTESTINE CARCINOMA	NASAL	191 days	193 days
paracetamol	LARGE INTESTINE CARCINOMA	INTRAVENOUS	191 days	193 days
calcium chloride dihydrate;glucose;potassium chloride;sodium chloride;sodium lactate	LARGE INTESTINE CARCINOMA	INTRAVENOUS DRIP	192 days	193 days
glucose;potassium chloride;sodium chloride;sodium lactate	LARGE INTESTINE CARCINOMA	INTRAVENOUS DRIP	192 days	193 days
haloperidol	INSOMNIA	INTRAVENOUS	193 days	193 days
sodium chloride	INSOMNIA	INTRAVENOUS	193 days	193 days
bromhexine hydrochloride	LARGE INTESTINE CARCINOMA	RESPIRATORY (INHALATION)	191 days	195 days
salbutamol sulfate	LARGE INTESTINE CARCINOMA	RESPIRATORY (INHALATION)	191 days	195 days
sodium chloride	LARGE INTESTINE CARCINOMA	RESPIRATORY (INHALATION)	191 days	195 days
metoclopramide hydrochloride	ILEUS PARALYTIC	INTRAVENOUS	192 days	195 days
zolpidem tartrate	INSOMNIA	ORAL	194 days	196 days
paracetamol	WOUND PAIN	ORAL	194 days	198 days

All Adverse Events							
Preferred Term	Onset Day	Resolution Day	Toxicity Grade	Causality	Action taken with Induction Drug	Action taken with Maintenance Drug	Action - Other
Muscle spasms	1	136	1	not related	dose not changed	dose not changed	none
Colon cancer	71	159	2	not related	dose not changed	dose not changed	medication required
Colon cancer	82*	115*	3	not related	not applicable	drug withdrawn	other treatment required + permanent study discontinuation
Nausea	83*	83*	1	not related	not applicable	dose not changed	none
Vomiting	83*	83*	1	not related	not applicable	dose not changed	none
Arthralgia	114*	116*	1	not related	not applicable	not applicable	none
Wound complication	114*	121*	2	not related	not applicable	not applicable	medication required
Ileus paralytic	115*	125*	2	not related	not applicable	not applicable	other treatment required
Insomnia	116*	120*	2	not related	not applicable	not applicable	medication required
* denotes the Maintenance study day.							

Hematology						
Study Day	Hemoglobin (g/dL)	Hematocrit (%)	Erythrocytes (x10^6/uL)	Platelets (x10^3/uL)	Reticulocytes (x10^6/uL)	Ery. Mean Corpuscular Volume (fL)
-16	11.8 (L)	37 (N)	4.4 (N)	393 (N)	0.089 (N)	84 (N)
1	12 (L)	37 (N)	4.5 (N)	318 (N)	0.088 (N)	82 (N)
15	11.5 (L)	36 (L)	4.4 (N)	326 (N)	0.087 (N)	82 (N)
29	11 (L)	35 (L)	4.3 (N)	375 (N)	0.078 (N)	81 (N)
43	11.5 (L)	37 (N)	4.6 (N)	367 (N)	0.078 (N)	81 (N)
71	11.7 (L)	38 (N)	4.9 (N)	286 (N)	0.097 (N)	77 (L)
-7*	11.7 (L)	38 (N)	4.9 (N)	286 (N)	0.097 (N)	77 (L)
17*	11.9 (L)	38 (N)	4.8 (N)	275 (N)	0.114 (N)	78 (L)
59*	11.4 (L)	37 (N)	4.7 (N)	274 (N)	0.057 (N)	79 (L)
99*	11.5 (L)	36 (L)	4.6 (N)	281 (N)	0.064 (N)	77 (L)
122*	11.1 (L)	35 (L)	4.4 (N)	324 (N)	0.094 (N)	79 (L)

* denotes the Maintenance study day.
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)
-16	11.31 (H)	9.32 (H)	1.65 (N)	0.28 (N)	0.02 (N)	0.02 (N)
1	8.99 (N)	6.71 (N)	2 (N)	0.22 (N)	0.04 (N)	0.02 (N)
15	7.92 (N)	5.55 (N)	2.01 (N)	0.31 (N)	0.03 (N)	0.02 (N)
29	9.38 (N)	6.86 (N)	2.11 (N)	0.37 (N)	0.02 (N)	0.02 (N)
43	6.96 (N)	4.93 (N)	1.79 (N)	0.2 (N)	0.03 (N)	0.02 (N)
71	9.34 (N)	7.55 (H)	1.49 (N)	0.26 (N)	0.02 (N)	0.02 (N)
-7*	9.34 (N)	7.55 (H)	1.49 (N)	0.26 (N)	0.02 (N)	0.02 (N)
17*	11 (H)	8.31 (H)	2.04 (N)	0.52 (N)	0.03 (N)	0.09 (N)
59*	6.44 (N)	3.26 (N)	2.59 (N)	0.36 (N)	0.02 (N)	0.2 (N)
99*	8.15 (N)	4.56 (N)	2.15 (N)	0.45 (N)	0.03 (N)	0.95 (H)
122*	7.07 (N)	3.54 (N)	1.63 (N)	0.28 (N)	0.07 (N)	1.56 (H)

* denotes the Maintenance study day.
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)
-16	Yes	17 (N)	21 (N)	70 (N)	0.2 (N)	0.68 (N)
1	No	20 (N)	26 (N)	64 (N)	0.3 (N)	0.71 (N)
15	Yes	25 (N)	28 (N)	64 (N)	<0.2 (L)	0.71 (N)
29	Yes	18 (N)	20 (N)	65 (N)	0.2 (N)	0.66 (N)
43	No	17 (N)	17 (N)	57 (N)	0.2 (N)	0.68 (N)
71	Yes	15 (N)	18 (N)	65 (N)	0.4 (N)	0.77 (N)
-7*	Yes	15 (N)	18 (N)	65 (N)	0.4 (N)	0.77 (N)
17*	No	18 (N)	16 (N)	64 (N)	0.2 (N)	0.77 (N)
59*	No	12 (N)	16 (N)	65 (N)	0.2 (N)	0.76 (N)
99*	Yes	11 (N)	14 (N)	70 (N)	0.3 (N)	0.78 (N)
122*	Yes	59 (H)	29 (N)	87 (N)	0.6 (N)	0.61 (N)
* denotes the Maintenance study day. 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)
-16	Yes	105 (N)	190 (N)	101 (H)	3.97 (N)
1	No	101.4 (N)	360 (H)	89 (N)	1.57 (N)
15	Yes	105.6 (N)	291 (N)	92 (N)	2.41 (N)
29	Yes	114.6 (N)	260 (N)	98 (N)	4.95 (N)
43	No	110.4 (N)	122 (N)	93 (N)	7.53 (N)
71	Yes	96.6 (N)	176 (N)	94 (N)	1.85 (N)
-7*	Yes	96.6 (N)	176 (N)	94 (N)	1.85 (N)
17*	No	97.8 (N)	153 (N)	103 (H)	2.77 (N)
59*	No	100.8 (N)	220 (N)	98 (N)	1.01 (N)
99*	Yes	96 (N)	103 (N)	87 (N)	3.71 (N)
122*	Yes	109.8 (N)	38 (L)	86 (N)	10.3 (H)
* denotes the Maintenance study day. 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)
-16	Yes	172 (L)	51 (N)	108 (N)	120 (N)
1	No	210 (N)	90 (H)	123 (N)	71 (N)
15	Yes	196 (N)	82 (H)	103 (N)	115 (N)
29	Yes	198 (N)	70 (N)	116 (N)	116 (N)
43	No	162 (L)	55 (N)	96 (N)	104 (N)
71	Yes	200 (N)	67 (N)	132 (H)	85 (N)
-7*	Yes	200 (N)	67 (N)	132 (H)	85 (N)
99*	Yes	171 (L)	40 (N)	118 (N)	112 (N)
* denotes the Maintenance study day. H = High; L = Low; N = Normal.					

被験者識別番号：[redacted]

投与群：寛解導入試験－フィルゴチニブ 100 mg 群（コホート B）；寛解維持試験－フィルゴチニブ 100 mg 群

治験薬の投与状況：寛解導入試験－完了；寛解維持試験－完了

ベースライン特性：本被験者は 1[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、ドイツからの参加であった。

胃炎（Day 27～37）（試験治療下の重篤な有害事象）（寛解導入試験）：
Day 27、Grade 2 の重篤な胃炎が発現した。寛解導入治験薬に対する処置は投与中断であった。寛解維持治験薬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 37、Grade 2 の本事象は回復した。

急性中耳炎（Day 253*～259*）（試験治療下の注目すべき有害事象［TE-AEI］）（寛解維持試験）：
Day 253*、Grade 2 の非重篤な急性中耳炎が発現した。寛解導入治験薬に対する処置は非該当であった。寛解維持治験薬に対する処置は変更なし。本事象は治験薬と関連なしと判断された。Day 259*、Grade 2 の本事象は回復した。

レンサ球菌性咽頭炎（Day 253*～259*）（TE-AEI）（寛解維持試験）：
Day 253*、Grade 2 の非重篤なレンサ球菌性咽頭炎が発現した。寛解導入治験薬に対する処置は非該当であった。寛解維持治験薬に対する処置は変更なし。本事象は治験薬と関連なしと判断された。Day 259*、Grade 2 の本事象は回復した。

その他の関連情報：特になし。
*寛解維持試験における study day

Medical History	
Medical History	**Resolution**
blood pressure increased	Ongoing
colitis ulcerative	Ongoing
vitamin d deficiency	Ongoing
acne	1 day

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
azathioprine	ULCERATIVE COLITIS	ORAL	About -2429 days	Ongoing
colecalciferol	VITAMIN D DEFICIENCY	ORAL	-228 days	Ongoing
mesalazine	ULCERATIVE COLITIS	ORAL	234 days	Ongoing
infliximab	ULCERATIVE COLITIS	INTRAVENOUS	About -329 days	-186 days
hydrocortisone acetate	ULCERATIVE COLITIS	RECTAL	-228 days	-62 days
prednisolone	ULCERATIVE COLITIS	ORAL	About -237 days	-28 days
macrogol 3350;potassium chloride;sodium bicarbonate;sodium chloride;sodium sulfate anhydrous	PREPARATION FOR ENDOSCOPY	ORAL	-6 days	-6 days
propofol	COLONOSCOPY PREMEDICATION	INTRAVENOUS	-5 days	-5 days
prednisolone	ULCERATIVE COLITIS	ORAL	-27 days	13 days
metoclopramide	NAUSEA AND VOMITING	ORAL	25 days	27 days
dimenhydrinate	NAUSEA	INTRAVENOUS	27 days	27 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
pantoprazole	DUODENITIS AND GASTRITIS	ORAL	32 days	68 days
macrogol 3350;potassium chloride;sodium bicarbonate;sodium chloride;sodium sulfate anhydrous	PREPARATION FOR ENDOSCOPY	ORAL	72 days	72 days
propofol	COLONOSCOPY PREMEDICATION	INTRAVENOUS	73 days	73 days
prednisolone	ULCERATIVE COLITIS	ORAL	14 days	144 days
prednisolone	ULCERATIVE COLITIS	ORAL	145 days	151 days
prednisolone	ULCERATIVE COLITIS	ORAL	152 days	158 days
prednisolone	ULCERATIVE COLITIS	ORAL	159 days	176 days
mesalazine	ULCERATIVE COLITIS	ORAL	-186 days	233 days
prednisolone	ULCERATIVE COLITIS	ORAL	226 days	247 days
penicillin nos	STREP THROAT PHARYNGITIS	ORAL	335 days	339 days
macrogol 3350;potassium chloride;sodium bicarbonate;sodium chloride;sodium sulfate anhydrous	PREPARATION FOR ENDOSCOPY	ORAL	406 days	406 days
propofol	COLONOSCOPY	INTRAVENOUS	407 days	407 days

All Adverse Events							
Preferred Term	Onset Day	Resolution Day	Toxicity Grade	Causality	Action taken with Induction Drug	Action taken with Maintenance Drug	Action - Other
Colitis	13	27	1	not related	dose not changed	not applicable	none
Nausea	20	27	2	not related	dose not changed	not applicable	medication required
Vomiting	20	27	2	not related	dose not changed	not applicable	medication required
Gastritis	27	37	2	not related	drug interrupted	not applicable	medication required
Lymphopenia	64*	98*	1	related	not applicable	dose not changed	none
Colitis	138*	166*	2	not related	not applicable	dose not changed	medication required
Otitis media acute	253*	259*	2	not related	not applicable	dose not changed	none
Pharyngitis streptococcal	253*	259*	2	not related	not applicable	dose not changed	medication required
* denotes the Maintenance study day.							

Hematology						
Study Day	Hemoglobin (g/dL)	Hematocrit (%)	Erythrocytes (x10^6/uL)	Platelets (x10^3/uL)	Reticulocytes (x10^6/uL)	Ery. Mean Corpuscular Volume (fL)
-62	13.7 (N)	46 (N)	4.9 (N)	378 (N)	0.103 (N)	93 (N)
-20	13.7 (N)	45 (N)	4.8 (N)	303 (N)	0.073 (N)	93 (N)
1	14.2 (N)	43 (N)	4.9 (N)	332 (N)	0.075 (N)	86 (N)
15	13.9 (N)	43 (N)	4.8 (N)	373 (N)	0.058 (N)	89 (N)
25	15.2 (N)	47 (N)	5.3 (N)	467 (H)	0.089 (N)	89 (N)
30	12.9 (N)	40 (N)	4.5 (N)	420 (H)	0.069 (N)	88 (N)
45	13.6 (N)	41 (N)	4.6 (N)	495 (H)	0.091 (N)	89 (N)
73	12.4 (L)	38 (L)	4.1 (L)	383 (N)	0.067 (N)	94 (N)
-9*	12.4 (L)	38 (L)	4.1 (L)	383 (N)	0.067 (N)	94 (N)
21*	12.1 (L)	38 (L)	4 (L)	390 (N)	0.09 (N)	96 (N)
63*	14 (N)	44 (N)	4.7 (N)	324 (N)	0.048 (N)	93 (N)
98*	13 (N)	40 (N)	4.3 (L)	302 (N)	0.049 (N)	94 (N)
152*	14 (N)	41 (N)	4.5 (N)	399 (N)	0.079 (N)	91 (N)
215*	14.7 (N)	47 (N)	4.7 (N)	310 (N)	0.059 (N)	100 (H)
271*	14.6 (N)	45 (N)	4.6 (N)	301 (N)	0.077 (N)	96 (N)
* denotes the Maintenance study day. 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)
-62	13.57 (H)					
-20	12.1 (H)	10.87 (H)	0.85 (L)	0.29 (N)	0.05 (N)	0.04 (N)
1	6.8 (N)	4.86 (N)	1.31 (N)	0.42 (N)	0.03 (N)	0.18 (N)
15	7.22 (N)	5.19 (N)	1.07 (N)	0.58 (N)	0.05 (N)	0.32 (N)
25	12.53 (H)	11.18 (H)	0.6 (L)	0.7 (N)	0.02 (N)	0.03 (N)
30	16.06 (H)	13.63 (H)	0.5 (L)	1.02 (H)	0.05 (N)	0.86 (H)
45	13.73 (H)	11.36 (H)	0.66 (L)	0.72 (N)	0.06 (N)	0.93 (H)
73	7.82 (N)	5.65 (N)	1.43 (N)	0.58 (N)	0.02 (N)	0.12 (N)
-9*	7.82 (N)	5.65 (N)	1.43 (N)	0.58 (N)	0.02 (N)	0.12 (N)
21*	6.52 (N)	4.53 (N)	1.52 (N)	0.34 (N)	0.03 (N)	0.1 (N)
63*	4.75 (N)	3.98 (N)	0.55 (L)	0.2 (N)	0.01 (N)	0.01 (N)
98*	4.62 (N)	3.32 (N)	0.91 (N)	0.34 (N)	0.01 (N)	0.04 (N)
152*	11.15 (H)	9.75 (H)	0.58 (L)	0.46 (N)	0.15 (N)	0.21 (N)
215*	4.44 (N)	3.02 (N)	1.03 (N)	0.32 (N)	0.06 (N)	0.02 (N)
271*	6.16 (N)	4.44 (N)	0.97 (N)	0.68 (N)	0.02 (N)	0.06 (N)

* denotes the Maintenance study day.
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)
-62	No	19 (N)	15 (N)	57 (N)	0.3 (N)	0.74 (N)
-20	No	12 (N)	15 (N)	60 (N)	0.2 (N)	0.67 (N)
1	No	12 (N)	14 (N)	75 (N)	0.3 (N)	0.81 (N)
15	No	9 (N)	12 (N)	73 (N)	0.4 (N)	0.83 (N)
25	No	17 (N)	16 (N)	77 (N)	0.4 (N)	0.74 (N)
30	No	10 (N)	14 (N)	63 (N)	0.5 (N)	0.63 (N)
45	No	35 (N)	20 (N)	81 (N)	0.4 (N)	0.79 (N)
73	Yes	9 (N)	12 (N)	73 (N)	0.8 (N)	0.85 (N)
-9*	Yes	9 (N)	12 (N)	73 (N)	0.8 (N)	0.85 (N)
21*	No	10 (N)	23 (N)	63 (N)	0.6 (N)	0.74 (N)
63*	No	18 (N)	19 (N)	110 (N)	0.3 (N)	0.75 (N)
152*	No	10 (N)	16 (N)	97 (N)	0.5 (N)	0.75 (N)
215*	No	15 (N)	19 (N)	119 (N)	0.4 (N)	0.76 (N)
271*	No	11 (N)	15 (N)	101 (N)	0.4 (N)	0.74 (N)
326*	Yes	16 (N)	22 (N)	77 (N)	1.3 (H)	0.67 (N)

* denotes the Maintenance study day.
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)
-62	No	155.4 (H)	27 (L)	92 (N)	1.28 (N)
-20	No	184.2 (H)	67 (N)	90 (N)	0.72 (N)
1	No	147.6 (H)	68 (N)	105 (H)	2.11 (N)
15	No	144.6 (H)	63 (N)	92 (N)	16 (H)
25	No	153.6 (H)	40 (N)	114 (H)	37 (H)
30	No	172.2 (H)	29 (L)	71 (N)	27.1 (H)
45	No	138.6 (H)	34 (L)	84 (N)	24.2 (H)
73	Yes	130.8 (H)	47 (N)	79 (N)	2.94 (N)
-9*	Yes	130.8 (H)	47 (N)	79 (N)	2.94 (N)
21*	No	155.4 (H)	473 (H)	96 (N)	0.76 (N)
63*	No	159 (H)	74 (N)	110 (H)	<0.20 (N)
152*	No	165 (H)	75 (N)	105 (H)	12.2 (H)
215*	No	165 (H)	161 (N)	82 (N)	0.67 (N)
271*	No	167.4 (H)	133 (N)	87 (N)	1.18 (N)
326*	Yes	183 (H)	286 (N)	59 (L)	1.51 (N)
* denotes the Maintenance study day. 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	No	162 (N)	41 (N)	99 (N)	128 (N)
73	Yes	166 (N)	44 (N)	109 (N)	96 (N)
-9*	Yes	166 (N)	44 (N)	109 (N)	96 (N)
326*	Yes	197 (N)	58 (N)	130 (H)	100 (N)
* denotes the Maintenance study day. H = High; L = Low; N = Normal.					

被験者識別番号：[redacted]

投与群：寛解導入試験－フィルゴチニブ 100 mg 群（コホート A）；寛解維持試験－プラセボ群

治験薬の投与状況：寛解導入試験－完了；寛解維持試験－治験実施計画書に規定された疾患の悪化により投与中止（Day 124*）

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、ポルトガルからの参加であった。

潰瘍性大腸炎（Day 124*～131*）（試験治療下の重篤な有害事象）（寛解維持試験）：
Day 124*、Grade 4 の重篤な潰瘍性大腸炎が発現した。寛解導入治験薬に対する処置は非該当であった。寛解維持治験薬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 131*、Grade 4 の本事象は回復した。

その他の関連情報：特になし。
*寛解維持試験における study day

Medical History	
Medical History	**Resolution**
arthropathy	Ongoing
colitis ulcerative	Ongoing
depression	Ongoing
dyslipidaemia	Ongoing
haemorrhoids	Ongoing
type 2 diabetes mellitus	Ongoing
intervertebral disc protrusion	-1428 days
anal fistula repair	About -98 days
latent tuberculosis	-26 days
abdominal pain	209 days

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
amitriptyline	DEPRESSIVE DISORDERS	ORAL	About -2137 days	Ongoing
gabapentin	OSTEOARTICULAR DISEASE	ORAL	About -1893 days	Ongoing
sertraline	DEPRESSIVE DISORDERS	ORAL	About -1072 days	Ongoing
lorazepam	DEPRESSIVE DISORDERS	ORAL	About -615 days	Ongoing
hydrocortisone	ULCERATIVE COLITIS	INTRAVENOUS	-86 days	-85 days
prednisolone	ULCERATIVE COLITIS	ORAL	-82 days	-75 days
prednisolone	ULCERATIVE COLITIS	ORAL	-74 days	-68 days
influenza vaccine inact split virion 4v	FLU PROPHYLAXIS	INTRAMUSCULAR	-65 days	-65 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
prednisolone	ULCERATIVE COLITIS	ORAL	-67 days	-61 days
prednisolone	ULCERATIVE COLITIS	ORAL	-60 days	-54 days
prednisolone	ULCERATIVE COLITIS	ORAL	-53 days	-47 days
prednisolone	ULCERATIVE COLITIS	ORAL	-46 days	-40 days
hepatitis b vaccine rhbsag (yeast)	HEPATITIS B VACCINE	INTRAMUSCULAR	About -67 days	About -37 days
pneumococcal vaccine conj 7v (crm197)	PNEUMONIA PROPHYLAXIS VACCINE	INTRAMUSCULAR	About -67 days	About -37 days
prednisolone	ULCERATIVE COLITIS	ORAL	-39 days	-33 days
prednisolone	ULCERATIVE COLITIS	ORAL	-32 days	-26 days
hepatitis b vaccine rhbsag (yeast)	HEPATITIS B VACCINE	INTRAMUSCULAR	About -36 days	About -6 days
paracetamol	RIGHT HYPOCHONDRIUM PAIN	ORAL	12 days	18 days
isoniazid	PROPHYLAXIS OF TUBERCULOSIS	ORAL	About -220 days	73 days
mesalazine	ULCERATIVE COLITIS	ORAL	About -250 days	86 days
prednisolone	ULCERATIVE COLITIS	ORAL	141 days	166 days
prednisolone	ULCERATIVE COLITIS	ORAL	167 days	173 days
prednisolone	ULCERATIVE COLITIS	ORAL	174 days	180 days
prednisolone	ULCERATIVE COLITIS	ORAL	181 days	187 days
lidocaine	DIGESTIVE ENDOSCOPY ANESTHESIA	TOPICAL	188 days	188 days
prednisolone	ULCERATIVE COLITIS	ORAL	188 days	188 days
acetylsalicylic acid	PROPHYLAXIS OF CARDIOVASCULAR EVENTS	ORAL	About -980 days	201 days
atorvastatin	DYSLIPIDEMIA	ORAL	About -766 days	201 days
azathioprine	ULCERATIVE COLITIS	ORAL	About -189 days	201 days
pantoprazole	PROPHYLAXIS OF GASTRIC DISORDERS	ORAL	-89 days	201 days
metformin	TYPE 2 DIABETES MELLITUS	ORAL	-82 days	201 days
mesalazine	ULCERATIVE COLITIS	ORAL	87 days	201 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
tapentadol	AE WORSENING OF OSTEOARTICULAR PAIN	ORAL	114 days	201 days
tetracaine hydrochloride;titanium dioxide;zinc oxide	ANAL FISSURES	TOPICAL	141 days	201 days
prednisolone	ULCERATIVE COLITIS	ORAL	189 days	202 days
blood, whole	SAE EXACERBATION OF UC	INTRAVENOUS	202 days	202 days
hydrocortisone	ULCERATIVE COLITIS	INTRAVENOUS	202 days	205 days
calcium acetate;magnesium aspartate;potassium acetate;sodium acetate;sodium chloride	NUTRITIONAL SUPPORT WHILE HOSPITALIZED DUE TO SAE EXACERBATION OF UC	INTRAVENOUS	202 days	209 days
enoxaparin sodium	THROMBOSIS PROPHYLAXIS	SUBCUTANEOUS	202 days	209 days
insulin	DIABETES MELLITUS TYPE 2	SUBCUTANEOUS	202 days	209 days
mesalazine	ULCERATIVE COLITIS	ORAL	202 days	209 days
pantoprazole	PROPHYLAXIS OF GASTRIC DISORDERS	INTRAVENOUS	202 days	209 days
potassium chloride	HYPOKALEMIA	INTRAVENOUS	202 days	209 days
potassium chloride	ULCERATIVE COLITIS	INTRAVENOUS	202 days	209 days
potassium chloride	ULCERATIVE COLITIS	ORAL	206 days	209 days
prednisolone	ULCERATIVE COLITIS	ORAL	205 days	215 days
infliximab	ULCERATIVE COLITIS	INTRAVENOUS	205 days	219 days
prednisolone	ULCERATIVE COLITIS	ORAL	216 days	222 days
azathioprine	ULCERATIVE COLITIS	ORAL	210 days	229 days
prednisolone	ULCERATIVE COLITIS	ORAL	223 days	229 days

All Adverse Events							
Preferred Term	Onset Day	Resolution Day	Toxicity Grade	Causality	Action taken with Induction Drug	Action taken with Maintenance Drug	Action - Other
Abdominal pain upper	12	18	2	not related	dose not changed	not applicable	medication required
Arthralgia	36*	Ongoing	2	not related	not applicable	dose not changed	medication required
Colitis ulcerative	56*	124*	2	not related	not applicable	dose not changed	medication required
Anal fissure	63*	Ongoing	2	not related	not applicable	dose not changed	medication required
Gastritis erosive	110*	Ongoing	2	not related	not applicable	dose not changed	medication required
Colitis ulcerative	124*	131*	4	not related	not applicable	not applicable	medication required
Hypokalaemia	128*	131*	2	not related	not applicable	not applicable	medication required
* denotes the Maintenance study day.							

Hematology						
Study Day	Hemoglobin (g/dL)	Hematocrit (%)	Erythrocytes (x10^6/uL)	Platelets (x10^3/uL)	Reticulocytes (x10^6/uL)	Ery. Mean Corpuscular Volume (fL)
-62	12.4 (L)	38 (L)	4.2 (L)	258 (N)	0.086 (N)	90 (N)
-26	13.4 (N)	41 (N)	4.7 (N)	252 (N)	0.108 (N)	88 (N)
1	12.5 (L)	38 (L)	4.5 (N)	249 (N)	0.083 (N)	85 (N)
15	12.7 (N)	40 (N)	4.5 (N)	281 (N)	0.081 (N)	88 (N)
29	11.7 (L)	36 (L)	4.2 (L)	241 (N)	0.07 (N)	88 (N)
43	10.8 (L)	35 (L)	3.8 (L)	206 (N)	0.04 (N)	91 (N)
69	11.3 (L)	34 (L)	3.8 (L)	227 (N)	0.086 (N)	92 (N)
-10*	11.3 (L)	34 (L)	3.8 (L)	227 (N)	0.086 (N)	92 (N)
19*	11.2 (L)	35 (L)	3.7 (L)	207 (N)	0.072 (N)	95 (N)
63*	8.6 (L)	27 (L)	2.6 (L)	87 (L)	0.041 (N)	103 (H)
82*	9.3 (L)	29 (L)	2.7 (L)	150 (N)	0.119 (N)	106 (H)
96*	9.3 (L)	29 (L)	2.7 (L)	113 (L)	0.096 (N)	109 (H)
110*	9.3 (L)	30 (L)	2.7 (L)	128 (L)	0.097 (N)	109 (H)
* denotes the Maintenance study day. 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)
-62	6.53 (N)	5.61 (N)	0.72 (L)	0.15 (N)	0.02 (N)	0.03 (N)
-26	7.22 (N)	5.26 (N)	1.46 (N)	0.36 (N)	0.02 (N)	0.13 (N)
1	6.4 (N)	4.14 (N)	1.5 (N)	0.44 (N)	0.02 (N)	0.3 (N)
15	7.78 (N)	4.97 (N)	2.05 (N)	0.37 (N)	0.03 (N)	0.36 (N)
29	4.14 (N)	2.69 (N)	1.14 (N)	0.07 (L)	0.02 (N)	0.22 (N)
43	2.59 (L)	1.29 (L)	1.11 (N)	0.03 (L)	0 (N)	0.16 (N)
69	3.88 (N)	2.59 (N)	1.05 (N)	0.18 (N)	0.02 (N)	0.04 (N)
-10*	3.88 (N)	2.59 (N)	1.05 (N)	0.18 (N)	0.02 (N)	0.04 (N)
19*	2.9 (L)	1.66 (L)	1.01 (N)	0.15 (N)	0.01 (N)	0.08 (N)
63*	1.43 (L)	0.85 (L)	0.5 (L)	0.05 (L)	0.01 (N)	0.03 (N)
82*	4.19 (N)	3.21 (N)	0.79 (L)	0.16 (N)	0.01 (N)	0.02 (N)
96*	3.65 (L)	2.77 (N)	0.74 (L)	0.1 (L)	0.02 (N)	0.02 (N)
110*	4 (N)	2.54 (N)	1.24 (N)	0.15 (N)	0.02 (N)	0.05 (N)
* denotes the Maintenance study day. 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)
-62	No	30 (N)	15 (N)	81 (N)	<0.2 (L)	0.75 (N)
-26	No	19 (N)	19 (N)	112 (N)	0.3 (N)	1.06 (N)
1	No	16 (N)	19 (N)	117 (N)	0.4 (N)	0.98 (N)
15	No	14 (N)	18 (N)	132 (H)	0.2 (N)	1.02 (N)
29	No	30 (N)	24 (N)	117 (N)	0.4 (N)	0.93 (N)
43	No	58 (H)	44 (H)	121 (N)	0.6 (N)	0.94 (N)
69	Yes	65 (H)	38 (H)	136 (H)	0.6 (N)	0.95 (N)
-10*	Yes	65 (H)	38 (H)	136 (H)	0.6 (N)	0.95 (N)
19*	No	23 (N)	20 (N)	126 (N)	0.4 (N)	0.97 (N)
63*	No	14 (N)	14 (N)	126 (N)	0.8 (N)	0.97 (N)
82*	No	21 (N)	11 (N)	93 (N)	0.7 (N)	0.89 (N)
96*	No	15 (N)	11 (N)	70 (N)	0.5 (N)	0.79 (N)
110*	No	14 (N)	10 (L)	73 (N)	0.5 (N)	0.89 (N)
* denotes the Maintenance study day. 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)
-62	No	123.6 (N)	18 (L)	222 (H)	3.53 (N)
-26	No	88.8 (N)	79 (N)	136 (H)	14 (H)
1	No	93.6 (N)	146 (N)	103 (H)	24.5 (H)
15	No	91.8 (N)	53 (N)	109 (H)	9.22 (N)
29	No	103.2 (N)	71 (N)	107 (H)	3.76 (N)
43	No	98.4 (N)	51 (N)	118 (H)	2.46 (N)
69	Yes	96 (N)	58 (N)	119 (H)	4.67 (N)
-10*	Yes	96 (N)	58 (N)	119 (H)	4.67 (N)
19*	No	92.4 (N)	50 (N)	130 (H)	6.33 (N)
63*	No	90 (N)	61 (N)	130 (H)	19.7 (H)
82*	No		25 (L)	175 (H)	
96*	No		24 (L)	164 (H)	
110*	No	102 (N)	27 (L)	95 (N)	6.61 (N)
* denotes the Maintenance study day. 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)
-62	No	212 (N)	105 (H)	111 (N)	100 (N)
1	No	149 (L)	35 (N)	87 (N)	191 (N)
43	No	123 (L)	40 (N)	64 (N)	131 (N)
69	Yes	143 (L)	38 (N)	78 (N)	178 (N)
-10*	Yes	143 (L)	38 (N)	78 (N)	178 (N)
63*	No	110 (L)	32 (N)	61 (N)	87 (N)
110*	No	165 (L)	72 (H)	84 (N)	99 (N)
* denotes the Maintenance study day. H = High; L = Low; N = Normal.					

被験者識別番号：[redacted]

投与群：寛解導入試験－フィルゴチニブ 200 mg 群（コホート A）

治験薬の投与状況：寛解導入試験－有害事象により投与中止（Day 61）；寛解維持試験－不参加

ベースライン特性：本被験者は 4[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。

デング熱（Day 55～61）（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［TE-AEI］）（寛解導入試験）：
Day 55、Grade 2 の重篤なデング熱が発現した。寛解導入治験薬に対する処置は投与中止であった。寛解維持治験薬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 61、Grade 2 の本事象は回復した。

癜風（Day 55～61）（投与中止に至った有害事象、TE-AEI）（寛解導入試験）：
Day 55、Grade 2 の非重篤な癜風が発現した。寛解導入治験薬に対する処置は投与中止であった。寛解維持治験薬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 61、Grade 2 の本事象は回復した。

その他の関連情報：被験者は、発熱及び悪寒を訴え入院した。被験者はデング熱ウイルス検査陽性の結果に基づきデング熱と診断され、治療として抗ウイルス療法が実施された。被験者は容体が安定した状態で退院した。

Medical History	
Medical History	**Resolution**
anaemia	Ongoing
colitis ulcerative	Ongoing
osteopenia	Ongoing

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
mesalazine	ULCERATIVE COLITIS	RECTAL	61 days	Ongoing
prednisolone	ULCERATIVE COLITIS	ORAL	-530 days	-511 days
prednisolone	ULCERATIVE COLITIS	ORAL	-510 days	-500 days
prednisolone	ULCERATIVE COLITIS	ORAL	-403 days	-383 days
prednisolone	ULCERATIVE COLITIS	ORAL	-382 days	-362 days
prednisolone	ULCERATIVE COLITIS	ORAL	-361 days	-341 days
mesalazine	ULCERATIVE COLITIS	ORAL	-530 days	-324 days
mesalazine	ULCERATIVE COLITIS	ORAL	-70 days	-37 days
prednisolone	ULCERATIVE COLITIS	ORAL	-36 days	54 days
paracetamol	DENGUE FEVER	INTRAMUSCULAR	55 days	56 days
paracetamol	FEVER	ORAL	55 days	58 days
artesunate	DENGUE FEVER	INTRAVENOUS	55 days	60 days
ceftriaxone	DENGUE FEVER	INTRAVENOUS	55 days	60 days
prednisolone	ULCERATIVE COLITIS	ORAL	55 days	61 days
calcium	OSTEOPENIA	ORAL	-70 days	67 days
colecalciferol	OSTEOPENIA	ORAL	-70 days	67 days
folic acid	ANEMIA	ORAL	-70 days	67 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
amlodipine	HYPERTENSION	ORAL	8 days	67 days
ketoconazole	PITYRIASIS VERSICOLOR	TOPICAL	55 days	67 days
protein supplements	NUTRITIONAL SUPPLIMENT	ORAL	55 days	67 days
sertaconazole	PITYRIASIS VERSICOLOR	TOPICAL	55 days	67 days
prednisolone	ULCERATIVE COLITIS	ORAL	62 days	68 days
prednisolone	ULCERATIVE COLITIS	ORAL	69 days	75 days
prednisolone	ULCERATIVE COLITIS	ORAL	76 days	82 days
prednisolone	ULCERATIVE COLITIS	ORAL	83 days	89 days
prednisolone	ULCERATIVE COLITIS	ORAL	90 days	96 days

All Adverse Events							
Preferred Term	Onset Day	Resolution Day	Toxicity Grade	Causality	Action taken with Induction Drug	Action taken with Maintenance Drug	Action - Other
Hypertension	8	Ongoing	1	not related	dose not changed	not applicable	medication required
Erectile dysfunction	46	Ongoing	1	not related	dose not changed	not applicable	none
Dengue fever	55	61	2	not related	drug withdrawn	not applicable	medication required + permanent study discontinuation
Tinea versicolour	55	61	2	not related	drug withdrawn	not applicable	medication required + permanent study discontinuation
* denotes the Maintenance study day.							

Hematology						
Study Day	Hemoglobin (g/dL)	Hematocrit (%)	Erythrocytes (x10^6/uL)	Platelets (x10^3/uL)	Reticulocytes (x10^6/uL)	Ery. Mean Corpuscular Volume (fL)
-37	9.7 (L)	33 (L)	4.5 (N)	332 (N)	0.069 (N)	73 (L)
-23	8.8 (L)	32 (L)	4.1 (L)	293 (N)	0.075 (N)	77 (L)
1	9.2 (L)	32 (L)	4.2 (L)	329 (N)	0.09 (N)	77 (L)
17	9 (L)	30 (L)	4 (L)	203 (N)	0.096 (N)	75 (L)
31	10 (L)	33 (L)	4.4 (L)	346 (N)	0.083 (N)	75 (L)
46	8.8 (L)	29 (L)	4 (L)	287 (N)	0.084 (N)	74 (L)
67	9 (L)	31 (L)	4 (L)	306 (N)	0.109 (N)	79 (N)
* denotes the Maintenance study day. 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)
-37	4.35 (N)	3.71 (N)	0.53 (L)	0.09 (L)	0.01 (N)	0.01 (N)
-23	4.81 (N)	2.17 (N)	2.23 (N)	0.32 (N)	0 (N)	0.08 (N)
1	7.97 (N)	5.62 (N)	1.76 (N)	0.52 (N)	0.01 (N)	0.06 (N)
17	8.02 (N)	6.08 (N)	1.44 (N)	0.43 (N)	0.02 (N)	0.05 (N)
31	7.1 (N)	5.35 (N)	1.36 (N)	0.31 (N)	0.01 (N)	0.07 (N)
46	7.66 (N)	5.8 (N)	1.33 (N)	0.44 (N)	0.02 (N)	0.08 (N)
67	7.25 (N)	5.63 (N)	1 (N)	0.55 (N)	0.03 (N)	0.05 (N)
* denotes the Maintenance study day. 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)
-37	Yes	21 (N)	29 (N)	96 (N)	0.2 (N)	0.89 (N)
1	Yes	18 (N)	18 (N)	78 (N)	0.2 (N)	0.87 (N)
17	Yes	21 (N)	33 (N)	90 (N)	<0.2 (L)	0.96 (N)
31	Yes	31 (N)	38 (H)	137 (H)	<0.2 (L)	0.95 (N)
46	Yes	22 (N)	27 (N)	79 (N)	<0.2 (L)	0.96 (N)
67	Yes	26 (N)	29 (N)	68 (N)	<0.2 (L)	0.85 (N)
* denotes the Maintenance study day. 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)
-37	Yes	81 (L)	47 (N)	113 (H)	1.27 (N)
1	Yes	83.4 (L)	26 (L)	82 (N)	34 (H)
17	Yes	75.6 (L)	33 (L)	84 (N)	2.99 (N)
31	Yes	76.2 (L)	53 (N)	101 (H)	1.53 (N)
46	Yes	75.6 (L)	76 (N)	100 (N)	2.61 (N)
67	Yes	76.2 (L)	24 (L)	97 (N)	7.91 (N)
* denotes the Maintenance study day. 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	182 (N)	80 (H)	90 (N)	81 (N)
67	Yes	163 (N)	52 (N)	112 (N)	79 (N)
* denotes the Maintenance study day. H = High; L = Low; N = Normal.					

被験者識別番号：[redacted]

投与群：寛解導入試験－フィルゴチニブ 200 mg 群（コホート B）；寛解維持試験－プラセボ群

治験薬の投与状況：寛解導入試験－完了；寛解維持試験－治験実施計画書に規定された疾患の悪化により投与中止（Day 175*）

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、日本からの参加であった。

咽頭炎（Day 34～40）（試験治療下の注目すべき有害事象［TE-AEI］）（寛解導入試験）：
Day 34、Grade 2 の非重篤な咽頭炎が発現した。寛解導入治験薬に対する処置は変更なし。寛解維持治験薬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 40、Grade 2 の本事象は回復した。

椎間板突出（Day 68～76）（試験治療下の重篤な有害事象）（寛解導入試験）：
Day 68、Grade 3 の重篤な椎間板突出が発現した。寛解導入治験薬に対する処置は変更なし。寛解維持治験薬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 76、Grade 3 の本事象は回復した。

咽頭炎（Day 14*～21*）（TE-AEI）（寛解維持試験）：
Day 14*、Grade 2 の非重篤な咽頭炎が発現した。寛解導入治験薬に対する処置は非該当であった。寛解維持治験薬に対する処置は変更なし。本事象は治験薬と関連ありと判断された。Day 21*、Grade 2 の本事象は回復した。

上気道感染（Day 29*～70*）（TE-AEI）（寛解維持試験）：
Day 29*、Grade 2 の非重篤な上気道感染が発現した。寛解導入治験薬に対する処置は非該当であった。寛解維持治験薬に対する処置は変更なし。本事象は治験薬と関連ありと判断された。Day 70*、Grade 2 の本事象は回復した。

胃腸炎（Day 71*～74*）（TE-AEI）（寛解維持試験）：
Day 71*、Grade 2 の非重篤な胃腸炎が発現した。寛解導入治験薬に対する処置は非該当であった。寛解維持治験薬に対する処置は変更なし。本事象は治験薬と関連ありと判断された。Day 74*、Grade 2 の本事象は回復した。

上気道感染（Day 130*～155*）（TE-AEI）（寛解維持試験）：
Day 130*、Grade 2 の非重篤な上気道感染が発現した。寛解導入治験薬に対する処置は非該当であった。寛解維持治験薬に対する処置は変更なし。本事象は治験薬と関連ありと判断された。Day 155*、Grade 2 の本事象は回復した。

その他の関連情報：特になし。

*寛解維持試験における study day

Medical History	
Medical History	**Resolution**
colitis ulcerative	Ongoing
intervertebral disc protrusion	Ongoing
seasonal allergy	Ongoing
leukapheresis	-390 days
immune thrombocytopenic purpura	-382 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
mesalazine	ULCERATIVE COLITIS	ORAL	About -541 days	Ongoing
bepotastine besilate	POLLINOSIS	ORAL	29 days	Ongoing
ferrous sodium citrate	ULCERATIVE COLITIS	ORAL	239 days	Ongoing
butyric acid	REGULATION OF INTESTINAL BACTERIA FLORA	ORAL	247 days	Ongoing
mesalazine	ULCERATIVE COLITIS	ORAL	About -2794 days	About -511 days
infliximab	ULCERATIVE COLITIS	INTRAVENOUS	-448 days	-434 days
azathioprine	ULCERATIVE COLITIS	ORAL	-410 days	-406 days
mesalazine	ULCERATIVE COLITIS	RECTAL	About -754 days	About -389 days
prednisolone sodium phosphate	ULCERATIVE COLITIS	RECTAL	About -754 days	About -389 days
prednisolone	ULCERATIVE COLITIS	ORAL	About -480 days	About -389 days
tacrolimus	ULCERATIVE COLITIS	ORAL	-399 days	-387 days
prednisolone	ULCERATIVE COLITIS	ORAL	-385 days	-384 days
tacrolimus	ULCERATIVE COLITIS	ORAL	-386 days	-383 days
prednisolone	ULCERATIVE COLITIS	ORAL	-383 days	-366 days
prednisolone	ULCERATIVE COLITIS	ORAL	-365 days	-318 days
prednisolone	ULCERATIVE COLITIS	ORAL	-317 days	-295 days
prednisolone	ULCERATIVE COLITIS	ORAL	-294 days	-247 days
prednisolone	ULCERATIVE COLITIS	ORAL	-246 days	-197 days
prednisolone	ULCERATIVE COLITIS	ORAL	-196 days	-134 days
prednisolone	ULCERATIVE COLITIS	ORAL	-133 days	-78 days
golimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	-246 days	-77 days
prednisolone	ULCERATIVE COLITIS	ORAL	-77 days	-21 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
prednisolone	ULCERATIVE COLITIS	ORAL	-20 days	-20 days
sodium picosulfate	PREPARATION FOR COLONOSCOPY	ORAL	-9 days	-9 days
mosapride citrate	PREPARATION FOR COLONOSCOPY	ORAL	-9 days	-8 days
ascorbic acid;macrogol 3350;potassium chloride;sodium ascorbate;sodium chloride;sodium sulfate	PREPARATION FOR COLONOSCOPY	ORAL	-8 days	-8 days
dimeticone	PREPARATION FOR COLONOSCOPY	ORAL	-8 days	-8 days
hyoscine butylbromide	SEDATION FOR COLONOSCOPY	INTRAVENOUS	-8 days	-8 days
midazolam	SEDATION FOR COLONOSCOPY	INTRAVENOUS	-8 days	-8 days
heparinoid	PREVENTION OF DRY SKIN	TOPICAL	-357 days	23 days
desloratadine	PHARYNGITIS	ORAL	34 days	40 days
garenoxacin mesilate monohydrate	PHARYNGITIS	ORAL	34 days	40 days
l-carbocysteine	PHARYNGITIS	ORAL	34 days	40 days
betamethasone sodium phosphate	ULCERATIVE COLITIS	INTRAVENOUS	66 days	66 days
pregabalin	WORSENING OF INTERVERTEBLE DISC HERNIATION	ORAL	66 days	68 days
paracetamol	WORSENING OF INTERVERTEBLE DISC HERNIATION	INTRAVENOUS	68 days	69 days
sodium picosulfate	PREPARATION FOR COLONOSCOPY	ORAL	69 days	69 days
mosapride citrate	PREPARATION FOR COLONOSCOPY	ORAL	69 days	70 days
ascorbic acid;macrogol 3350;potassium chloride;sodium ascorbate;sodium chloride;sodium sulfate	PREPARATION FOR COLONOSCOPY	ORAL	70 days	70 days
dimeticone	PREPARATION FOR COLONOSCOPY	ORAL	70 days	70 days
hyoscine butylbromide	SEDATION FOR COLONOSCOPY	INTRAVENOUS	70 days	70 days
midazolam	SEDATION FOR COLONOSCOPY	INTRAVENOUS	70 days	70 days
loxoprofen sodium dihydrate	INTERVERTEBLE DISC HERNIATION	ORAL	67 days	85 days
rebamipide	PREVENTION OF GASTRIC ULCER	ORAL	70 days	85 days
desloratadine	PHARYNGITIS	ORAL	91 days	96 days
garenoxacin mesilate monohydrate	PHARYNGITIS	ORAL	91 days	96 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
l-carbocysteine	PHARYNGITIS	ORAL	91 days	96 days
prednisolone	ULCERATIVE COLITIS	ORAL	-19 days	99 days
caffeine	UPPER RESPIRATORY TRACT INFECTION	ORAL	104 days	107 days
chlorphenamine maleate	UPPER RESPIRATORY TRACT INFECTION	ORAL	104 days	107 days
dihydrocodeine phosphate	UPPER RESPIRATORY TRACT INFECTION	ORAL	104 days	107 days
ibuprofen	UPPER RESPIRATORY TRACT INFECTION	ORAL	104 days	107 days
pseudoephedrine hydrochloride	UPPER RESPIRATORY TRACT INFECTION	ORAL	104 days	107 days
azithromycin	UPPER RESPIRATORY TRACT INFECTION	ORAL	108 days	110 days
ambroxol hydrochloride	UPPER RESPIRATORY TRACT INFECTION	ORAL	108 days	112 days
bilastine	UPPER RESPIRATORY TRACT INFECTION	ORAL	108 days	112 days
l-carbocysteine	UPPER RESPIRATORY TRACT INFECTION	ORAL	108 days	112 days
loxoprofen	UPPER RESPIRATORY TRACT INFECTION	ORAL	110 days	112 days
rebamipide	PREVENTION OF GASTRIC ULCER	ORAL	110 days	112 days
prednisolone	ULCERATIVE COLITIS	ORAL	100 days	113 days
clarithromycin	UPPER RESPIRATORY TRACT INFECTION	ORAL	113 days	119 days
prednisolone	ULCERATIVE COLITIS	ORAL	114 days	127 days
alendronate sodium	PREVENTION OF OSTEOPOROSIS	ORAL	-366 days	139 days
alfacalcidol	PREVENTION OF OSTEOPOROSIS	ORAL	-374 days	140 days
ferrous sodium citrate	ULCERATIVE COLITIS	ORAL	100 days	140 days
dextromethorphan hydrobromide	UPPER RESPIRATORY TRACT INFECTION	ORAL	113 days	145 days
caffeine;paracetamol;promethazine methylene disalicylate;salicylamide	UPPER RESPIRATORY TRACT INFECTION	ORAL	141 days	145 days
clarithromycin	UPPER RESPIRATORY TRACT INFECTION	ORAL	141 days	145 days
glucose;sodium chloride;sodium lactate	INFECTIOUS GASTROENTERITIS	INTRAVENOUS	146 days	146 days
paracetamol	INFECTIOUS GASTROENTERITIS	ORAL	146 days	146 days
clarithromycin	INFECTIOUS GASTROENTERITIS	ORAL	146 days	149 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
rabeprazole sodium	PREVENTION OF GASTRIC ULCER	ORAL	About -754 days	187 days
mecobalamin	INTERVERTEBRAL DISC HERNIATION	ORAL	94 days	199 days
pregabalin	INTERVERTEBRAL DISC HERNIATION	ORAL	94 days	199 days
bilastine	UPPER RESPIRATORY TRACT INFECTION	ORAL	205 days	211 days
dextromethorphan hydrobromide	UPPER RESPIRATORY TRACT INFECTION	ORAL	205 days	211 days
l-carbocysteine	UPPER RESPIRATORY TRACT INFECTION	ORAL	205 days	211 days
tosufloxacin tosilate monohydrate	UPPER RESPIRATORY TRACT INFECTION	ORAL	205 days	211 days
azithromycin	UPPER RESPIRATORY TRACT INFECTION	ORAL	217 days	219 days
bilastine	UPPER RESPIRATORY TRACT INFECTION	ORAL	217 days	223 days
ferrous sodium citrate	ULCERATIVE COLITIS	ORAL	141 days	225 days
dextromethorphan hydrobromide	UPPER RESPIRATORY TRACT INFECTION	ORAL	217 days	230 days
l-carbocysteine	UPPER RESPIRATORY TRACT INFECTION	ORAL	217 days	230 days
folic acid;iron;vitamin b12 nos	ULCERATIVE COLITIS	ORAL	232 days	238 days
bacillus mesentericus;clostridium butyricum;enterococcus faecalis	REGULATION OF INTESTINAL BACTERIA FLORA	ORAL	-209 days	246 days

All Adverse Events							
Preferred Term	Onset Day	Resolution Day	Toxicity Grade	Causality	Action taken with Induction Drug	Action taken with Maintenance Drug	Action - Other
Pharyngitis	34	40	2	related	dose not changed	not applicable	medication required
Intervertebral disc protrusion	65	68	2	not related	dose not changed	not applicable	medication required
Intervertebral disc protrusion	68	76	3	not related	dose not changed	not applicable	medication required
Pharyngitis	14*	21*	2	related	not applicable	dose not changed	medication required
Upper respiratory tract infection	29*	70*	2	related	not applicable	dose not changed	medication required
Gastroenteritis	71*	74*	2	related	not applicable	dose not changed	medication required

All Adverse Events							
Preferred Term	Onset Day	Resolution Day	Toxicity Grade	Causality	Action taken with Induction Drug	Action taken with Maintenance Drug	Action - Other
Upper respiratory tract infection	130*	155*	2	related	not applicable	dose not changed	medication required
Colitis ulcerative	157*	Ongoing	2	related	not applicable	dose not changed	none
* denotes the Maintenance study day.							

Hematology						
Study Day	Hemoglobin (g/dL)	Hematocrit (%)	Erythrocytes (x10^6/uL)	Platelets (x10^3/uL)	Reticulocytes (x10^6/uL)	Ery. Mean Corpuscular Volume (fL)
-20	14.6 (N)	45 (N)	5.4 (N)	272 (N)	0.072 (N)	84 (N)
1	13.2 (N)	41 (N)	4.9 (N)	268 (N)	0.047 (N)	83 (N)
15	13.4 (N)	41 (N)	5 (N)	285 (N)	0.058 (N)	81 (N)
29	13.4 (N)	39 (N)	5 (N)	232 (N)	0.054 (N)	79 (N)
43	12.5 (L)	37 (L)	4.7 (N)	307 (N)	0.053 (N)	80 (N)
70	14.2 (N)	45 (N)	5.4 (N)	274 (N)	0.085 (N)	82 (N)
-6*	14.2 (N)	45 (N)	5.4 (N)	274 (N)	0.085 (N)	82 (N)
24*	12.4 (L)	38 (L)	4.7 (N)	227 (N)	0.059 (N)	80 (N)
66*	12.6 (L)	38 (L)	4.8 (N)	194 (N)	0.048 (N)	80 (N)
113*	12.8 (N)	40 (N)	4.9 (N)	206 (N)	0.071 (N)	82 (N)
164*	13 (N)	44 (N)	5 (N)	235 (N)	0.08 (N)	87 (N)
* denotes the Maintenance study day. 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)
-20	10.32 (N)	8.74 (H)	1.3 (N)	0.19 (N)	0.03 (N)	0.06 (N)
1	5.38 (N)	3.21 (N)	1.68 (N)	0.34 (N)	0.04 (N)	0.11 (N)
15	6.46 (N)	4.34 (N)	1.58 (N)	0.38 (N)	0.03 (N)	0.13 (N)
29	6.13 (N)	3.94 (N)	1.68 (N)	0.33 (N)	0.05 (N)	0.13 (N)
43	5.49 (N)	3.4 (N)	1.57 (N)	0.27 (N)	0.04 (N)	0.2 (N)
70	9.17 (N)	7.29 (H)	1.29 (N)	0.43 (N)	0.05 (N)	0.1 (N)
-6*	9.17 (N)	7.29 (H)	1.29 (N)	0.43 (N)	0.05 (N)	0.1 (N)
24*	5.43 (N)	3.72 (N)	1.19 (N)	0.38 (N)	0.04 (N)	0.1 (N)
66*	5.46 (N)	3.73 (N)	1.18 (N)	0.28 (N)	0.06 (N)	0.22 (N)
113*	5.44 (N)	3.45 (N)	1.45 (N)	0.28 (N)	0.05 (N)	0.21 (N)
164*	5.01 (N)	3.02 (N)	1.5 (N)	0.19 (N)	0.07 (N)	0.23 (N)
* denotes the Maintenance study day. 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)
-20	Yes	11 (N)	12 (N)	67 (N)	0.2 (N)	0.61 (N)
1	Yes	14 (N)	16 (N)	65 (N)	0.3 (N)	0.64 (N)
15	Yes	10 (N)	15 (N)	60 (N)	0.3 (N)	0.66 (N)
29	Yes	11 (N)	16 (N)	67 (N)	0.4 (N)	0.7 (N)
43	No	8 (N)	14 (N)	62 (N)	0.2 (N)	0.66 (N)
70	Yes	9 (N)	15 (N)	65 (N)	0.5 (N)	0.77 (N)
-6*	Yes	9 (N)	15 (N)	65 (N)	0.5 (N)	0.77 (N)
24*	Yes	8 (N)	13 (N)	58 (N)	0.4 (N)	0.67 (N)
66*	Yes	11 (N)	15 (N)	62 (N)	0.3 (N)	0.67 (N)
113*	Yes	14 (N)	16 (N)	57 (N)	0.3 (N)	0.66 (N)
164*	Yes	12 (N)	15 (N)	66 (N)	0.3 (N)	0.69 (N)
* denotes the Maintenance study day. 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)
-20	Yes	166.8 (H)	58 (N)	98 (N)	3.87 (N)
1	Yes	160.2 (H)	87 (N)	78 (N)	5.61 (N)
15	Yes	160.2 (H)	97 (N)	80 (N)	2.86 (N)
29	Yes	151.8 (H)	93 (N)	83 (N)	3.33 (N)
43	No	162 (H)	78 (N)	91 (N)	3.87 (N)
70	Yes	131.4 (H)	287 (N)	89 (N)	2.06 (N)
-6*	Yes	131.4 (H)	287 (N)	89 (N)	2.06 (N)
24*	Yes	157.8 (H)	87 (N)	92 (N)	2.63 (N)
66*	Yes	157.2 (H)	89 (N)	97 (N)	5.82 (N)
113*	Yes	160.2 (H)	109 (N)	86 (N)	4.52 (N)
164*	Yes	154.2 (H)	94 (N)	85 (N)	6.69 (N)
* denotes the Maintenance study day. 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)
-20	Yes	215 (N)	87 (H)	133 (H)	57 (N)
1	Yes	195 (N)	60 (N)	125 (N)	43 (L)
15	Yes	206 (N)	68 (H)	141 (H)	44 (L)
29	Yes	197 (N)	70 (H)	131 (H)	50 (N)
70	Yes	193 (N)	60 (N)	126 (N)	74 (N)
-6*	Yes	193 (N)	60 (N)	126 (N)	74 (N)
113*	Yes	172 (N)	56 (N)	127 (N)	42 (L)
* denotes the Maintenance study day. H = High; L = Low; N = Normal.					

被験者識別番号：[redacted]

投与群：寛解導入試験－フィルゴチニブ 200 mg 群（コホート B）

治験薬の投与状況：寛解導入試験－有害事象により投与中止（Day 15）；寛解維持試験－不参加

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、民族は非ヒスパニック／ラテン系、ポーランドからの参加であった。

貧血（Day 9～25）（試験治療下の重篤な有害事象［TE-SAE］）（寛解導入試験）：
Day 9、Grade 2 の重篤な貧血が発現した。寛解導入治験薬に対する処置は変更なし。寛解維持治験薬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 25、Grade 2 の本事象は回復した。

クロストリジウム・ディフィシレ感染（Day 18～25）（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）（寛解導入試験）：
Day 18、Grade 3 の重篤なクロストリジウム・ディフィシレ感染が発現した。寛解導入治験薬に対する処置は投与中止であった。寛解維持治験薬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 25、Grade 3 の本事象は回復した。

その他の関連情報：鉄レベルが低かったため、被験者は鉄の静脈内投与を受けるため入院した。入院中、被験者はクロストリジウム・ディフィシレ感染と診断され、治療として抗生剤の投与を受けた。

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

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
mesalazine	ULCERATIVE COLITIS	ORAL	About -225 days	Ongoing
ethinylestradiol;norelgestromin	CONTRACEPTION	TOPICAL	-105 days	Ongoing
azathioprine	ULCERATIVE COLITIS	ORAL	-776 days	-752 days
methylprednisolone	ULCERATIVE COLITIS	ORAL	-603 days	-590 days
vedolizumab	ULCERATIVE COLITIS	INTRAVENOUS	-467 days	-419 days
vedolizumab	ULCERATIVE COLITIS	SUBCUTANEOUS	-370 days	-301 days
fentanyl	ANESTESHIA FOR SIGMORECTOSCOPY	INTRAVENOUS	-7 days	-7 days
midazolam	ANESTESHIA FOR SIGMORECTOSCOPY	INTRAVENOUS	-7 days	-7 days
sodium phosphate monobasic (anhydrous);sodium phosphate monobasic (monohydrate)	PREPARATION FOR SIGMORECTOSCOPY	RECTAL	-7 days	-7 days
ciprofloxacin	HOSPITAL TREATMENT FOR CLOSTRIDIUM DIFFICILE	OTHER	About 1 day	About 48 days
clorazepate dipotassium	AE - DIFFICULTY FALLING ASLEEP	OTHER	About 1 day	About 48 days

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
drotaverine hydrochloride	HOSPITAL TREATMENT FOR CLOSTRIDIUM DIFFICILE	OTHER	About 1 day	About 48 days
furosemide	HOSPITAL TREATMENT FOR CLOSTRIDIUM DIFFICILE	OTHER	About 1 day	About 48 days
iron isomaltoside 1000	HOSPITAL TREATMENT FOR LOW IRON LEWEL	OTHER	About 1 day	About 48 days
metronidazole	CLOSTRIDIUM DIFFICILE	OTHER	About 1 day	About 48 days
pantoprazole	HOSPITAL TREATMENT FOR CLOSTRIDIUM DIFFICILE	OTHER	About 1 day	About 48 days

All Adverse Events							
Preferred Term	Onset Day	Resolution Day	Toxicity Grade	Causality	Action taken with Induction Drug	Action taken with Maintenance Drug	Action - Other
Anaemia	9	25	2	not related	dose not changed	not applicable	medication required
Anxiety	9	25	1	not related	dose not changed	not applicable	none
Initial insomnia	9	25	1	not related	dose not changed	not applicable	medication required
Clostridium difficile infection	18	25	3	not related	drug withdrawn	not applicable	medication required + permanent study discontinuation
* denotes the Maintenance study day.							

Hematology						
Study Day	Hemoglobin (g/dL)	Hematocrit (%)	Erythrocytes (x10^6/uL)	Platelets (x10^3/uL)	Reticulocytes (x10^6/uL)	Ery. Mean Corpuscular Volume (fL)
-33	9.9 (L)	32 (L)	3.9 (L)	438 (H)	0.087 (N)	81 (N)
1	8.8 (L)	29 (L)	3.8 (L)	557 (H)	0.074 (N)	77 (L)
50	12.4 (N)	38 (N)	4.3 (N)	332 (N)	0.111 (N)	90 (N)
* denotes the Maintenance study day. 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)
-33	3.92 (N)	2.21 (N)	1.33 (N)	0.26 (N)	0.02 (N)	0.1 (N)
1	3.37 (L)	1.84 (L)	1.31 (N)	0.15 (N)	0.02 (N)	0.05 (N)
50	5.69 (N)	3.47 (N)	1.82 (N)	0.24 (N)	0.04 (N)	0.12 (N)
* denotes the Maintenance study day. 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)
-33	Yes	13 (N)	16 (N)	63 (N)	0.2 (N)	0.68 (N)
1	Yes	9 (N)	15 (N)	62 (N)	<0.2 (L)	0.67 (N)
50	Yes	19 (N)	19 (N)	61 (N)	0.2 (N)	0.89 (N)
* denotes the Maintenance study day. 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)
-33	Yes	94.2 (N)	33 (N)	108 (H)	5.25 (N)
1	Yes	93 (N)	24 (L)	93 (N)	47.9 (H)
50	Yes	71.4 (L)	33 (N)	91 (N)	6.12 (N)
* denotes the Maintenance study day. 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)
-33	Yes	166 (N)	70 (N)	80 (N)	105 (N)
1	Yes	140 (L)	58 (N)	62 (N)	109 (N)
50	Yes	164 (N)	72 (N)	68 (N)	120 (N)
* denotes the Maintenance study day. H = High; L = Low; N = Normal.					

被験者識別番号：[redacted]

投与群：寛解導入試験－プラセボ群（コホート A）

治験薬の投与状況：寛解導入試験－有害事象により投与中止（Day 69）；寛解維持試験－不参加

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、米国からの参加であった。

潰瘍性大腸炎（Day 53～65）（試験治療下の重篤な有害事象［TE-SAE］、投与中止に至った有害事象）（寛解導入試験）：
Day 53、Grade 3 の重篤な潰瘍性大腸炎が発現した。寛解導入治験薬に対する処置は投与中止であった。寛解維持治験薬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 65、Grade 3 の本事象は回復した。

潰瘍性大腸炎（Day 86～継続）（TE-SAE）（寛解導入試験）：
Day 86、Grade 3 の重篤な潰瘍性大腸炎が発現した。寛解導入治験薬に対する処置は非該当であった。寛解維持治験薬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。試験終了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**
anxiety	Ongoing
arthralgia	Ongoing
colitis ulcerative	Ongoing
deep vein thrombosis	Ongoing
fatigue	Ongoing
gastrooesophageal reflux disease	Ongoing
hypertension	Ongoing
lower limb fracture	About -9437 days
spinal fracture	About -9437 days
upper limb fracture	About -9437 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
lisinopril	HYPERTENSION	ORAL	-18 days	Ongoing
paracetamol	BACK AND LEG PAIN	ORAL	-18 days	Ongoing
lorazepam	SUSPECTED ANXIETY	ORAL	86 days	Ongoing
mesalazine	ULCERATIVE COLITIS	ORAL	86 days	Ongoing
mesalazine	ULCERATIVE COLITIS	RECTAL	86 days	Ongoing
morphine	ULCERATIVE COLITIS	ORAL	86 days	Ongoing
omeprazole	GASTROESOPHAGEAL REFLUX DISEASE	ORAL	86 days	Ongoing
oxycodone	ULCERATIVE COLITIS	ORAL	86 days	Ongoing
prednisone	ULCERATIVE COLITIS	ORAL	86 days	Ongoing
apixaban	BLOOD CLOTS	ORAL	93 days	Ongoing
prednisone	ULCERATIVE COLITIS	ORAL	About -305 days	About -186 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
mesalazine	ULCERATIVE COLITIS	ORAL	-81 days	-30 days
acetylsalicylic acid;caffeine;paracetamol	BACK AND LEG PAIN	ORAL	About -2497 days	-18 days
magnesium sulfate;potassium sulfate;sodium sulfate	ULCERATIVE COLITIS	ORAL	-5 days	-5 days
propofol	ANESTHESIA	INTRAVENOUS DRIP	-4 days	-4 days
prednisone	ULCERATIVE COLITIS	ORAL	42 days	53 days
morphine	ULCERATIVE COLITIS	INTRAVENOUS DRIP	53 days	53 days
ondansetron	ULCERATIVE COLITIS	INTRAVENOUS DRIP	53 days	53 days
methylprednisolone sodium succinate	ULCERATIVE COLITIS	INTRAVENOUS DRIP	53 days	59 days
sodium chloride	ULCERATIVE COLITIS	INTRAVENOUS DRIP	53 days	59 days
mesalazine	WORSENING ULCERATIVE COLITIS	RECTAL	62 days	65 days
prednisone	ULCERATIVE COLITIS	ORAL	60 days	71 days
prednisone	ULCERATIVE COLITIS	ORAL	72 days	85 days

All Adverse Events							
Preferred Term	Onset Day	Resolution Day	Toxicity Grade	Causality	Action taken with Induction Drug	Action taken with Maintenance Drug	Action - Other
Colitis ulcerative	29	52	3	not related	dose not changed	not applicable	none
Colitis ulcerative	53	65	3	not related	drug withdrawn	not applicable	medication required + permanent study discontinuation
Colitis ulcerative	86	Ongoing	3	not related	not applicable	not applicable	medication required
Haemoglobin abnormal	99	Ongoing	3	not related	not applicable	not applicable	none
* denotes the Maintenance study day.							

Hematology						
Study Day	Hemoglobin (g/dL)	Hematocrit (%)	Erythrocytes (x10^6/uL)	Platelets (x10^3/uL)	Reticulocytes (x10^6/uL)	Ery. Mean Corpuscular Volume (fL)
-18	14.6 (N)	45 (N)	5.8 (N)	227 (N)	0.171 (H)	78 (L)
1	15.2 (N)	46 (N)	5.9 (N)	221 (N)	0.115 (N)	77 (L)
15	15.3 (N)	45 (N)	5.8 (N)	206 (N)	0.148 (H)	77 (L)
28	15.4 (N)	45 (N)	5.8 (N)	191 (N)	0.141 (H)	78 (L)
42	15.8 (N)	47 (N)	5.8 (N)	269 (N)	0.149 (H)	80 (N)
69	11.8 (L)	37 (L)	4.5 (N)	183 (N)	0.152 (H)	82 (N)
99	6.8 (L)	24 (L)	3.2 (L)		0.153 (H)	75 (L)
* denotes the Maintenance study day. 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)
-18	4.99 (N)	3.02 (N)	1.34 (N)	0.36 (N)	0.02 (N)	0.24 (N)
1	5.68 (N)	3.38 (N)	1.44 (N)	0.38 (N)	0.08 (N)	0.4 (N)
15	5.19 (N)	3.32 (N)	1.2 (N)	0.38 (N)	0.04 (N)	0.25 (N)
28	5.59 (N)	3.14 (N)	1.69 (N)	0.42 (N)	0.06 (N)	0.29 (N)
42	6 (N)	3.76 (N)	1.35 (N)	0.47 (N)	0.14 (N)	0.29 (N)
69	8.5 (N)	7.24 (H)	0.69 (L)	0.51 (N)	0.02 (N)	0.05 (N)
99	8.01 (N)	5.96 (N)	1.37 (N)	0.56 (N)	0.02 (N)	0.1 (N)
* denotes the Maintenance study day. 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)
-18	Yes	33 (N)	34 (N)	72 (N)	0.8 (N)	0.76 (N)
1	No	30 (N)	28 (N)	80 (N)	0.5 (N)	0.71 (N)
15	Yes	53 (H)	44 (H)	67 (N)	0.5 (N)	0.78 (N)
28	Yes	35 (N)	32 (N)	69 (N)	0.5 (N)	0.81 (N)
42	Yes	29 (N)	31 (N)	84 (N)	0.5 (N)	0.84 (N)
69	No	33 (N)	21 (N)	62 (N)	0.4 (N)	0.76 (N)
99	Yes	20 (N)	18 (N)	56 (N)	0.3 (N)	0.74 (N)
* denotes the Maintenance study day. 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)
-18	Yes	145.5 (H)	226 (N)	93 (N)	1.12 (N)
1	No	154.4 (H)	251 (N)	101 (H)	1.68 (N)
15	Yes	142.1 (H)	418 (H)	103 (H)	1.33 (N)
28	Yes	136.8 (H)	275 (N)	94 (N)	2.61 (N)
42	Yes	127.1 (H)	309 (H)	105 (H)	6.63 (N)
69	No	131.7 (H)	76 (N)	109 (H)	0.7 (N)
99	Yes	140.2 (H)	45 (N)	84 (N)	15.1 (H)
* denotes the Maintenance study day. 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)
-18	Yes	193 (N)	44 (N)	130 (H)	113 (N)
1	No	167 (L)	37 (N)	123 (N)	107 (N)
15	Yes	209 (N)	48 (N)	158 (H)	122 (N)
69	No	167 (L)	64 (H)	105 (N)	77 (N)
99	Yes	142 (L)	62 (N)	77 (N)	89 (N)
* denotes the Maintenance study day. H = High; L = Low; N = Normal.					

被験者識別番号：[redacted]

投与群：寛解導入試験－フィルゴチニブ 200 mg 群（コホート A）；寛解維持試験－フィルゴチニブ 200 mg 群

治験薬の投与状況：寛解導入試験－完了；寛解維持試験－完了

ベースライン特性：本被験者は 2[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。

発熱（Day 6*～13*）（試験治療下の重篤な有害事象）（寛解維持試験）：
Day 6*、Grade 3 の重篤な発熱が発現した。寛解導入治験薬に対する処置は非該当であった。寛解維持治験薬に対する処置は変更なし。本事象は治験薬と関連なしと判断された。Day 13*、Grade 3 の本事象は回復した。

インフルエンザ（Day 175*～181*）（試験治療下の注目すべき有害事象）（寛解維持試験）：
Day 175*、Grade 2 の非重篤なインフルエンザが発現した。寛解導入治験薬に対する処置は非該当であった。寛解維持治験薬に対する処置は変更なし。本事象は治験薬と関連なしと判断された。Day 181*、Grade 2 の本事象は回復した。

その他の関連情報：特になし。
*寛解維持試験における study day

Medical History	
Medical History	**Resolution**
colitis ulcerative	Ongoing
rhinitis allergic	Ongoing
pneumonia	About -8153 days
herpes zoster	About -2674 days

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
mesalazine	ULCERATIVE COLITIS	ORAL	-311 days	-294 days
prednisolone	ULCERATIVE COLITIS	ORAL	-153 days	-133 days
mercaptopurine	ULCERATIVE COLITIS	ORAL	-102 days	-80 days
ascorbic acid;macrogol 3350;potassium chloride;sodium ascorbate;sodium chloride;sodium sulfate	PREPARATION FOR COLONOSCOPY	ORAL	-2 days	-2 days
glucose;potassium chloride;sodium chloride;sodium lactate	PREPARATION FOR COLONOSCOPY	INTRAVENOUS	-2 days	-2 days
lidocaine	PREPARATION FOR COLONOSCOPY	TOPICAL	-2 days	-2 days
naloxone hydrochloride	PREPARATION FOR COLONOSCOPY	INTRAVENOUS	-2 days	-2 days
pethidine hydrochloride	PREPARATION FOR COLONOSCOPY	INTRAVENOUS	-2 days	-2 days
ascorbic acid;macrogol 3350;potassium chloride;sodium ascorbate;sodium chloride;sodium sulfate	PREPARATION FOR COLONOSCOPY	ORAL	69 days	69 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
glucose;potassium chloride;sodium chloride;sodium lactate	PREPARATION FOR COLONOSCOPY	INTRAVENOUS	69 days	69 days
hyoscine butylbromide	PREPARATION FOR COLONOSCOPY	INTRAVENOUS	69 days	69 days
lidocaine	PREPARATION FOR COLONOSCOPY	TOPICAL	69 days	69 days
naloxone hydrochloride	PREPARATION FOR COLONOSCOPY	INTRAVENOUS	69 days	69 days
pethidine hydrochloride	PREPARATION FOR COLONOSCOPY	INTRAVENOUS	69 days	69 days
calcium chloride;potassium chloride;sodium lactate	FEVER	INTRAVENOUS	81 days	81 days
paracetamol	FEVER	ORAL	81 days	82 days
iohexol	CONTRAST-ENHANCED COMPUTED TOMOGRAPHY	SUBCUTANEOUS	82 days	82 days
paracetamol	FEVER	INTRAVENOUS	81 days	83 days
calcium chloride;potassium chloride;sodium lactate	FEVER	INTRAVENOUS	83 days	88 days
ampicillin sodium;sulbactam sodium	FEVER	INTRAVENOUS	84 days	88 days
sodium chloride	FEVER	INTRAVENOUS	84 days	88 days
prednisolone	ULCERATIVE COLITIS	ORAL	-32 days	98 days
metoclopramide hydrochloride	NAUSEA	ORAL	141 days	142 days
betamethasone valerate;gentamicin sulfate	ATHEROMA(LEFT EAR)	TRANSDERMAL	230 days	251 days
laninamivir octanoate	INFLUENZA TYPE A	RESPIRATORY (INHALATION)	253 days	253 days
paracetamol	FEVER DUE TO INFLUENZA TYPE A	ORAL	253 days	254 days
loxoprofen sodium	FEVER, EPIGASTRIC PAIN	ORAL	341 days	346 days
metoclopramide hydrochloride	NAUSEA	ORAL	341 days	346 days
timepidium bromide	EPIGASTRIC PAIN	ORAL	341 days	346 days
ascorbic acid;macrogol 3350;potassium chloride;sodium ascorbate;sodium chloride;sodium sulfate	PREPARATION FOR COLONOSCOPY	ORAL	410 days	410 days
hyoscine butylbromide	PREPARATION FOR COLONOSCOPY	INTRAVENOUS	410 days	410 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
lidocaine	PREPARATION FOR COLONOSCOPY	TOPICAL	410 days	410 days
naloxone hydrochloride	PREPARATION FOR COLONOSCOPY	INTRAVENOUS	410 days	410 days
pethidine hydrochloride	PREPARATION FOR COLONOSCOPY	INTRAVENOUS	410 days	410 days
sodium chloride	PREPARATION FOR COLONOSCOPY	INTRAVENOUS	410 days	410 days

All Adverse Events							
Preferred Term	Onset Day	Resolution Day	Toxicity Grade	Causality	Action taken with Induction Drug	Action taken with Maintenance Drug	Action - Other
Pyrexia	4*	5*	2	not related	not applicable	dose not changed	medication required
Pyrexia	6*	13*	3	not related	not applicable	dose not changed	medication required
Hot flush	50*	66*	1	not related	not applicable	dose not changed	none
Nausea	50*	66*	2	not related	not applicable	dose not changed	medication required
Dermal cyst	153*	175*	2	not related	not applicable	dose not changed	medication required
Influenza	175*	181*	2	not related	not applicable	dose not changed	medication required
Abdominal pain upper	263*	269*	2	not related	not applicable	dose not changed	medication required
Nausea	263*	269*	2	not related	not applicable	dose not changed	medication required
Pyrexia	263*	269*	2	not related	not applicable	dose not changed	medication required
* denotes the Maintenance study day.							

Hematology						
Study Day	Hemoglobin (g/dL)	Hematocrit (%)	Erythrocytes (x10^6/uL)	Platelets (x10^3/uL)	Reticulocytes (x10^6/uL)	Ery. Mean Corpuscular Volume (fL)
-17	13 (N)	38 (N)	4.4 (N)	329 (N)	0.106 (N)	88 (N)
1	13.8 (N)	41 (N)	4.7 (N)	315 (N)	0.083 (N)	87 (N)
18	12.7 (N)	39 (N)	4.3 (N)	300 (N)	0.096 (N)	90 (N)
29	13.2 (N)	40 (N)	4.5 (N)	253 (N)	0.088 (N)	89 (N)
43	14.1 (N)	42 (N)	4.7 (N)	271 (N)	0.094 (N)	89 (N)
69	13 (N)	39 (N)	4.3 (N)	260 (N)	0.094 (N)	91 (N)
-9*	13 (N)	39 (N)	4.3 (N)	260 (N)	0.094 (N)	91 (N)
22*	12 (N)	36 (N)	4 (L)	359 (N)	0.136 (H)	89 (N)
64*	12.3 (N)	38 (N)	4 (L)	274 (N)	0.085 (N)	94 (N)
106*	13.6 (N)	41 (N)	4.5 (N)	273 (N)	0.079 (N)	92 (N)
162*	13.7 (N)	40 (N)	4.4 (N)	277 (N)	0.112 (N)	91 (N)
218*	13.9 (N)	40 (N)	4.4 (N)	263 (N)	0.083 (N)	91 (N)
275*	14 (N)	41 (N)	4.4 (N)	282 (N)	0.105 (N)	93 (N)
333*	14.5 (N)	42 (N)	4.6 (N)	298 (N)	0.131 (H)	93 (N)
* denotes the Maintenance study day. 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)
-17	6.1 (N)	3.22 (N)	2.15 (N)	0.4 (N)	0.04 (N)	0.29 (N)
1	6.77 (N)	4.89 (N)	1.35 (N)	0.37 (N)	0.04 (N)	0.11 (N)
18	5.62 (N)	3.57 (N)	1.55 (N)	0.3 (N)	0.05 (N)	0.15 (N)
29	5.76 (N)	4 (N)	1.39 (N)	0.24 (N)	0.03 (N)	0.1 (N)
43	5.7 (N)	3.56 (N)	1.7 (N)	0.33 (N)	0.01 (N)	0.11 (N)
69	7.07 (N)	5.25 (N)	1.45 (N)	0.27 (N)	0.02 (N)	0.07 (N)
-9*	7.07 (N)	5.25 (N)	1.45 (N)	0.27 (N)	0.02 (N)	0.07 (N)
22*	4.65 (N)	2.44 (N)	1.78 (N)	0.25 (N)	0.05 (N)	0.12 (N)
64*	5.39 (N)	3.61 (N)	1.53 (N)	0.19 (N)	0.01 (N)	0.06 (N)
106*	5.9 (N)	3.22 (N)	2.28 (N)	0.23 (N)	0.02 (N)	0.15 (N)
162*	5.52 (N)	2.98 (N)	2.22 (N)	0.23 (N)	0.02 (N)	0.08 (N)
218*	6.32 (N)	4.39 (N)	1.66 (N)	0.22 (N)	0.02 (N)	0.03 (N)
275*	7.03 (N)	5.02 (N)	1.48 (N)	0.29 (N)	0.03 (N)	0.21 (N)
333*	6.06 (N)	3.83 (N)	1.96 (N)	0.19 (N)	0.02 (N)	0.07 (N)
* denotes the Maintenance study day. 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)
-17	Yes	13 (N)	15 (N)	61 (N)	0.4 (N)	0.64 (N)
1	Yes	16 (N)	18 (N)	68 (N)	0.7 (N)	0.79 (N)
18	Yes	12 (N)	15 (N)	57 (N)	0.5 (N)	0.68 (N)
29	Yes	12 (N)	15 (N)	61 (N)	0.6 (N)	0.84 (N)
43	No	12 (N)	16 (N)	61 (N)	0.8 (N)	0.88 (N)
69	Yes	12 (N)	14 (N)	63 (N)	0.5 (N)	0.76 (N)
-9*	Yes	12 (N)	14 (N)	63 (N)	0.5 (N)	0.76 (N)
22*	No	20 (N)	16 (N)	64 (N)	0.4 (N)	0.8 (N)
64*	Yes	10 (N)	17 (N)	46 (N)	0.6 (N)	0.75 (N)
106*	Yes	19 (N)	19 (N)	49 (N)	0.3 (N)	0.63 (N)
162*	Yes	12 (N)	15 (N)	43 (N)	0.5 (N)	0.68 (N)
218*	No	13 (N)	21 (N)	46 (N)	0.8 (N)	0.72 (N)
275*	Yes	13 (N)	15 (N)	46 (N)	0.6 (N)	0.69 (N)
333*	Yes	19 (N)	19 (N)	50 (N)	0.6 (N)	0.79 (N)
* denotes the Maintenance study day. 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)
-17	Yes	137.4 (H)	81 (N)	67 (L)	0.98 (N)
1	Yes	108 (N)	52 (N)	85 (N)	2.91 (N)
18	Yes	123.6 (H)	46 (N)	87 (N)	0.2 (N)
29	Yes	104.4 (N)	60 (N)	142 (H)	<0.20 (N)
43	No	97.8 (N)	56 (N)	80 (N)	0.33 (N)
69	Yes	112.2 (N)	60 (N)	87 (N)	4.9 (N)
-9*	Yes	112.2 (N)	60 (N)	87 (N)	4.9 (N)
22*	No	102.6 (N)	36 (N)	79 (N)	0.54 (N)
64*	Yes	112.2 (N)	94 (N)	114 (H)	<0.20 (N)
106*	Yes	132.6 (H)	67 (N)	79 (N)	<0.20 (N)
162*	Yes	126.6 (H)	61 (N)	78 (N)	<0.20 (N)
218*	No	118.2 (H)	638 (H)	91 (N)	0.2 (N)
275*	Yes	126.6 (H)	65 (N)	99 (N)	<0.20 (N)
333*	Yes	111 (N)	81 (N)	83 (N)	<0.20 (N)
* denotes the Maintenance study day. 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	210 (N)	63 (N)	152 (H)	69 (N)
69	Yes	177 (N)	67 (N)	118 (N)	44 (N)
-9*	Yes	177 (N)	67 (N)	118 (N)	44 (N)
106*	Yes	176 (N)	57 (N)	120 (N)	73 (N)
333*	Yes	199 (N)	60 (N)	143 (H)	61 (N)
* denotes the Maintenance study day. H = High; L = Low; N = Normal.					

被験者識別番号：[redacted]

投与群：寛解導入試験－プラセボ群（コホート B）

治験薬の投与状況：寛解導入試験－有害事象により投与中止（Day 9）；寛解維持試験－不参加

ベースライン特性：本被験者は 1[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。

好中球減少症（Day 1～継続）（投与中止に至った有害事象）（寛解導入試験）：
Day 1、Grade 2 の非重篤な好中球減少症が発現した。寛解導入治験薬に対する処置は投与中止であった。寛解維持治験薬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。試験終了時点で本事象は未回復であった。

潰瘍性大腸炎（Day 17～継続）（試験治療下の重篤な有害事象）（寛解導入試験）：
Day 17、Grade 3 の重篤な潰瘍性大腸炎が発現した。寛解導入治験薬に対する処置は非該当であった。寛解維持治験薬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。試験終了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**
colitis ulcerative	Ongoing

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
esomeprazole magnesium	PREVENTION OF GASTRIC ULCERS	ORAL	-233 days	Ongoing
clostridium butyricum	FUNCTIONAL REGULATION OF INTESTINE	ORAL	-231 days	Ongoing
ferrous sodium citrate	ANEMIA DUE TO ULCERATIRE COLITIS	ORAL	24 days	Ongoing
infliximab	ULCERATIVE COLITIS	INTRAVENOUS	-457 days	-112 days
ascorbic acid;macrogol 3350;potassium chloride;sodium ascorbate;sodium chloride;sodium sulfate	COLONOSCOPY PREP	ORAL	-5 days	-5 days
flumazenil	COLONOSCOPY PREP	INTRAVENOUS	-5 days	-5 days
glucose;potassium chloride;sodium chloride;sodium lactate	COLONOSCOPY PEEP	INTRAVENOUS	-5 days	-5 days
hyoscine butylbromide	COLONOSCOPY PREP	INTRAVENOUS	-5 days	-5 days
lidocaine	COLONOSCOPY PREP	TOPICAL	-5 days	-5 days
midazolam	COLONOSCOPY PREP	INTRAVENOUS	-5 days	-5 days
naloxone hydrochloride	COLONOSCOPY PREP	INTRAVENOUS	-5 days	-5 days
pethidine hydrochloride	COLONOSCOPY PREP	INTRAVENOUS	-5 days	-5 days
mercaptopurine	ULCERATIVE COLITIS	ORAL	-217 days	10 days
tacrolimus	ULCERATIVE COLITIS	ORAL	18 days	22 days

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
tacrolimus	ULCERATIVE COLITIS	ORAL	23 days	25 days
tacrolimus	ULCERATIVE COLITIS	ORAL	26 days	51 days

All Adverse Events							
Preferred Term	**Onset Day**	**Resolution Day**	**Toxicity Grade**	**Causality**	**Action taken with Induction Drug**	**Action taken with Maintenance Drug**	**Action - Other**
Neutropenia	1	Ongoing	2	related	drug withdrawn	not applicable	permanent study discontinuation
Colitis ulcerative	17	Ongoing	3	not related	not applicable	not applicable	medication required
* denotes the Maintenance study day.							

Hematology						
Study Day	Hemoglobin (g/dL)	Hematocrit (%)	Erythrocytes (x10^6/uL)	Platelets (x10^3/uL)	Reticulocytes (x10^6/uL)	Ery. Mean Corpuscular Volume (fL)
-19	9.6 (L)	28 (L)	2.7 (L)	428 (H)	0.06 (N)	104 (H)
-14	8.4 (L)	24 (L)	2.3 (L)	413 (H)	0.05 (N)	104 (H)
1	8.7 (L)	26 (L)	2.5 (L)	352 (N)	0.079 (N)	105 (H)
8	8.3 (L)	25 (L)	2.4 (L)	407 (H)		108 (H)
10	7.8 (L)	24 (L)	2.2 (L)	407 (H)	0.063 (N)	108 (H)
37	10.4 (L)	33 (L)	3 (L)	328 (N)	0.156 (H)	109 (H)
* denotes the Maintenance study day. 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)
-19	2.8 (L)	1.49 (L)	1.03 (N)	0.2 (N)	0.03 (N)	0.06 (N)
-14	3.35 (L)	1.51 (L)	1.34 (N)	0.17 (N)	0 (N)	0.1 (N)
1	2.14 (L)	0.73 (L)	0.92 (N)	0.17 (N)	0 (N)	0.11 (N)
8	2.04 (L)	0.63 (L)	1.06 (N)	0.14 (N)	0.02 (N)	0.1 (N)
10	2.63 (L)	0.92 (L)	1.18 (N)	0.24 (N)	0.05 (N)	0.03 (N)
37	4.94 (N)	2.52 (N)	1.88 (N)	0.15 (N)	0.05 (N)	0.05 (N)
* denotes the Maintenance study day. 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)
-19	Yes	6 (N)	10 (L)	69 (N)	0.4 (N)	0.76 (N)
1	Yes	8 (N)	11 (N)	64 (N)	0.3 (N)	0.69 (N)
8	Yes	7 (N)	9 (L)	65 (N)	0.4 (N)	0.66 (N)
10	Yes	10 (N)	11 (N)	70 (N)	0.4 (N)	0.53 (N)
37	No	11 (N)	15 (N)	80 (N)	0.2 (N)	0.67 (N)
* denotes the Maintenance study day. 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)
-19	Yes	91.8 (N)	31 (L)	109 (H)	2.95 (N)
1	Yes	97.2 (N)	28 (L)	95 (N)	3.27 (N)
8	Yes	102.6 (N)	24 (L)	90 (N)	
10	Yes	126.6 (H)	26 (L)	105 (H)	5.25 (N)
37	No	102.6 (N)	287 (N)	115 (H)	0.21 (N)
* denotes the Maintenance study day. 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	116 (N)	49 (N)	55 (N)	89 (N)
8	Yes	113 (L)	50 (N)	45 (N)	101 (N)
10	Yes	120 (N)	53 (N)	54 (N)	107 (N)
* denotes the Maintenance study day. H = High; L = Low; N = Normal.					

被験者識別番号：[redacted]

投与群：寛解導入試験－フィルゴチニブ 200 mg 群（コホート B）；寛解維持試験－フィルゴチニブ 200 mg 群

治験薬の投与状況：寛解導入試験－完了；寛解維持試験－完了

ベースライン特性：本被験者は 2[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、インドからの参加であった。

裂肛（Day 22～22）（試験治療下の重篤な有害事象）（寛解導入試験）：
Day 22、Grade 3 の重篤な裂肛が発現した。寛解導入治験薬に対する処置は変更なし。寛解維持治験薬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 22、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**
mesalazine	ULCERATIVE COLITIS	ORAL	-1669 days	Ongoing
adalimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	-1014 days	-1014 days
adalimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	-1000 days	-1000 days
adalimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	-983 days	-983 days
adalimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	-969 days	-969 days
adalimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	-951 days	-951 days
adalimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	-928 days	-928 days
macrogol;potassium chloride;sodium bicarbonate;sodium chloride;sodium sulfate anhydrous	BOWEL PREPERATION FOR COLONOSCOPY	ORAL	-3 days	-3 days
ofloxacin;ornidazole	ANTI DIARRHEAL	ORAL	22 days	26 days
diltiazem hydrochloride	FOR ANAL FISSURE	TOPICAL	22 days	35 days
hyoscine butylbromide	FOR RELIEF OF SPASM	ORAL	22 days	35 days
paracetamol;tramadol hydrochloride	PAINKILLER	ORAL	22 days	35 days
rabeprazole sodium	FOR ACIDITY	ORAL	22 days	35 days
folic acid	VITAMIN SUPPLIMENT	ORAL	17 days	46 days
macrogol;potassium chloride;sodium bicarbonate;sodium chloride;sodium sulfate anhydrous	BOWEL PREPERATION FOR COLONOSCOPY	ORAL	73 days	73 days
folic acid	VITAMIN SUPPLEMENT	ORAL	99 days	122 days

All Adverse Events							
Preferred Term	Onset Day	Resolution Day	Toxicity Grade	Causality	Action taken with Induction Drug	Action taken with Maintenance Drug	Action - Other
Anal fissure	22	22	3	not related	dose not changed	not applicable	medication required
* denotes the Maintenance study day.							

Hematology						
Study Day	Hemoglobin (g/dL)	Hematocrit (%)	Erythrocytes (x10^6/uL)	Platelets (x10^3/uL)	Reticulocytes (x10^6/uL)	Ery. Mean Corpuscular Volume (fL)
-34	6.5 (L)	25 (L)	4.2 (N)	351 (N)	0.088 (N)	60 (L)
-13	8.6 (L)	33 (L)	4.7 (N)	305 (N)		70 (L)
1	8.3 (L)	32 (L)	4.4 (N)	364 (N)	0.058 (N)	71 (L)
17	8.5 (L)	32 (L)	4.5 (N)	385 (N)	0.068 (N)	71 (L)
35	8.3 (L)	32 (L)	4.4 (N)	541 (H)	0.059 (N)	72 (L)
57	7.8 (L)	30 (L)	4.2 (N)	260 (N)	0.075 (N)	73 (L)
70	7.8 (L)	30 (L)	4.3 (N)	225 (N)	0.075 (N)	70 (L)
73	8.1 (L)	33 (L)	4.5 (N)	241 (N)	0.056 (N)	73 (L)
-13*	8.1 (L)	33 (L)	4.5 (N)	241 (N)	0.056 (N)	73 (L)
14*	7.8 (L)	29 (L)	4.3 (N)	208 (N)	0.092 (N)	68 (L)
23*	10 (L)	35 (N)	4.8 (N)	443 (H)	0.081 (N)	73 (L)
56*	10.7 (L)	34 (N)	4.3 (N)	288 (N)	0.039 (N)	79 (N)
101*	12.1 (N)	41 (N)	4.9 (N)	259 (N)	0.064 (N)	84 (N)
160*	11 (L)	39 (N)	4.7 (N)	287 (N)	0.087 (N)	82 (N)
211*	10 (L)	36 (N)	4.5 (N)	220 (N)	0.062 (N)	81 (N)
270*	9.1 (L)	34 (N)	4.6 (N)	218 (N)	0.082 (N)	73 (L)
328*	8.2 (L)	31 (L)	4.5 (N)	299 (N)	0.063 (N)	69 (L)
* denotes the Maintenance study day. 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)
-34	7.38 (N)	3.9 (N)	2.87 (N)	0.54 (N)	0.04 (N)	0.03 (N)
-13	9.67 (N)	7.01 (N)	1.55 (N)	1.06 (H)	0.03 (N)	0.02 (N)
1	6.4 (N)	3.45 (N)	2.57 (N)	0.29 (N)	0.03 (N)	0.06 (N)
17	11.88 (H)	8.71 (H)	2.49 (N)	0.57 (N)	0.05 (N)	0.06 (N)
35	5.82 (N)	2.74 (N)	2.7 (N)	0.32 (N)	0.02 (N)	0.03 (N)
57	8.68 (N)	5.34 (N)	2.78 (N)	0.5 (N)	0.03 (N)	0.04 (N)
70	7.29 (N)	4.59 (N)	2.08 (N)	0.54 (N)	0.04 (N)	0.04 (N)
73	6.12 (N)	3.9 (N)	1.82 (N)	0.35 (N)	0.02 (N)	0.03 (N)
-13*	6.12 (N)	3.9 (N)	1.82 (N)	0.35 (N)	0.02 (N)	0.03 (N)
14*	5.11 (N)	2.35 (N)	2.44 (N)	0.28 (N)	0.04 (N)	0.02 (N)
23*	8.63 (N)	6.12 (N)	1.97 (N)	0.21 (N)	0.11 (N)	0.22 (N)
56*	8.27 (N)	5.72 (N)	2.19 (N)	0.18 (N)	0.04 (N)	0.15 (N)
101*	6.07 (N)	3.71 (N)	2.07 (N)	0.19 (N)	0.05 (N)	0.05 (N)
160*	6.35 (N)	3.36 (N)	2.52 (N)	0.36 (N)	0.06 (N)	0.04 (N)
211*	7.24 (N)	5.14 (N)	1.55 (N)	0.47 (N)	0.05 (N)	0.03 (N)
270*	7.35 (N)	4.93 (N)	1.53 (N)	0.77 (N)	0.06 (N)	0.04 (N)
328*	5.64 (N)	3.93 (N)	1.3 (N)	0.33 (N)	0.04 (N)	0.03 (N)

* denotes the Maintenance study day.
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)
-34	Yes	<4 (L)	17 (N)	77 (N)	<0.2 (L)	0.51 (N)
1	Yes	<4 (L)	13 (N)	81 (N)	<0.2 (L)	0.46 (N)
17	Yes	<4 (L)	13 (N)	94 (N)	0.2 (N)	0.51 (N)
35	Yes	<4 (L)	17 (N)	83 (N)	<0.2 (L)	0.52 (N)
57	Yes	<4 (L)	15 (N)	86 (N)	0.2 (N)	0.49 (N)
73	Yes	<4 (L)	17 (N)	88 (N)	0.2 (N)	0.49 (N)
-13*	Yes	<4 (L)	17 (N)	88 (N)	0.2 (N)	0.49 (N)
14*	Yes	<4 (L)	16 (N)	71 (N)	0.2 (N)	0.52 (N)
56*	Yes	<4 (L)	15 (N)	60 (N)	0.2 (N)	0.52 (N)
101*	Yes	<4 (L)	15 (N)	71 (N)	<0.2 (L)	0.54 (N)
160*	Yes	<4 (L)	17 (N)	70 (N)	0.3 (N)	0.57 (N)
211*	Yes	<4 (L)	19 (N)	66 (N)	0.3 (N)	0.53 (N)
270*	Yes	5 (L)	18 (N)	66 (N)	0.2 (N)	0.55 (N)
328*	Yes					

* denotes the Maintenance study day.
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)
-34	Yes	123 (H)	29 (N)	89 (N)	0.54 (N)
1	Yes	130.8 (H)	22 (L)	97 (N)	3.09 (N)
17	Yes	114 (N)	22 (L)	91 (N)	3.04 (N)
35	Yes	114.6 (N)	25 (L)	97 (N)	2.12 (N)
57	Yes	127.2 (H)	92 (N)	98 (N)	0.23 (N)
73	Yes	126.6 (H)	42 (N)	94 (N)	0.4 (N)
-13*	Yes	126.6 (H)	42 (N)	94 (N)	0.4 (N)
14*	Yes	123 (H)	43 (N)	88 (N)	<0.20 (N)
56*	Yes	130.2 (H)	45 (N)	92 (N)	<0.20 (N)
101*	Yes	124.2 (H)	43 (N)	90 (N)	0.53 (N)
160*	Yes	124.8 (H)	69 (N)	94 (N)	0.25 (N)
211*	Yes	135.6 (H)	155 (N)	92 (N)	1.16 (N)
270*	Yes	133.2 (H)	58 (N)	87 (N)	1.34 (N)
328*	Yes				1.37 (N)
* denotes the Maintenance study day. 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)
-34	Yes	133 (N)	82 (H)	48 (N)	50 (N)
1	Yes	148 (N)	68 (N)	77 (N)	65 (N)
35	Yes	159 (N)	84 (H)	66 (N)	93 (N)
73	Yes	188 (N)	119 (H)	76 (N)	42 (N)
-13*	Yes	188 (N)	119 (H)	76 (N)	42 (N)
101*	Yes	200 (N)	126 (H)	85 (N)	59 (N)
160*	Yes	210 (N)	115 (H)	102 (N)	64 (N)
211*	Yes	191 (N)	111 (H)	89 (N)	51 (N)
270*	Yes	181 (N)	104 (H)	88 (N)	61 (N)
328*	Yes	162 (N)	84 (H)	83 (N)	
* denotes the Maintenance study day. H = High; L = Low; N = Normal.					

被験者識別番号：[redacted]

投与群：寛解導入試験－フィルゴチニブ 100 mg 群（コホート A）

治験薬の投与状況：寛解導入試験－完了；寛解維持試験－不参加

ベースライン特性：本被験者は 2[redacted] 歳の黒人又はアフリカ系米国人女性であった。その他の特性として、民族は非ヒスパニック／ラテン系、米国からの参加であった。

蜂巣炎（Day 3 頃～63 頃）（試験治療下の注目すべき有害事象）（寛解導入試験）：
Day 3 頃に、Grade 2 の非重篤な蜂巣炎が発現した。寛解導入治験薬に対する処置は変更なし。寛解維持治験薬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 63 頃に、Grade 2 の本事象は回復した。

卵巣嚢胞破裂（Day 65～67）（試験治療下の重篤な有害事象）（寛解導入試験）：
Day 65、Grade 3 の重篤な卵巣嚢胞破裂が発現した。寛解導入治験薬に対する処置は変更なし。寛解維持治験薬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 67、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**
anxiety	Ongoing
arthritis	Ongoing
colitis ulcerative	Ongoing
ovarian cyst	Ongoing
pneumonia	About -91 days
rash	-30 days
rash	-30 days

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
ethinylestradiol;ferrous fumarate;norethisterone acetate	ORAL CONTRACEPTIVE	ORAL	About -1245 days	Ongoing
mesalazine	ULCERATIVE COLITIS	RECTAL	-2350 days	-2336 days
sulfasalazine	ULCERATIVE COLITIS	ORAL	About -3071 days	About -1976 days
prednisone	ULCERATIVE COLITIS	ORAL	About -1763 days	About -1672 days
prednisone	ULCERATIVE COLITIS	ORAL	About -1641 days	About -1521 days
budesonide	ULCERATIVE COLITIS	ORAL	About -1002 days	About -942 days

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
mesalazine	ULCERATIVE COLITIS	RECTAL	-903 days	About -790 days
propofol	FLEX-SIG SEDATION	INTRAVENOUS	-21 days	-21 days
sodium phosphate dibasic;sodium phosphate monobasic	FLEX-SIG PREP	RECTAL	-21 days	-21 days
amoxicillin	RIGHT ARM CELLULITIS	ORAL	8 days	8 days
mesalazine	ULCERATIVE COLITIS	ORAL	-391 days	About 32 days
iohexol	CT SCAN (CONTRAST)	INTRAVENOUS	65 days	65 days
sodium chloride	REHYDRATION THERAPY FOR INTRACTALBE NAUSEA DURING HOSPITALIZATION (R/T OVARIAN CYST RUPTURE)	INTRAVENOUS	65 days	67 days
propofol	FLEX-SIG SEDATION	INTRAVENOUS	73 days	73 days
sodium phosphate dibasic;sodium phosphate monobasic	FLEX-SIG PREP	RECTAL	73 days	73 days

All Adverse Events							
Preferred Term	Onset Day	Resolution Day	Toxicity Grade	Causality	Action taken with Induction Drug	Action taken with Maintenance Drug	Action - Other
Cellulitis	About 3	About 63	2	not related	dose not changed	not applicable	medication required
Drug hypersensitivity	About 3	About 32	1	not related	dose not changed	not applicable	none
Ovarian cyst ruptured	65	67	3	not related	dose not changed	not applicable	medication required + other treatment required
* denotes the Maintenance study day.							

Hematology						
Study Day	Hemoglobin (g/dL)	Hematocrit (%)	Erythrocytes (x10^6/uL)	Platelets (x10^3/uL)	Reticulocytes (x10^6/uL)	Ery. Mean Corpuscular Volume (fL)
-48	14.8 (N)	47 (N)	5.4 (N)	267 (N)	0.068 (N)	87 (N)
1	14.1 (N)	43 (N)	4.9 (N)	243 (N)	0.101 (N)	88 (N)
15	14.4 (N)	47 (N)	5.3 (N)	351 (N)	0.095 (N)	89 (N)
28	14.4 (N)	46 (N)	5.3 (N)	238 (N)	0.077 (N)	88 (N)
43	13.5 (N)	45 (N)	5 (N)	277 (N)	0.069 (N)	90 (N)
73	13.5 (N)	42 (N)	4.8 (N)	255 (N)	0.063 (N)	86 (N)
* denotes the Maintenance study day. 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)
-48	10.24 (N)	6.29 (N)	2.75 (N)	0.89 (N)	0.06 (N)	0.25 (N)
1	10.37 (N)	7.58 (H)	1.88 (N)	0.61 (N)	0.03 (N)	0.28 (N)
15	11.17 (H)	7.06 (N)	2.99 (N)	0.85 (N)	0.06 (N)	0.22 (N)
28	9.97 (N)	6.97 (N)	2.08 (N)	0.63 (N)	0.03 (N)	0.26 (N)
43	8.52 (N)	5.24 (N)	2.51 (N)	0.62 (N)	0.02 (N)	0.13 (N)
73	7.44 (N)	4.89 (N)	1.82 (N)	0.56 (N)	0.01 (N)	0.16 (N)
* denotes the Maintenance study day. 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)
-48	No	10 (N)	19 (N)	71 (N)	0.4 (N)	0.73 (N)
1	Yes	10 (N)	17 (N)	82 (N)	0.5 (N)	0.73 (N)
15	Yes	17 (N)	23 (N)	77 (N)	0.5 (N)	0.78 (N)
28	Yes	13 (N)	21 (N)	74 (N)	0.4 (N)	0.78 (N)
43	Yes	13 (N)	20 (N)	70 (N)	0.2 (N)	0.82 (N)
73	Yes			64 (N)	<0.2 (L)	0.8 (N)
* denotes the Maintenance study day. 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)
-48	No	118.3 (H)	89 (N)	106 (H)	0.45 (N)
1	Yes	120.9 (H)	106 (N)	91 (N)	1.22 (N)
15	Yes	114.7 (N)	90 (N)	73 (N)	0.44 (N)
28	Yes	115.6 (H)	85 (N)	94 (N)	0.59 (N)
43	Yes	109.1 (N)	98 (N)	78 (N)	0.96 (N)
73	Yes	110.9 (N)		86 (N)	2.79 (N)
* denotes the Maintenance study day. 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	217 (N)	94 (H)	116 (N)	61 (N)
73	Yes	191 (N)	90 (H)	91 (N)	81 (N)
* denotes the Maintenance study day. H = High; L = Low; N = Normal.					

被験者識別番号：[redacted]

投与群：寛解導入試験－プラセボ群（コホート B）

治験薬の投与状況：寛解導入試験－有害事象により投与中止（Day 65）；寛解維持試験－不参加

ベースライン特性：本被験者は 3[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。

脳血管発作（Day 65～110）（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）（寛解導入試験）：
Day 65、Grade 4 の重篤な脳血管発作が発現した。寛解導入治験薬に対する処置は投与中止であった。寛解維持治験薬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 110、Grade 4 の本事象は回復した。

その他の関連情報：寛解導入試験の Day 65 に Grade 4 の脳血管発作が発現した。診察時に、全感覚運動障害、左半側空間無視、左側半盲及び構語障害が認められた。磁気共鳴画像検査結果に基づき、被験者は右頸動脈末端の亜閉塞性血栓を伴う右シルビウス溝及び右側後部虚血性脳血管発作と診断された。コンピューター断層撮影による追跡検査の結果、右大脳半球に 7 mm の正中線偏位を伴う重度の浮腫並びに右大脳鎌下及び鉤ヘルニアが認められた。その後、緊急の頭蓋骨部分切除術が実施された。さらに、アスピリンが投与され、治療薬としてアトルバスタチン、メチルプレドニゾロン及びエノキサパリンが投与された。被験者は退院し、脳卒中の後遺症が認められた。

Medical History	
Medical History	**Resolution**
colitis ulcerative	Ongoing
pancreatitis acute	About -640 days

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
prednisolone	ULCERATIVE COLITIS	ORAL	About 61 days	Ongoing
acetylsalicylic acid	CEREBROVASCULAR STROKKE	ORAL	65 days	Ongoing
enoxaparin	CEREBROVASCULAR STROKKE	SUBCUTANEOUS	65 days	Ongoing
paracetamol	CEREBROVASCULAR STROKKE	OTHER	65 days	Ongoing
golimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	About -1158 days	About -1098 days
golimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	About -1128 days	About -977 days
adalimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	About -670 days	About -551 days
mesalazine	ULCERATIVE COLITIS	ORAL	-1004 days	About -306 days
infliximab	ULCERATIVE COLITIS	INTRAVENOUS	About -580 days	About -247 days
vedolizumab	ULCERATIVE COLITIS	INTRAVENOUS	About -274 days	About -94 days
prednisone	ULCERATIVE COLITIS	ORAL	About -62 days	65 days
atorvastatin	CEREBROVASCULAR STROKKE	ORAL	65 days	About 65 days
ceftriaxone sodium	CEREBROVASCULAR STROKKE	INTRAVENOUS	65 days	About 65 days
hydrocortisone sodium succinate	ULCERATIVE COLITIS	INTRAVENOUS	65 days	About 65 days
insulin	CEREBROVASCULAR STROKKE	SUBCUTANEOUS	65 days	About 65 days
methylprednisolone	CEREBROVASCULAR BROKE	INTRAVENOUS	65 days	About 65 days
metronidazole	CEREBROVASCULAR STROKKE	INTRAVENOUS	65 days	About 65 days
prednisolone	ULCERATIVE COLITIS	INTRAVENOUS	65 days	About 65 days

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
gentamicin	CEREBROVASCULAR STROKKE	INTRAVENOUS	77 days	About 91 days
piperacillin;tazobactam	CEREBROVASCULAR STROKKE	INTRAVENOUS	77 days	About 91 days

All Adverse Events							
Preferred Term	**Onset Day**	**Resolution Day**	**Toxicity Grade**	**Causality**	**Action taken with Induction Drug**	**Action taken with Maintenance Drug**	**Action - Other**
Cerebrovascular accident	65	110	4	not related	drug withdrawn	not applicable	medication required + other treatment required + permanent study discontinuation
* denotes the Maintenance study day.							

Hematology						
Study Day	Hemoglobin (g/dL)	Hematocrit (%)	Erythrocytes (x10^6/uL)	Platelets (x10^3/uL)	Reticulocytes (x10^6/uL)	Ery. Mean Corpuscular Volume (fL)
-28	15.3 (N)	49 (N)	5.6 (N)	450 (H)	0.071 (N)	88 (N)
-11	15.6 (N)	50 (N)	5.7 (N)	485 (H)	0.083 (N)	87 (N)
1	15.1 (N)	45 (N)	5.4 (N)		0.091 (N)	84 (N)
12	15 (N)	46 (N)	5.3 (N)	512 (H)	0.112 (N)	86 (N)
* denotes the Maintenance study day. 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)
-28	12.88 (H)	7.98 (H)	3.69 (N)	1.01 (H)	0.08 (N)	0.13 (N)
-11	12.32 (H)	6.33 (N)	5.01 (H)	0.81 (N)	0.06 (N)	0.11 (N)
1	12.58 (H)	7.12 (N)	4.36 (H)	0.81 (N)	0.07 (N)	0.23 (N)
12	18.9 (H)	11.42 (H)	5.55 (H)	1.48 (H)	0.2 (N)	0.24 (N)
* denotes the Maintenance study day. 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)
-28	No	25 (N)	14 (N)	54 (N)	0.4 (N)	0.84 (N)
-11	No	25 (N)	14 (N)	56 (N)	0.6 (N)	0.96 (N)
1	No	23 (N)	15 (N)	49 (N)	0.6 (N)	0.9 (N)
12	No	19 (N)	10 (L)	53 (N)	0.4 (N)	0.83 (N)
27	Yes	21 (N)	13 (N)	54 (N)	0.5 (N)	0.92 (N)
41	No	16 (N)	11 (N)	46 (N)	0.4 (N)	0.89 (N)
* denotes the Maintenance study day. 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)
-28	No	120.6 (N)	89 (N)	88 (N)	3.37 (N)
-11	No	105 (N)	80 (N)	86 (N)	
1	No	110.4 (N)	68 (N)	92 (N)	7.94 (N)
12	No	121.2 (N)	72 (N)	66 (L)	4 (N)
27	Yes	112.2 (N)	55 (N)	74 (N)	22.4 (H)
41	No	112.2 (N)	61 (N)	92 (N)	11.8 (H)
* denotes the Maintenance study day. 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)
-11	No	239 (N)	59 (N)	153 (H)	186 (N)
1	No	211 (N)	46 (N)	132 (H)	213 (N)
* denotes the Maintenance study day. H = High; L = Low; N = Normal.					