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 51）；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、米国からの参加であった。

蜂巣炎（Day 52～81）（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、試験治療下の注目すべき有害事象［TE-AEI］）（寛解導入試験）：
Day 52、Grade 3 の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 81、Grade 3 の本事象は回復した。

骨髄炎（Day 53～81）（TE-SAE、TE-AEI）（寛解導入試験）：
Day 53、Grade 3 の重篤な骨髄炎が発現した。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 81、Grade 3 の本事象は回復した。

潰瘍性大腸炎（Day 54～81）（TE-SAE）（寛解導入試験）：
Day 54、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。Day 81、Grade 3 の本事象は回復した。

その他の関連情報：治験責任医師によると、本被験者は右つま先をぶつけたため徐々に赤く腫れあがった。その後被験者は、寛解導入試験 Day 52 に蜂巣炎及び皮下組織膿瘍疑いのため入院した。右足指の創面切除術を受け、第 5 足指が切除された。被験者は最終的に骨髄炎と診断され、抗生剤の静脈内投与による治療が行われた。

Medical History	
Medical History	**Resolution**
colitis ulcerative	Ongoing
haemorrhoids	Ongoing
osteoporosis	Ongoing
pseudopolyposis	Ongoing
rheumatoid arthritis	Ongoing
scoliosis	Ongoing
vitamin d deficiency	Ongoing
caesarean section	-9332 days
hysterectomy	-4385 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
balsalazide sodium	ULCERATIVE COLITIS	ORAL	-2174 days	Ongoing
mercaptopurine	ULCERATIVE COLITIS	ORAL	-1832 days	Ongoing
fish oil	NUTRITIONAL SUPPLEMENT	ORAL	About-1484 days	Ongoing
calcium	NUTRITIONAL SUPPLEMENT	ORAL	About-1272 days	Ongoing
vitamins nos	NUTRITIONAL SUPPLEMENT	ORAL	About-1119 days	Ongoing
hydrocodone bitartrate;paracetamol	RIGHT FOOT PAIN	ORAL	48 days	Ongoing

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
prednisone	RIGHT FOOT PAIN	ORAL	48 days	Ongoing
prednisone	ULCERATIVE COLITIS	ORAL	-1876 days	About-1689 days
prednisone	ULCERATIVE COLITIS	ORAL	-1260 days	-1166 days
budesonide	ULCERATIVE COLITIS	ORAL	-418 days	-398 days
prednisone	ULCERATIVE COLITIS	ORAL	-398 days	-367 days
prednisone	ULCERATIVE COLITIS	ORAL	-322 days	About-269 days
mesalazine	ULCERATIVE COLITIS	RECTAL	-351 days	About-238 days
magnesium sulfate;potassium sulfate;sodium sulfate	BOWEL PREP	ORAL	-8 days	-7 days
midazolam hydrochloride	PROCEDURAL SEDATION	INTRAVENOUS	-7 days	-7 days
propofol	PROCEDURAL SEDATION	INTRAVENOUS	-7 days	-7 days
triamcinolone acetonide	RIGHT FOOT PAIN	INTRAMUSCULAR	48 days	48 days
ciprofloxacin	CELLULITIS RIGHT FOOT	ORAL	52 days	62 days
hydromorphone hydrochloride	RIGHT FOOT PAIN	INTRAVENOUS	52 days	81 days
vancomycin	OSTEOMYELITIS	INTRAVENOUS	52 days	81 days
meropenem	CELLULITIS RIGHT FOOT	INTRAVENOUS	53 days	81 days
methylprednisolone sodium succinate	ULCERATIVE COLITIS	INTRAVENOUS	54 days	81 days
paracetamol	FEVER	ORAL	54 days	81 days
nystatin	CANDIDIA PROPHYLAXIS	ORAL	58 days	81 days
saccharomyces boulardii	C. DIFF PROPHYLAXIS	ORAL	58 days	81 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
Thrombocytopenia	About 37	81	1	not related	not applicable	not applicable	none
Arthralgia	38	Ongoing	2	not related	dose not changed	not applicable	none
Oedema peripheral	38	Ongoing	2	not related	dose not changed	not applicable	none
Pain in extremity	43	81	2	not related	dose not changed	not applicable	medication required
Cellulitis	52	81	3	related	drug withdrawn	not applicable	medication required + other treatment required
Malnutrition	52	81	1	not related	not applicable	not applicable	none
Osteomyelitis	53	81	3	not related	not applicable	not applicable	medication required + other treatment required + permanent study discontinuation

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	53	60	3	not related	not applicable	not applicable	medication required
Anaemia	54	81	2	not related	not applicable	not applicable	other treatment required
Colitis ulcerative	54	81	3	not related	not applicable	not applicable	medication required
Hypoalbuminaemia	54	81	1	not related	not applicable	not applicable	none
Meniscus injury	57	Ongoing	2	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)
-28	12 (N)	36 (N)	4.1 (N)	284 (N)	0.081 (N)	88 (N)
1	12.9 (N)	39 (N)	4.4 (N)	276 (N)	0.076 (N)	89 (N)
15	12.3 (N)	37 (N)	4.1 (N)	263 (N)	0.066 (N)	90 (N)
29	12.1 (N)	35 (N)	4 (L)	299 (N)	0.054 (N)	88 (N)
43	12 (N)	35 (N)	3.9 (L)	340 (N)	0.068 (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)
-28	6.46 (N)	3.09 (N)	2.84 (N)	0.36 (N)	0.04 (N)	0.12 (N)
1	8.03 (N)	3.94 (N)	3.46 (N)	0.36 (N)	0.06 (N)	0.22 (N)
15	6.54 (N)	3.36 (N)	2.62 (N)	0.34 (N)	0.03 (N)	0.19 (N)
29	8.51 (N)	5.15 (N)	2.4 (N)	0.47 (N)	0.03 (N)	0.45 (N)
43	11.38 (H)	8.69 (H)	2.12 (N)	0.41 (N)	0.05 (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)
-28		20 (N)	21 (N)	60 (N)	0.4 (N)	0.69 (N)
1		19 (N)	26 (N)	52 (N)	0.6 (N)	0.65 (N)
15		16 (N)	20 (N)	52 (N)	0.4 (N)	0.7 (N)
29	Yes	16 (N)	21 (N)	54 (N)	0.6 (N)	0.75 (N)
43	Yes	11 (N)	16 (N)	56 (N)	0.4 (N)	0.77 (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		77.5 (N)	288 (H)	81 (N)	1.27 (N)
1		82.2 (N)	226 (H)	63 (L)	1.2 (N)
15		75.8 (N)	188 (N)	95 (N)	3.47 (N)
29	Yes	70.7 (L)	312 (H)	97 (N)	3.44 (N)
43	Yes	69.5 (L)	130 (N)	96 (N)	4.36 (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)
-28		197 (N)			155 (N)
1		227 (N)			88 (N)
15		215 (N)			78 (N)
29	Yes	214 (N)	71 (N)	131 (H)	74 (N)
43	Yes	198 (N)	66 (N)	116 (N)	97 (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 22）；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。

潰瘍性大腸炎（Day 22～70）（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 22、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 70、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
computerised tomogram head	Ongoing
dizziness	Ongoing
gastritis	Ongoing
gastrooesophageal reflux disease	Ongoing
haemorrhoids	Ongoing
hypertension	Ongoing
iron deficiency anaemia	Ongoing
lipoma	Ongoing
persistent depressive disorder	Ongoing
renal cyst	Ongoing

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
mesalazine	ULCERATIVE COLITIS	ORAL	-1704 days	Ongoing
trimebutine maleate	IMPROVEMENT OF BOWEL MOTILITY	ORAL	-1582 days	Ongoing
calcium dobesilate	PROPHYLAXIS OF OSTEOPOROSIS	ORAL	-1526 days	Ongoing
ramipril	HYPERTENSION	ORAL	-1526 days	Ongoing
tianeptine sodium	DYSTHYMIA	ORAL	-1470 days	Ongoing
betahistine hydrochloride	DIZZINESS	ORAL	-1246 days	Ongoing
omeprazole	GASTRITIS	ORAL	-868 days	Ongoing
ferrous sulfate,folic acid	IRON DEFICIENCY ANEMIA	ORAL	-812 days	Ongoing

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
methylprednisolone	ULCERATIVE COLITIS	ORAL	-34 days	Ongoing
albumin tannate	TREATMENT AFTER HOSPITALIZATION DUE TO UC EXACERBATION, DIARRHEA	ORAL	92 days	Ongoing
enzyme preparations	TREATMENT AFTER HOSPITALIZATION DUE TO UC EXACERBATION	ORAL	92 days	Ongoing
pantoprazole sodium sesquihydrate	IN THE TREATMENT OF GASTRO-INTESTINAL DISEASES CAUSED BY HYDROCHLORIC ACID	ORAL	92 days	Ongoing
saccharomyces boulardii	TREATMENT AFTER HOSPITALIZATION DUE TO UC EXACERBATION, DIARRHEA	ORAL	92 days	Ongoing
investigational drug	ULCERATIVE COLITIS	SUBCUTANEOUS	-1835 days	-742 days
azathioprine	ULCERATIVE COLITIS	ORAL	About -1040 days	About -675 days
vedolizumab	ULCERATIVE COLITIS	INTRAVENOUS	-685 days	-685 days
ozanimod	ULCERATIVE COLITIS	ORAL	-526 days	-343 days
investigational drug	ULCERATIVE COLITIS	INTRAVENOUS	-266 days	-182 days
methylprednisolone	ULCERATIVE COLITIS	ORAL	-43 days	-35 days
atorvastatin	DURING HOSPITALIZATION DUE TO EXACERBATION OF UC	ORAL	22 days	35 days
hydrocortisone sodium succinate	ULCERATIVE COLITIS	INTRAVENOUS	22 days	35 days
iron isomaltoside 1000	DURING HOSPITALIZATION DUE TO EXACERBATION OF UC	INTRAVENOUS	22 days	35 days
mesalazine	ULCERATIVE COLITIS	ORAL	22 days	35 days
metronidazole	DURING HOSPITALIZATION DUE TO EXACERBATION OF UC	ORAL	22 days	35 days
prednisone	ULCERATIVE COLITIS	ORAL	22 days	35 days
enoxaparin sodium	DURING HOSPITALIZATION DUE TO EXACERBATION OF UC AND SCREENING TO BIOLOGIC TREATMENT	SUBCUTANEOUS	66 days	69 days
metronidazole	DURING HOSPITALIZATION DUE TO EXACERBATION OF UC AND SCREENING TO BIOLOGIC TREATMENT	ORAL	66 days	69 days
hydrocortisone sodium succinate	ULCERATIVE COLITIS	INTRAVENOUS	66 days	70 days
iron isomaltoside 1000	DURING HOSPITALIZATION DUE TO EXACERBATION OF UC AND SCREENING TO BIOLOGIC TREATMENT	INTRAVENOUS	66 days	70 days
albumin human	TREATMENT DURING HOSPITALIZATION OF CYTOMEGALY	INTRAVENOUS	70 days	91 days
albumin tannate	TREATMENT DURING HOSPITALIZATION OF CYTOMEGALY	ORAL	70 days	91 days
enoxaparin sodium	TREATMENT DURING HOSPITALIZATION OF CYTOMEGALY	SUBCUTANEOUS	70 days	91 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
ganciclovir	CYTOMEGALY	INTRAVENOUS	70 days	91 days
hydrocortisone	TREATMENT DURING HOSPITALIZATION OF CYTOMEGALY	INTRAVENOUS	70 days	91 days
metronidazole	TREATMENT DURING HOSPITALIZATION OF CYTOMEGALY	ORAL	70 days	91 days
nystatin	TREATMENT DURING HOSPITALIZATION OF CYTOMEGALY	ORAL	70 days	91 days
pancreatin	TREATMENT DURING HOSPITALIZATION OF CYTOMEGALY	ORAL	70 days	91 days
pantoprazole sodium sesquihydrate	TREATMENT DURING HOSPITALIZATION OF CYTOMEGALY	ORAL	70 days	91 days
paracetamol	TREATMENT DURING HOSPITALIZATION OF CYTOMEGALY	UNKNOWN	70 days	91 days
potassium chloride	TREATMENT DURING HOSPITALIZATION OF CYTOMEGALY	INTRAVENOUS	70 days	91 days
potassium chloride	TREATMENT DURING HOSPITALIZATION OF CYTOMEGALY	ORAL	70 days	91 days
saccharomyces boulardii	TREATMENT DURING HOSPITALIZATION OF CYTOMEGALY	ORAL	70 days	91 days
sodium chloride	TREATMENT DURING HOSPITALIZATION OF CYTOMEGALY	UNKNOWN	70 days	91 days
torasemide	TREATMENT DURING HOSPITALIZATION OF CYTOMEGALY	ORAL	70 days	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
Colitis ulcerative	22	70	3	not related	drug withdrawn	not applicable	permanent study discontinuation
Cytomegalovirus infection	70	91	3	related	not applicable	not applicable	medication required
Colitis ulcerative	71	Ongoing	2	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)
-28	12.3 (N)	38 (N)	4.4 (N)	251 (N)	0.053 (N)	86 (N)
1	11.9 (N)	36 (N)	4.3 (N)	303 (N)	0.062 (N)	84 (N)
15	10.7 (L)	33 (L)	3.9 (N)	347 (N)	0.067 (N)	85 (N)
101	11.4 (L)	35 (N)	3.8 (L)	598 (H)	0.074 (N)	92 (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	11.9 (H)	10.46 (H)	1.19 (N)	0.09 (L)	0.05 (N)	0.12 (N)
1	9.25 (N)	7.92 (H)	1.08 (N)	0.15 (N)	0.01 (N)	0.08 (N)
15	6.35 (N)	5.02 (N)	1.21 (N)	0.13 (N)	0 (N)	0 (N)
101	7.7 (N)	4.57 (N)	2.36 (N)	0.66 (N)	0.06 (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)
-28	Yes	22 (N)	18 (N)	70 (N)	0.4 (N)	0.87 (N)
1	Yes	25 (N)	16 (N)	85 (N)	0.3 (N)	0.81 (N)
15	Yes	19 (N)	15 (N)	79 (N)	0.3 (N)	0.88 (N)
101	Yes	16 (N)	14 (N)	170 (H)	0.2 (N)	0.6 (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	78 (N)	58 (N)	138 (H)	2.43 (N)
1	Yes	81.6 (N)	56 (N)	144 (H)	18.5 (H)
15	Yes	73.2 (L)	53 (N)	146 (H)	20.1 (H)
101	Yes	97.8 (N)	28 (N)	106 (H)	19.1 (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)
1	Yes	159 (L)	72 (N)	71 (N)	62 (N)
101	Yes	122 (L)	52 (N)	60 (N)	95 (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－有害事象により投与中止（Day 285*）

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、ドイツからの参加であった。

虫垂炎（Day 278*～284*）（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 278*、Grade 2 の重篤な虫垂炎が発現した。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 284*、Grade 2 の本事象は回復した。

その他の関連情報：腹痛の悪化が認められ、虫垂炎と診断された。低侵襲虫垂切除術が実施され、手術から完全回復した。
*寛解維持試験における study day

Medical History	
Medical History	**Resolution**
abdominal pain	Ongoing
abdominal pain	Ongoing
abdominal pain	Ongoing
colitis ulcerative	Ongoing
haemorrhoids	Ongoing
onychomycosis	Ongoing

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
hyoscine butylbromide;paracetamol	ABDOMINAL CRAMPS	ORAL	About -2725 days	Ongoing
hyoscine butylbromide;paracetamol	ABDOMINAL PAIN	ORAL	About -2725 days	Ongoing
metamizole sodium	ABDOMINAL PAIN	ORAL	About -2725 days	Ongoing
paracetamol	ABDOMINAL PAIN	ORAL	About -2725 days	Ongoing
mesalazine	ULCERATIVE COLITIS	ORAL	-637 days	Ongoing
azathioprine	ULCERATIVE COLITIS	ORAL	-367 days	Ongoing
terbinafine hydrochloride	NAIL MYCOSIS	ORAL	-43 days	Ongoing
tofacitinib citrate	ULCERATIVE COLITIS	ORAL	375 days	Ongoing
adalimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	-1910 days	-550 days
vedolizumab	ULCERATIVE COLITIS	INTRAVENOUS	-545 days	-406 days
infliximab	ULCERATIVE COLITIS	INTRAVENOUS DRIP	-397 days	-77 days
budesonide	ULCERATIVE COLITIS	ORAL	-301 days	-36 days
citric acid;magnesium oxide;sodium picosulfate	BOWEL CLEANSING PREPARATION	ORAL	-7 days	-6 days
propofol	SEDATION DURING ENDOSCOPY	INTRAVENOUS	-6 days	-6 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
sodium phosphate dibasic;sodium phosphate monobasic	BOWEL CLEANSING PREPARATION	RECTAL	74 days	74 days
allantoin;cinchocaine hydrochloride;diphenylpyraline hydrochloride	PERIANALTHROMBOSIS	TOPICAL	80 days	87 days
methocarbamol	BACK PAIN	ORAL	148 days	153 days
contrast media	CTEXAMINATION	INTRAVENOUS	359 days	359 days
contrast media	CTEXAMINATION	ORAL	359 days	359 days
hyoscine butylbromide	WORSENING OF ABDOMINAL PAIN	INTRAVENOUS	358 days	364 days
metamizole	WORSENING OB ABDOMINAL PAIN	INTRAVENOUS	358 days	364 days
cefuroxime	APPENDICITIS	INTRAVENOUS	About 351 days	About 365 days
metronidazole	APPENDICITIS	INTRAVENOUS	About 351 days	About 365 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	18	291	1	related	dose not changed	not applicable	none
Haemorrhoids thrombosed	74	87	1	not related	dose not changed	dose not changed	medication required
Back pain	68*	76*	1	not related	not applicable	dose not changed	medication required
Vertigo	82*	Ongoing	1	not related	not applicable	dose not changed	none
Abdominal pain	278*	284*	1	not related	not applicable	not applicable	none
Appendicitis	278*	284*	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)
1	15.6 (N)	45 (N)	4.7 (N)	246 (N)	0.082 (N)	96 (N)
29	16 (N)	46 (N)	4.9 (N)	273 (N)	0.092 (N)	93 (N)
45	16.4 (N)	47 (N)	5 (N)	253 (N)	0.099 (N)	94 (N)
74	16.2 (N)	46 (N)	4.9 (N)	243 (N)	0.099 (N)	94 (N)
-7*	16.2 (N)	46 (N)	4.9 (N)	243 (N)	0.099 (N)	94 (N)
20*	16 (N)	45 (N)	4.8 (N)	252 (N)	0.092 (N)	93 (N)
61*	16.6 (N)	47 (N)	5 (N)	251 (N)	0.061 (N)	93 (N)
77*	16.1 (N)	46 (N)	4.8 (N)	253 (N)	0.097 (N)	95 (N)
103*	16.4 (N)	48 (N)	4.9 (N)	249 (N)	0.079 (N)	97 (H)
160*	15.6 (N)	44 (N)	4.5 (N)	230 (N)	0.07 (N)	98 (H)
211*	16.3 (N)	52 (N)	4.8 (N)	226 (N)	0.074 (N)	107 (H)
271*	16.4 (N)	47 (N)	4.8 (N)	243 (N)	0.079 (N)	98 (H)
286*	16.6 (N)	49 (N)	4.9 (N)	289 (N)	0.064 (N)	99 (H)
316*	16.5 (N)	49 (N)	4.9 (N)	261 (N)	0.073 (N)	102 (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)
1	6.55 (N)	4.82 (N)	0.99 (N)	0.37 (N)	0.06 (N)	0.31 (N)
29	5.43 (N)	3.94 (N)	1.03 (N)	0.27 (N)	0.03 (N)	0.16 (N)
45	4.6 (N)	3.14 (N)	0.96 (N)	0.35 (N)	0.03 (N)	0.12 (N)
74	5.4 (N)	4.13 (N)	0.8 (L)	0.33 (N)	0.03 (N)	0.1 (N)
-7*	5.4 (N)	4.13 (N)	0.8 (L)	0.33 (N)	0.03 (N)	0.1 (N)
20*	4.39 (N)	3.02 (N)	0.91 (N)	0.29 (N)	0.03 (N)	0.15 (N)
61*	5.22 (N)	3.81 (N)	1 (N)	0.32 (N)	0.03 (N)	0.06 (N)
77*	4.41 (N)	3.14 (N)	0.9 (L)	0.26 (N)	0.03 (N)	0.07 (N)
103*	5.49 (N)	4.51 (N)	0.61 (L)	0.31 (N)	0.03 (N)	0.04 (N)
160*	4.23 (N)	3.22 (N)	0.71 (L)	0.2 (N)	0.02 (N)	0.07 (N)
211*	3.16 (L)	2.36 (N)	0.54 (L)	0.19 (N)	0.02 (N)	0.04 (N)
271*	4 (N)	2.92 (N)	0.76 (L)	0.23 (N)	0.02 (N)	0.07 (N)
288*	5.12 (N)	3.93 (N)	0.77 (L)	0.35 (N)	0.03 (N)	0.06 (N)
316*	3.57 (L)	2.45 (N)	0.82 (L)	0.22 (N)	0.04 (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)
-20	No	40 (N)	32 (N)	172 (H)	0.7 (N)	1.03 (N)
1	No	20 (N)	17 (N)	148 (H)	0.4 (N)	1.19 (N)
15	No	29 (N)	22 (N)	180 (H)	0.5 (N)	1.14 (N)
29	No	19 (N)	18 (N)	177 (H)	0.5 (N)	1.45 (H)
45	No	26 (N)	18 (N)	181 (H)	0.5 (N)	1.01 (N)
74	No	24 (N)	19 (N)	157 (H)	0.8 (N)	1.11 (N)
-7*	No	24 (N)	19 (N)	157 (H)	0.8 (N)	1.11 (N)
20*	No	24 (N)	19 (N)	171 (H)	0.6 (N)	1.14 (N)
61*	No	27 (N)	20 (N)	175 (H)	0.8 (N)	1.39 (H)
77*	No	31 (N)	23 (N)	150 (H)	0.9 (N)	1.03 (N)
103*	No	29 (N)	23 (N)	162 (H)	1.1 (N)	0.98 (N)
160*	No	27 (N)	23 (N)	164 (H)	0.8 (N)	1.06 (N)
211*	No	29 (N)	25 (N)	152 (H)	1.1 (N)	1.06 (N)
271*	No	32 (N)	21 (N)	147 (H)	0.8 (N)	1.13 (N)
288*	No	65 (H)	56 (H)	152 (H)	0.5 (N)	0.92 (N)
316*	No	37 (N)	27 (N)	135 (H)	0.8 (N)	1.22 (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	No	109.8 (N)	116 (N)	95 (N)	1.13 (N)
1	No	94.2 (N)	79 (N)	96 (N)	2.62 (N)
15	No	99.6 (N)	101 (N)	90 (N)	0.31 (N)
29	No	78 (L)	99 (N)	96 (N)	0.7 (N)
45	No	111.6 (N)	86 (N)	104 (H)	0.37 (N)
74	No	100.8 (N)	84 (N)	132 (H)	0.71 (N)
-7*	No	100.8 (N)	84 (N)	132 (H)	0.71 (N)
20*	No	97.8 (N)	93 (N)	104 (H)	0.45 (N)
61*	No	82.2 (L)	76 (N)	102 (H)	0.27 (N)
77*	No		96 (N)	114 (H)	0.34 (N)
103*	No	114.6 (N)	99 (N)	115 (H)	0.4 (N)
160*	No	103.8 (N)	102 (N)	100 (H)	0.36 (N)
211*	No	103.2 (N)	106 (N)	115 (H)	0.2 (N)
271*	No	99 (N)	106 (N)	122 (H)	0.27 (N)
288*	No	118.8 (N)	57 (N)	108 (H)	4.6 (N)
316*	No	90.6 (N)	98 (N)	93 (N)	0.22 (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)
-20	No	255 (N)	56 (N)	162 (H)	151 (N)
1	No	197 (N)	44 (N)	118 (N)	187 (N)
15	No	228 (N)			205 (N)
29	No	224 (N)	53 (N)	137 (H)	230 (N)
45	No	220 (N)	55 (N)	139 (H)	166 (N)
74	No	245 (N)	58 (N)	157 (H)	114 (N)
-7*	No	245 (N)	58 (N)	157 (H)	114 (N)
20*	No	230 (N)	48 (N)	142 (H)	262 (N)
61*	No	219 (N)	51 (N)	140 (H)	159 (N)
103*	No	223 (N)	54 (N)	153 (H)	89 (N)
288*	No	195 (N)	44 (N)	115 (N)	225 (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－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。

椎間板突出（Day 65～69）（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 69、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**
back pain	Ongoing
colitis ulcerative	Ongoing
osteoarthritis	Ongoing
vasectomy	About -6388 days

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
mesalazine	ULCERATIVE COLITIS	ORAL	-29 days	Ongoing
prednisone	ULCERATIVE COLITIS	ORAL	-29 days	Ongoing
infliximab	ULCERATIVE COLITIS	INTRAVENOUS	-1114 days	-1023 days
adalimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	-995 days	-931 days
golimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	-919 days	-919 days
tacrolimus	ULCERATIVE COLITIS	ORAL	-905 days	-888 days
vedolizumab	ULCERATIVE COLITIS	INTRAVENOUS	-881 days	-77 days
propofol	SEDATION DURING ENDOSCOPY	INTRAVENOUS	-1 day	-1 day
sodium phosphate dibasic;sodium phosphate monobasic	BOWEL CLEANSING PREPARATION	RECTAL	-1 day	-1 day
metamizole sodium	LUMBAGO	ORAL	14 days	69 days
naloxone hydrochloride;tilidine hydrochloride	LUMBAGO	ORAL	14 days	69 days
propofol	SEDATION DURING ENCOSCOPY	INTRAVENOUS	71 days	71 days
sodium phosphate dibasic;sodium phosphate monobasic	BOWEL CLEANSING PREPARATION	RECTAL	71 days	71 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
Back pain	10	64	3	not related	dose not changed	not applicable	medication required
Intervertebral disc protrusion	65	69	3	not related	dose not changed	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)
-16	15.8 (N)	47 (N)	5.1 (N)	176 (N)	0.143 (H)	93 (N)
1	15 (N)	45 (N)	4.8 (N)		0.154 (H)	93 (N)
15	16.4 (N)	49 (N)	5.2 (N)	182 (N)	0.132 (H)	95 (N)
29	15.2 (N)	49 (N)	4.8 (N)	152 (N)	0.132 (H)	102 (H)
36	15.4 (N)	48 (N)	4.8 (N)	166 (N)	0.162 (H)	101 (H)
71	15 (N)	45 (N)	4.6 (N)	173 (N)	0.158 (H)	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)
-16	7.42 (N)	6.14 (N)	0.89 (L)	0.33 (N)	0.02 (N)	0.03 (N)
1	6.42 (N)	5.36 (N)	0.65 (L)	0.38 (N)	0.02 (N)	0.02 (N)
15	6.74 (N)	4.38 (N)	1.85 (N)	0.46 (N)	0.02 (N)	0.03 (N)
29	5.34 (N)	3.48 (N)	1.45 (N)	0.36 (N)	0.02 (N)	0.02 (N)
36	6.05 (N)	3.97 (N)	1.59 (N)	0.47 (N)	0.01 (N)	0.01 (N)
71	5.07 (N)	3.45 (N)	1.29 (N)	0.28 (N)	0.02 (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)
-16	Yes	31 (N)	18 (N)	56 (N)	0.6 (N)	1.06 (N)
1	Yes	35 (N)	20 (N)	64 (N)	0.6 (N)	1.01 (N)
15	Yes	25 (N)	18 (N)	58 (N)	0.4 (N)	1.16 (N)
29	No	26 (N)	17 (N)	50 (N)	0.5 (N)	1.03 (N)
36	No	27 (N)	18 (N)	54 (N)	0.5 (N)	1.05 (N)
71	Yes	41 (N)	20 (N)	46 (N)	0.4 (N)	0.93 (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	129.6 (H)	73 (N)	110 (H)	1.9 (N)
1	Yes	137.4 (H)	71 (N)	110 (H)	2.27 (N)
15	Yes	112.2 (N)	48 (N)	96 (N)	1.02 (N)
29	No	129.6 (H)	59 (N)	96 (N)	0.75 (N)
36	No	126.6 (H)	55 (N)	100 (H)	0.85 (N)
71	Yes	145.8 (H)	59 (N)	100 (H)	7.68 (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	227 (N)	75 (H)	136 (H)	112 (N)
71	Yes	198 (N)	67 (N)	113 (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 B）

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、米国からの参加であった。

帯状疱疹（Day 39～80）（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 の非重篤な帯状疱疹が発現した。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 80、Grade 2 の本事象は回復した。

出血性十二指腸潰瘍（Day 52～55）（試験治療下の重篤な有害事象）（寛解導入試験）：
Day 52、Grade 3 の重篤な出血性十二指腸潰瘍が発現した。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 55、Grade 3 の本事象は回復した。

その他の関連情報：帯状疱疹感染は背中右側の単一の皮膚分節に認められた。全身症状は認められなかった。治療薬として、バラシクロビルが投与された。

Medical History	
Medical History	**Resolution**
abdominal pain	Ongoing
anxiety	Ongoing
cardiac failure congestive	Ongoing
cardiometabolic syndrome	Ongoing
chronic kidney disease	Ongoing
colitis ulcerative	Ongoing
depression	Ongoing
drug hypersensitivity	Ongoing
fluid retention	Ongoing
gastrooesophageal reflux disease	Ongoing
hepatosplenomegaly	Ongoing
hiatus hernia	Ongoing
hyperlipidaemia	Ongoing
hypertension	Ongoing
iron deficiency anaemia	Ongoing
large intestine polyp	Ongoing
obesity	Ongoing
osteoarthritis	Ongoing
palpitations	Ongoing
peripheral venous disease	Ongoing
pulmonary hypertension	Ongoing
sleep apnoea syndrome	Ongoing
tremor	Ongoing
vitamin d deficiency	Ongoing

Medical History	
Medical History	**Resolution**
tonsillitis	About -17247 days
deep vein thrombosis	About -12864 days
herpes zoster	About -11768 days
cholelithiasis	About -9842 days
pancreatitis	About -9577 days
female sterilisation	About -4088 days
cervical radiculopathy	About -811 days
pleural effusion	About -811 days
pneumonia	About -811 days
haemorrhoids	-6 days

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
propranolol	TREMORS	ORAL	About -2636 days	Ongoing
sertraline	DEPRESSION	ORAL	About -2636 days	Ongoing
bumetanide	FLUID RETENTION	ORAL	About -810 days	Ongoing
hyoscyamine	ABDOMINAL PAIN	ORAL	About -810 days	Ongoing
sulfasalazine	ULCERATIVE COLITIS	ORAL	About -810 days	Ongoing
clonazepam	ANXIETY	ORAL	About -444 days	Ongoing
hydrocodone	ABDOMINAL PAIN	ORAL	About -444 days	Ongoing
pantoprazole	GASTRITIS	ORAL	55 days	Ongoing
prednisone	ULCERATIVE COLITIS	ORAL	56 days	Ongoing
infliximab	ULCERATIVE COLITIS	INTRAVENOUS DRIP	-1267 days	-1128 days
infliximab	ULCERATIVE COLITIS	INTRAVENOUS BOLUS	-1127 days	About -872 days
prednisone	ULCERATIVE COLITIS	ORAL	-888 days	-32 days
diclofenac	OSTEOARTHRITIS	TOPICAL	About -444 days	-20 days
magnesium sulfate;potassium sulfate;sodium sulfate	COLONOSCOPY PREP	ORAL	-7 days	-7 days
calcium chloride;potassium chloride;sodium lactate	PROCEDURE SEDATION	INTRAVENOUS	-6 days	-6 days
lidocaine	PROCEDURE SEDATION	INTRAVENOUS	-6 days	-6 days
propofol	PROCEDURE SEDATION	INTRAVENOUS	-6 days	-6 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
ferric carboxymaltose	WORSENING IRON DEFICIENCY ANEMIA	INTRAVENOUS	27 days	27 days
ascorbic acid;iron pentacarbonyl	IRON DEFICIENCY ANEMIA	ORAL	3 days	28 days
ferric carboxymaltose	WORSENING IRON DEFICIENCY ANEMIA	INTRAVENOUS	43 days	43 days
valaciclovir	HERPES ZOSTER	ORAL	39 days	45 days
prednisone	ULCERATIVE COLITIS	ORAL	-31 days	53 days
magnesium citrate	COLONOSCOPY PREP	ORAL	53 days	53 days
paracetamol	HERPES ZOSTER	ORAL	53 days	53 days
sodium chloride	PROPHYLAXIS HYDRATION	INTRAVENOUS	52 days	54 days
amlodipine	WORSENING HYPERTENSION	ORAL	53 days	54 days
levofloxacin	EMPIRIC TREATMENT SECONDARY TO RECTAL BLEEDING	ORAL	53 days	54 days
metronidazole	EMPIRIC TREATMENT SECONDARY TO RECTAL BLEEDING	ORAL	53 days	54 days
oxycodone	HERPES ZOSTER	ORAL	53 days	54 days
pantoprazole	GASTRITIS	INTRAVENOUS	53 days	54 days
glycopyrronium bromide	PROCEDURE SEDATION	INTRAVENOUS	54 days	54 days
hydromorphone hydrochloride	HERPES ZOSTER	INTRAVENOUS	54 days	54 days
lidocaine	PROCEDURE SEDATION	INTRAVENOUS	54 days	54 days
midazolam hydrochloride	PROCEDURE SEDATION	INTRAVENOUS	54 days	54 days
methylprednisolone sodium succinate	EMPIRIC TREATMENT SECONDARY TO RECTAL BLEEDING	INTRAVENOUS BOLUS	53 days	55 days
sucralfate	DUODENAL ULCER	ORAL	54 days	69 days
magnesium sulfate;potassium sulfate;sodium sulfate	COLONOSCOPY PREP	ORAL	71 days	71 days
lidocaine	PROCEDURE SEDATION	INTRAVENOUS	72 days	72 days
propofol	PROCEDURE SEDATION	INTRAVENOUS	72 days	72 days
oxycodone hydrochloride;paracetamol	HERPES ZOSTER	ORAL	39 days	80 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	15	43	3	not related	dose not changed	not applicable	medication required
Herpes zoster	39	80	2	not related	dose not changed	not applicable	medication required
Duodenal ulcer haemorrhage	52	55	3	not related	dose not changed	not applicable	medication required + other treatment required
Hypertension	53	54	2	not related	dose not changed	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
Duodenal ulcer	54	80	3	not related	dose not changed	not applicable	medication required
Gastritis	54	Ongoing	2	not related	dose not changed	not applicable	medication required
Haemorrhoids	54	Ongoing	1	not related	dose not changed	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)
-20	8.5 (L)	30 (L)	3.7 (L)	242 (N)	0.144 (H)	80 (N)
1	8.5 (L)	31 (L)	3.9 (L)	243 (N)		80 (N)
15	7.8 (L)	31 (L)	3.8 (L)	252 (N)	0.202 (H)	82 (N)
27	7.8 (L)	29 (L)	3.6 (L)	257 (N)		81 (N)
43	9.5 (L)	34 (N)	3.9 (L)	175 (N)	0.207 (H)	88 (N)
72	9.7 (L)	35 (N)	3.7 (L)	225 (N)	0.146 (H)	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)
-20	9.96 (N)	7.48 (H)	1.71 (N)	0.61 (N)	0.05 (N)	0.11 (N)
1	12.13 (H)	8.59 (H)	2.51 (N)	0.74 (N)	0.08 (N)	0.21 (N)
15	10.64 (N)	6.53 (N)	3.26 (N)	0.68 (N)	0.08 (N)	0.1 (N)
27	10.49 (N)	7.22 (N)	2.47 (N)	0.63 (N)	0.05 (N)	0.13 (N)
43	6.3 (N)	4.14 (N)	1.47 (N)	0.49 (N)	0.05 (N)	0.14 (N)
72	7.31 (N)	4.58 (N)	2.2 (N)	0.38 (N)	0.03 (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)
-20	No	11 (N)	13 (N)	59 (N)	0.2 (N)	0.94 (N)
1	Yes	11 (N)	12 (N)	67 (N)	<0.2 (L)	0.9 (N)
15	No	13 (N)	14 (N)	61 (N)	<0.2 (L)	0.93 (N)
27	No	13 (N)	12 (N)	55 (N)	<0.2 (L)	1 (N)
43	Yes	12 (N)	13 (N)	56 (N)	<0.2 (L)	0.8 (N)
72	Yes	17 (N)	16 (N)	54 (N)	0.2 (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)
-20	No	178.8 (H)	30 (N)	117 (H)	13.5 (H)
1	Yes	181 (H)	27 (N)	86 (N)	6.52 (N)
15	No	184.9 (H)	46 (N)	105 (H)	5.26 (N)
27	No	172.7 (H)	48 (N)	124 (H)	5.02 (N)
43	Yes	220.1 (H)	36 (N)	125 (H)	8.21 (N)
72	Yes	206.9 (H)	77 (N)	88 (N)	8.63 (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	178 (N)	49 (N)	115 (N)	139 (N)
72	Yes	237 (N)	46 (N)	165 (H)	140 (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 6[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。

胸痛（Day 67～68）（試験治療下の重篤な有害事象）（寛解導入試験）：
Day 67、Grade 2 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 68、Grade 2 の本事象は回復した。

気管支炎（Day 151*～174*）（試験治療下の注目すべき有害事象［TE-AEI］）（寛解維持試験）：
Day 151*、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 174*、Grade 2 の本事象は回復した。

中耳炎（Day 158*～163*）（TE-AEI）（寛解維持試験）：
Day 158*、Grade 2 の非重篤な中耳炎が発現した。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 163*、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**
arthritis	Ongoing
blood cholesterol increased	Ongoing
carpal tunnel syndrome	Ongoing
colitis ulcerative	Ongoing
dry eye	Ongoing
fluid retention	Ongoing
gastrointestinal arteriovenous malformation	Ongoing
gastrooesophageal reflux disease	Ongoing
haemorrhoids	Ongoing
hepatic steatosis	Ongoing
hypertension	Ongoing
hypertriglyceridaemia	Ongoing
obesity	Ongoing
osteoarthritis	Ongoing
polyuria	Ongoing
seasonal allergy	Ongoing
sleep apnoea syndrome	Ongoing
type 2 diabetes mellitus	Ongoing
vitamin d deficiency	Ongoing
vocal cord polyp	About -9252 days
hysterectomy	About -7426 days
uterine haemorrhage	About -7426 days

Medical History	
Medical History	**Resolution**
depression	About -3774 days
non-cardiac chest pain	About -2678 days
gastrointestinal bacterial overgrowth	About -1827 days
rectocele	-1287 days
nasal congestion	About -1217 days
meniscus injury	About -852 days
mastitis	About -670 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
ezetimibe	HIGH CHOLESTEROL	ORAL	About -3773 days	Ongoing
pravastatin	HIGH CHOLESTEROL	ORAL	About -3773 days	Ongoing
glimepiride	TYPE 2 DIABETES MELLITUS	ORAL	About -3042 days	Ongoing
sitagliptin	TYPE 2 DIABETES MELLITUS	ORAL	About -3042 days	Ongoing
colecalciferol	VITAMIN D DEFICIENCY	ORAL	About -2677 days	Ongoing
pantoprazole	GERD	ORAL	About -2677 days	Ongoing
fexofenadine	SEASONAL ALLERGIES	ORAL	About -2312 days	Ongoing
mesalazine	ULCERATIVE COLITIS	ORAL	-2136 days	Ongoing
vitamin e nos	SUPPLEMENT	ORAL	About -1946 days	Ongoing
oxybutynin hydrochloride	POLYURIA	ORAL	About -1581 days	Ongoing
insulin human;insulin human injection, isophane	TYPE 2 DIABETES MELLITUS	SUBCUTANEOUS	About -1216 days	Ongoing
gemfibrozil	HYPERTRIGLYCERIDEMIA	ORAL	About -485 days	Ongoing
bumetanide	WORSENING HYPERTENSION	ORAL	42 days	Ongoing
nifedipine	WORSENING HYPERTENSION	ORAL	128 days	Ongoing
meloxicam	PLANTAR FASCIITIS	ORAL	353 days	Ongoing
infliximab	ULCERATIVE COLITIS	INTRAVENOUS BOLUS	-2288 days	-2192 days
adalimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	About -973 days	About -761 days
adalimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	About -791 days	-750 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
mesalazine	ULCERATIVE COLITIS	RECTAL	-55 days	-38 days
bumetanide	FLUID RETENTION	ORAL	About -2312 days	41 days
glucose oxidase;lactoferrin;lactoperoxidase;lysozyme	SUPPLEMENT	ORAL	About -212 days	46 days
acetylsalicylic acid	CHEST PAIN	ORAL	67 days	67 days
clopidogrel	THROMBOSIS PROPHYLAXIS	ORAL	67 days	67 days
glyceryl trinitrate	CHEST PAIN	SUBLINGUAL	67 days	67 days
morphine	CHEST PAIN	INTRAVENOUS	67 days	67 days
ondansetron	NAUSEA	INTRAVENOUS	67 days	67 days
pantoprazole	CHEST PAIN	INTRAVENOUS	67 days	67 days
potassium chloride	HYPOKALEMIA	ORAL	67 days	67 days
glyceryl trinitrate	CHEST PAIN	TOPICAL	67 days	68 days
magnesium sulfate;potassium sulfate;sodium sulfate	COLONOSCOPY PREP	ORAL	69 days	69 days
lidocaine	COLONOSCOPY SEDATION	INTRAVENOUS	70 days	70 days
propofol	COLONOSCOPY SEDATION	INTRAVENOUS	70 days	70 days
diltiazem	WORSENING HYPERTENSION	ORAL	112 days	128 days
dexamethasone	RASH	INTRAMUSCULAR	238 days	238 days
hydroxyzine hydrochloride	RASH	ORAL	238 days	238 days
azithromycin	MILD RIGHT OTITIS MEDIA	ORAL	234 days	239 days
codeine phosphate;guaifenesin	BRONCHITIS	ORAL	234 days	239 days
hydroxyzine hydrochloride	RASH	ORAL	239 days	240 days
prednisone	RASH	ORAL	238 days	243 days
betamethasone	RIGHT KNEE EFFUSION	INTRA-ARTICULAR	353 days	353 days
meloxicam	RIGHT KNEE EFFUSION	ORAL	353 days	383 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	42	140	2	not related	not applicable	dose not changed	medication required
Chest pain	67	68	2	not related	dose not changed	not applicable	medication required
Hypokalaemia	67	68	2	not related	dose not changed	not applicable	medication required
Nausea	67	67	2	not related	dose not changed	not applicable	medication required
Chest pain	69	Ongoing	2	not related	not applicable	dose not changed	none
Chest discomfort	38*	53*	2	not related	not applicable	dose not changed	other treatment required
Bronchitis	151*	174*	2	not 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
Otitis media	158*	163*	2	not related	not applicable	dose not changed	medication required
Rash	158*	164*	2	not related	not applicable	dose not changed	medication required
Joint effusion	277*	302*	2	not related	not applicable	dose not changed	medication required
Plantar fasciitis	277*	Ongoing	2	not related	not applicable	dose not changed	medication required
Synovial cyst	302*	Ongoing	2	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)
-18	12.9 (N)	39 (N)	4.6 (N)	279 (N)	0.086 (N)	86 (N)
1	12.6 (N)	37 (N)	4.4 (N)	281 (N)	0.07 (N)	85 (N)
15	11.9 (N)	36 (N)	4.2 (N)	272 (N)	0.078 (N)	86 (N)
29	12.3 (N)	37 (N)	4.3 (N)	272 (N)	0.065 (N)	86 (N)
44	11.9 (N)	37 (N)	4.2 (N)	247 (N)	0.054 (N)	89 (N)
70	13.9 (N)	41 (N)	4.8 (N)	268 (N)	0.066 (N)	86 (N)
-7*	13.9 (N)	41 (N)	4.8 (N)	268 (N)	0.066 (N)	86 (N)
25*	13 (N)	37 (N)	4.4 (N)	240 (N)	0.066 (N)	85 (N)
64*	12.8 (N)	38 (N)	4.3 (N)	262 (N)	0.086 (N)	89 (N)
108*	12.8 (N)	37 (N)	4.3 (N)	277 (N)	0.084 (N)	87 (N)
158*	12.4 (N)	36 (N)	4.1 (N)	319 (N)	0.092 (N)	87 (N)
219*	13.2 (N)	39 (N)	4.4 (N)	311 (N)	0.071 (N)	88 (N)
275*	13.1 (N)	39 (N)	4.4 (N)	310 (N)	0.067 (N)	90 (N)
333*	13.1 (N)	39 (N)	4.3 (N)	281 (N)	0.053 (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)
-18	7.17 (N)	3.59 (N)	2.73 (N)	0.4 (N)	0.03 (N)	0.41 (N)
1	5.28 (N)	2.28 (N)	2.13 (N)	0.41 (N)	0.02 (N)	0.43 (N)
15	5.26 (N)	2.44 (N)	2.23 (N)	0.32 (N)	0.02 (N)	0.26 (N)
29	4.53 (N)	1.81 (L)	2.17 (N)	0.36 (N)	0 (N)	0.18 (N)
44	4.82 (N)	2.1 (N)	2.31 (N)	0.28 (N)	0.02 (N)	0.12 (N)
70	5.59 (N)	2.71 (N)	2.41 (N)	0.31 (N)	0.03 (N)	0.14 (N)
-7*	5.59 (N)	2.71 (N)	2.41 (N)	0.31 (N)	0.03 (N)	0.14 (N)
25*	5.82 (N)	3.43 (N)	1.92 (N)	0.28 (N)	0.03 (N)	0.17 (N)
64*	5.64 (N)	3.04 (N)	2.26 (N)	0.24 (N)	0.02 (N)	0.08 (N)
108*	5.72 (N)	2.84 (N)	2.22 (N)	0.39 (N)	0.03 (N)	0.25 (N)
158*	6.32 (N)	3.34 (N)	2.12 (N)	0.45 (N)	0.03 (N)	0.36 (N)
219*	7.33 (N)	4.24 (N)	2.3 (N)	0.54 (N)	0.04 (N)	0.21 (N)
275*	5.8 (N)	3.2 (N)	2.1 (N)	0.3 (N)	0.02 (N)	0.19 (N)
333*	5.47 (N)	2.92 (N)	2.08 (N)	0.32 (N)	0.03 (N)	0.11 (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	No	24 (N)	21 (N)	63 (N)	0.3 (N)	0.86 (N)
1	Yes	24 (N)	18 (N)	56 (N)	0.3 (N)	0.83 (N)
15	No	30 (N)	27 (N)	54 (N)	0.3 (N)	0.89 (N)
29	Yes	43 (H)	32 (N)	61 (N)	0.2 (N)	0.86 (N)
44	No	33 (N)	25 (N)	61 (N)	0.3 (N)	0.79 (N)
70	Yes	51 (H)	43 (H)	60 (N)	0.3 (N)	0.8 (N)
-7*	Yes	51 (H)	43 (H)	60 (N)	0.3 (N)	0.8 (N)
25*	No	21 (N)	20 (N)	57 (N)	0.3 (N)	0.95 (N)
64*	No	29 (N)	26 (N)	66 (N)	0.3 (N)	0.95 (N)
108*	Yes	29 (N)	25 (N)	61 (N)	0.3 (N)	0.89 (N)
158*	No	27 (N)	23 (N)	65 (N)	0.3 (N)	0.94 (N)
219*	No	22 (N)	21 (N)	67 (N)	0.3 (N)	0.99 (N)
275*	No	24 (N)	23 (N)	56 (N)	0.2 (N)	0.97 (N)
333*	Yes	31 (N)	27 (N)	61 (N)	0.3 (N)	0.76 (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	No	107.8 (N)	99 (N)	113 (H)	0.65 (N)
1	Yes	111.7 (N)	109 (N)	220 (H)	0.5 (N)
15	No	105.6 (N)	182 (N)	285 (H)	<0.20 (N)
29	Yes	108.8 (N)	157 (N)	203 (H)	0.53 (N)
44	No	118.5 (H)	125 (N)	152 (H)	0.3 (N)
70	Yes	113.8 (N)	123 (N)	174 (H)	0.55 (N)
-7*	Yes	113.8 (N)	123 (N)	174 (H)	0.55 (N)
25*	No	96.7 (N)	137 (N)	219 (H)	0.39 (N)
64*	No	95 (N)	94 (N)	180 (H)	0.24 (N)
108*	Yes	102 (N)	102 (N)	154 (H)	0.27 (N)
158*	No	96.5 (N)	91 (N)	141 (H)	0.26 (N)
219*	No	92.9 (N)	81 (N)	207 (H)	0.31 (N)
275*	No	95.3 (N)	92 (N)	143 (H)	0.31 (N)
333*	Yes	117.7 (H)	75 (N)	115 (H)	0.22 (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)
1	Yes	156 (L)	49 (N)	107 (N)	90 (N)
70	Yes	202 (N)	50 (N)	142 (H)	141 (N)
-7*	Yes	202 (N)	50 (N)	142 (H)	141 (N)
108*	Yes	189 (N)	55 (N)	128 (N)	83 (N)
333*	Yes	229 (N)	63 (N)	163 (H)	109 (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－完了；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、ロシアからの参加であった。

処置による腸管穿孔（Day 71～86）（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 71、Grade 3 の重篤な処置による腸管穿孔が発現した。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 86、Grade 3 の本事象は回復した。

その他の関連情報：Week 10（寛解導入試験 Day 71）に結腸内視鏡検査が実施され、ブジー法による S 状結腸狭窄の拡張術が行われた。結腸内視鏡検査中に結腸穿孔が生じた。被験者は入院し、その後腸管切除術が実施された。

Medical History	
Medical History	**Resolution**
anaemia	Ongoing
chronic gastritis	Ongoing
colitis ulcerative	Ongoing

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
sulfasalazine	ULCERATIVE COLITIS	ORAL	-294 days	Ongoing
omeprazole	CHRONIC GASTRITIS	ORAL	-281 days	Ongoing
matricaria recutita	CHRONIC GASTRITIS	ORAL	About -147 days	Ongoing
ciprofloxacin	CHRONIC GASTRIRIS	INTRAVENOUS	-148 days	-126 days
ferric hydroxide polymaltose complex	ANEMIA	ORAL	-148 days	-126 days
metronidazole	CHRONIC GASTRITIS	INTRAVENOUS	-148 days	-126 days
platyphylline	CHRONIC GASTRITIS	UNKNOWN	-148 days	-126 days
prednisolone	ULCERATIVE COLITIS	ORAL	-187 days	About -120 days
ferric carboxymaltose	ANEMIA	INTRAVENOUS	-54 days	-54 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	12	13	1	not related	dose not changed	not applicable	none
Procedural intestinal perforation	71	86	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)
-71	7.5 (L)	27 (L)	3.6 (L)	625 (H)	0.104 (N)	74 (L)
-24	9.1 (L)	35 (L)	4.3 (L)	520 (H)	0.076 (N)	81 (N)
1	8.3 (L)	31 (L)	4 (L)	502 (H)	0.059 (N)	77 (L)
19	9.6 (L)	37 (L)	4.4 (L)	415 (H)	0.106 (N)	82 (N)
29	10.3 (L)	39 (N)	4.6 (N)	360 (N)	0.098 (N)	85 (N)
61	12.3 (L)	45 (N)	5.3 (N)	374 (N)	0.078 (N)	85 (N)
70	12.3 (L)	42 (N)	5.2 (N)	344 (N)	0.078 (N)	81 (N)
105	11.9 (L)	39 (N)	4.8 (N)	385 (N)	0.067 (N)	81 (N)
134	11.7 (L)	38 (L)	4.6 (N)	393 (N)	0.076 (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)
-71	5.41 (N)	2.73 (N)	1.83 (N)	0.52 (N)	0.12 (N)	0.2 (N)
-24	6.22 (N)	3.5 (N)	2.01 (N)	0.57 (N)	0.05 (N)	0.09 (N)
1	8.02 (N)	5.14 (N)	2.08 (N)	0.55 (N)	0.08 (N)	0.18 (N)
19	6.66 (N)	4.37 (N)	1.74 (N)	0.36 (N)	0.06 (N)	0.13 (N)
29	7.39 (N)	5.03 (N)	1.75 (N)	0.43 (N)	0.07 (N)	0.11 (N)
61	8.95 (N)	5.52 (N)	2.79 (N)	0.46 (N)	0.07 (N)	0.1 (N)
70	7.2 (N)	4.31 (N)	2.23 (N)	0.51 (N)	0.05 (N)	0.1 (N)
105	6.88 (N)	4.11 (N)	2.03 (N)	0.48 (N)	0.04 (N)	0.22 (N)
134	7.86 (N)	4.64 (N)	2.3 (N)	0.55 (N)	0.07 (N)	0.3 (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)
-71	Yes	9 (N)	13 (N)	55 (N)	<0.2 (L)	0.8 (N)
-24	Yes	10 (N)	13 (N)	68 (N)	0.2 (N)	0.88 (N)
1	Yes	10 (N)	13 (N)	61 (N)	<0.2 (L)	0.72 (N)
19	Yes	8 (N)	13 (N)	61 (N)	<0.2 (L)	0.76 (N)
29	Yes	8 (N)	15 (N)	62 (N)	0.2 (N)	0.76 (N)
61	Yes	15 (N)	17 (N)	73 (N)	0.2 (N)	0.81 (N)
70	Yes	11 (N)	20 (N)	68 (N)	0.2 (N)	0.8 (N)
105	Yes	13 (N)	14 (N)	71 (N)	0.2 (N)	0.74 (N)
134	Yes	13 (N)	16 (N)	66 (N)	0.3 (N)	0.78 (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)
-71	Yes	144 (H)	148 (N)	85 (N)	7.72 (N)
-24	Yes	129.6 (H)	108 (N)	91 (N)	8.16 (N)
1	Yes	157.8 (H)	151 (N)	88 (N)	5.46 (N)
19	Yes	151.2 (H)	83 (N)	92 (N)	2.33 (N)
29	Yes	154.2 (H)	196 (N)	81 (N)	3.01 (N)
61	Yes	144 (H)	111 (N)	86 (N)	1.81 (N)
70	Yes	144.6 (H)	163 (N)	82 (N)	3.13 (N)
105	Yes	157.2 (H)	112 (N)	92 (N)	3.68 (N)
134	Yes	153 (H)	133 (N)	93 (N)	2.05 (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	164 (N)	43 (N)	111 (N)	83 (N)
19	Yes	177 (N)	43 (N)	112 (N)	124 (N)
70	Yes	191 (N)	47 (N)	131 (H)	128 (N)
105	Yes	192 (N)	48 (N)	129 (N)	112 (N)
134	Yes	198 (N)	49 (N)	130 (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 266*）

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、インドからの参加であった。

大脳静脈洞血栓症（Day 267*～継続）（試験治療下の注目すべき有害事象［TE-AEI］、投与中止に至った有害事象）（寛解維持試験）：
Day 267*、Grade 2 の非重篤な大脳静脈洞血栓症が発現した。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。

出血性梗塞（Day 267*～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 267*、Grade 4 の重篤な出血性梗塞が発現した。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。

静脈血栓症（Day 267*～継続）（TE-AEI、投与中止に至った有害事象）（寛解維持試験）：
Day 267*、Grade 2 の非重篤な静脈血栓症が発現した。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：治験責任医師によると、本被験者は寛解維持試験 Day 267 に治験実施施設に来院し、急性発症した左側四肢の脱力、歩行困難、右眼瞼下垂、傾眠状態及び頭痛を訴えた。被験者は検査のため入院した。頭部のコンピューター断層撮影検査及び磁気共鳴脳静脈造影検査の結果、頭蓋内静脈洞血栓症、出血性梗塞及び全般性脳浮腫が認められた。また、6～7 mm の正中線偏位を伴う圧排効果（mass effect）が認められた。被験者は緊急の減圧開頭術のため集中治療室へ転送され、低分子量ヘパリンが投与された。被験者は回復し、退院する際にワルファリンが処方された。
*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**
folic acid	SUPPLEMENT	ORAL	-258 days	Ongoing
calcium carbonate;colecalciferol	SUPPLEMENT	ORAL	345 days	Ongoing
mesalazine	ULCERATIVE COLITIS	ORAL	345 days	Ongoing
minerals nos;vitamins nos	SUPPLEMENT	ORAL	345 days	Ongoing
pantoprazole sodium sesquihydrate	ACUTE HAEMORRHAGIC INFARCT	ORAL	345 days	Ongoing
paracetamol	ACUTE HAEMORRHAGIC INFARCT	ORAL	345 days	Ongoing
prednisolone	ULCERATIVE COLITIS	ORAL	345 days	Ongoing
levetiracetam	ACUTE HAEMORRHAGIC INFARCT	ORAL	346 days	Ongoing

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
folic acid	SUPPLEMENT	ORAL	350 days	Ongoing
glycerol	ACUTE HAEMORRHAGIC INFARCT	ORAL	350 days	Ongoing
warfarin	ACUTE HEMORRHAGIC INFARCT	ORAL	352 days	Ongoing
mesalazine	ULCERATIVE COLITIS	ORAL	-2028 days	-2018 days
prednisolone	ULCERATIVE COLITIS	ORAL	-2017 days	-2003 days
prednisolone	ULCERATIVE COLITIS	ORAL	-2002 days	-1987 days
prednisolone	ULCERATIVE COLITIS	ORAL	-1986 days	-1957 days
prednisolone	ULCERATIVE COLITIS	ORAL	-1956 days	-1948 days
azathioprine	ULCERATIVE COLITIS	ORAL	-1947 days	-1938 days
prednisolone	ULCERATIVE COLITIS	ORAL	-1947 days	-1938 days
prednisolone	ULCERATIVE COLITIS	ORAL	-1937 days	-1928 days
prednisolone	ULCERATIVE COLITIS	ORAL	-1927 days	-1918 days
prednisolone	ULCERATIVE COLITIS	ORAL	-1917 days	-1913 days
prednisolone	ULCERATIVE COLITIS	ORAL	-1912 days	-1883 days
azathioprine	ULCERATIVE COLITIS	ORAL	-1937 days	-1822 days
prednisolone	ULCERATIVE COLITIS	ORAL	-1882 days	-1822 days
prednisolone	ULCERATIVE COLITIS	ORAL	-1821 days	-1807 days
prednisolone	ULCERATIVE COLITIS	ORAL	-1806 days	-1792 days
mesalazine	ULCERATIVE COLITIS	ORAL	-2017 days	-1994 days
mesalazine	ULCERATIVE COLITIS	ORAL	-1753 days	-1748 days
prednisolone	ULCERATIVE COLITIS	ORAL	-827 days	-813 days
prednisolone	ULCERATIVE COLITIS	ORAL	-812 days	-798 days
prednisolone	ULCERATIVE COLITIS	ORAL	-797 days	-783 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
prednisolone	ULCERATIVE COLITIS	ORAL	-782 days	-768 days
prednisolone	ULCERATIVE COLITIS	ORAL	-767 days	-753 days
mesalazine	ULCERATIVE COLITIS	ORAL	-827 days	-727 days
azathioprine	ULCERATIVE COLITIS	ORAL	-1821 days	-477 days
mesalazine	ULCERATIVE COLITIS	ORAL	-726 days	-289 days
azathioprine	ULCERATIVE COLITIS	ORAL	-476 days	-257 days
mesalazine	ULCERATIVE COLITIS	ORAL	-288 days	-132 days
prednisolone	ULCERATIVE COLITIS	ORAL	-110 days	-106 days
prednisolone	ULCERATIVE COLITIS	ORAL	-105 days	-101 days
prednisolone	ULCERATIVE COLITIS	ORAL	-100 days	-96 days
prednisolone	ULCERATIVE COLITIS	ORAL	-95 days	-91 days
prednisolone	ULCERATIVE COLITIS	ORAL	-90 days	-86 days
prednisolone	ULCERATIVE COLITIS	ORAL	-85 days	-81 days
macrogol;potassium chloride;sodium bicarbonate;sodium chloride;sodium sulfate anhydrous	FOR COLON PREPARATION FOR COLONOSCOPY	ORAL	-11 days	-11 days
propofol	FOR SHORT GENERAL SEDATION FOR COLONOSOPY	INTRAVENOUS	-11 days	-11 days
omeprazole	GASTRITIS	ORAL	36 days	42 days
macrogol;potassium chloride;sodium bicarbonate;sodium chloride;sodium sulfate anhydrous	FOR COLON PREPAATION FOR COLONOSCOPY	ORAL	73 days	73 days
propofol	FOR SHORT GENEAL SEDATION FOR COLONOSCOPYI	INTRAVENOUS	73 days	73 days
calcium carbonate;colecalciferol	JOINT PAIN	ORAL	228 days	258 days
bacillus coagulans;bacillus mesentericus;clostridium butyricum;enterococcus faecalis	ACUTE ENTERITIS	ORAL	339 days	342 days
dicycloverine hydrochloride;paracetamol	ACUTE ENTERITIS	ORAL	339 days	342 days
azathioprine	ULCERATIVE COLITIS	ORAL	-256 days	343 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
mesalazine	ULCERATIVE COLITIS	ORAL	-131 days	343 days
fentanyl	ACUTE HAEMORRHAGIC INFARCT	INTRAVENOUS	344 days	344 days
mannitol	ACUTE HAEMORRHAGIC INFARCT	INTRAVENOUS	344 days	344 days
midazolam	ACUTE HAEMORRHAGIC INFARCT	INTRAVENOUS	344 days	344 days
ondansetron hydrochloride	ACUTE HAEMORRHAGIC INFARCT	INTRAVENOUS	344 days	344 days
pantoprazole sodium sesquihydrate	ACUTE HAEMORRHAGIC INFARCT	INTRAVENOUS	344 days	344 days
paracetamol	ACUTE HAEMORRHAGIC INFARCT	INTRAVENOUS	344 days	344 days
levetiracetam	ACUTE HAEMORRHAGIC INFARCT	INTRAVENOUS	344 days	345 days
norepinephrine	ACUTE HEMORRHAGIC INFARCT	INTRAVENOUS	344 days	346 days
sodium chloride	ACUTE HEMORRHAGIC INFARCT	INTRAVENOUS	344 days	346 days
cefoperazone sodium;sulbactam sodium	ACUTE HAEMORRHAGIC INFARCT	INTRAVENOUS	344 days	348 days
blood cells, packed human	PROPHYLACTIC FOR BLOOD LOSS	INTRAVENOUS	347 days	348 days
sodium chloride	ACUTE HAEMORRHAGIC INFARCT	INTRAVENOUS	344 days	350 days
enoxaparin sodium	ACUTE HEMORRHAGIC INFARCT	SUBCUTANEOUS	346 days	352 days
macrogol 3350	CONSTIPATION PREVENTION	ORAL	346 days	354 days
benzalkonium chloride;choline salicylate	PROPHYLACTIC AND ORAL CARE	ORAL	350 days	354 days
hypromellose	PROPHYLACTIC AND EYE CARE	INTRAOCULAR	350 days	354 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
Gastritis	36	42	1	not related	dose not changed	not applicable	medication required
Arthralgia	144*	174*	1	not related	not applicable	dose not changed	medication required
Enteritis	262*	263*	1	not related	not applicable	dose not changed	medication required
Cerebral venous sinus thrombosis	267*	Ongoing	2	not related	not applicable	drug withdrawn	medication required + permanent study discontinuation
Haemorrhagic infarction	267*	Ongoing	4	not related	not applicable	drug withdrawn	medication required + permanent study discontinuation
Venous thrombosis	267*	Ongoing	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)
-22	9.9 (L)	33 (L)	3 (L)	355 (N)	0.066 (N)	108 (H)
1	9.9 (L)	32 (L)	3 (L)	422 (H)	0.05 (N)	108 (H)
15	9.2 (L)	31 (L)	2.8 (L)	376 (N)	0.041 (N)	109 (H)
29	10 (L)	33 (L)	3 (L)	493 (H)	0.059 (N)	112 (H)
42	9.4 (L)	32 (L)	2.9 (L)	448 (H)	0.046 (N)	110 (H)
71	9.5 (L)	34 (N)	3.1 (L)	422 (H)	0.027 (L)	107 (H)
-7*	9.5 (L)	34 (N)	3.1 (L)	422 (H)	0.027 (L)	107 (H)
25*	10 (L)	34 (N)	3.3 (L)	359 (N)	0.025 (L)	103 (H)
62*	10.6 (L)	35 (N)	3.6 (L)	389 (N)	0.062 (N)	97 (N)
106*	10.4 (L)	34 (N)	3.4 (L)	422 (H)	0.045 (N)	98 (N)
162*	9.8 (L)	34 (N)	3.3 (L)	497 (H)	0.033 (N)	103 (H)
221*	10.7 (L)	34 (N)	3.4 (L)	407 (H)	0.061 (N)	100 (H)
293*	12 (N)	39 (N)	3.9 (L)	377 (N)	0.106 (N)	99 (H)
321*	11.5 (L)	38 (N)	3.8 (L)	348 (N)	0.032 (N)	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)
-22	5.29 (N)	3.45 (N)	1.44 (N)	0.18 (N)	0.07 (N)	0.15 (N)
1	5.56 (N)	3.8 (N)	1.39 (N)	0.19 (N)	0.1 (N)	0.1 (N)
15	4.13 (N)	2.37 (N)	1.51 (N)	0.13 (N)	0.05 (N)	0.07 (N)
29	5.69 (N)	3.95 (N)	1.46 (N)	0.17 (N)	0.06 (N)	0.05 (N)
42	5.11 (N)	2.93 (N)	1.81 (N)	0.2 (N)	0.03 (N)	0.13 (N)
71	2.79 (L)	0.95 (L)	1.56 (N)	0.17 (N)	0 (N)	0.08 (N)
-7*	2.79 (L)	0.95 (L)	1.56 (N)	0.17 (N)	0 (N)	0.08 (N)
25*	6.65 (N)	5 (N)	1.31 (N)	0.21 (N)	0.04 (N)	0.09 (N)
62*	8.97 (N)	6.55 (N)	1.96 (N)	0.3 (N)	0.08 (N)	0.07 (N)
106*	4.19 (N)	2.65 (N)	1.27 (N)	0.17 (N)	0.05 (N)	0.06 (N)
162*	5.64 (N)	4.23 (N)	1.16 (N)	0.12 (N)	0.05 (N)	0.08 (N)
221*	8.48 (N)	6.83 (N)	1.06 (N)	0.39 (N)	0.08 (N)	0.11 (N)
293*	20.23 (H)	18.3 (H)	1.3 (N)	0.52 (N)	0.06 (N)	0.06 (N)
321*	4.87 (N)	2.57 (N)	1.84 (N)	0.16 (N)	0.1 (N)	0.19 (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	Yes	6 (N)	18 (N)	49 (N)	0.4 (N)	0.66 (N)
1	Yes	9 (N)	21 (N)	50 (N)	0.3 (N)	0.58 (N)
15	Yes	17 (N)	14 (N)	79 (N)	<0.2 (L)	1.02 (N)
29	Yes	9 (N)	21 (N)	50 (N)	0.4 (N)	0.58 (N)
42	Yes	8 (N)	21 (N)	50 (N)	0.3 (N)	0.63 (N)
71	Yes	10 (N)	23 (N)	49 (N)	0.5 (N)	0.66 (N)
-7*	Yes	10 (N)	23 (N)	49 (N)	0.5 (N)	0.66 (N)
25*	Yes	11 (N)	24 (N)	54 (N)	0.4 (N)	0.67 (N)
62*	Yes	10 (N)	25 (N)	54 (N)	0.4 (N)	0.66 (N)
106*	Yes	11 (N)	27 (N)	50 (N)	0.5 (N)	0.64 (N)
162*	Yes	9 (N)	22 (N)	43 (N)	0.5 (N)	0.68 (N)
221*	Yes	11 (N)	23 (N)	51 (N)	0.3 (N)	0.62 (N)
293*	Yes	23 (N)	33 (N)	70 (N)	0.5 (N)	0.72 (N)
321*	Yes	11 (N)	26 (N)	65 (N)	<0.2 (L)	0.68 (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	Yes	88.8 (N)	104 (N)	88 (N)	7.45 (N)
1	Yes	101.4 (N)	96 (N)	64 (L)	2.34 (N)
15	Yes	57.6 (L)	46 (N)		23.5 (H)
29	Yes	103.2 (N)	140 (N)	90 (N)	2.21 (N)
42	Yes	94.2 (N)	147 (N)	82 (N)	0.54 (N)
71	Yes	91.8 (N)	199 (H)	82 (N)	<0.20 (N)
-7*	Yes	91.8 (N)	199 (H)	82 (N)	<0.20 (N)
25*	Yes	90 (N)	203 (H)	71 (N)	0.35 (N)
62*	Yes	92.4 (N)	215 (H)	75 (N)	1.12 (N)
106*	Yes	94.8 (N)	243 (H)	91 (N)	<0.20 (N)
162*	Yes	91.8 (N)	175 (N)	85 (N)	0.59 (N)
221*	Yes	100.2 (N)	139 (N)	66 (L)	15.3 (H)
293*	Yes	80.4 (N)	33 (N)	101 (H)	155 (H)
321*	Yes	85.8 (N)	139 (N)	74 (N)	1.14 (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)
-22	Yes	135 (L)	55 (N)	73 (N)	58 (N)
1	Yes	141 (N)	54 (N)	82 (N)	53 (N)
15	Yes	196 (N)	89 (H)	103 (N)	108 (N)
71	Yes	143 (N)	53 (N)	88 (N)	52 (N)
-7*	Yes	143 (N)	53 (N)	88 (N)	52 (N)
106*	Yes	140 (L)	60 (N)	85 (N)	50 (N)
233*	Yes	163 (N)	68 (N)	98 (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）

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 47）；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、米国からの参加であった。

菌血症（Day 47～58）（試験治療下の注目すべき有害事象［TE-AEI］）（寛解導入試験）：
Day 47、Grade 2 の非重篤な菌血症が発現した。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 58、Grade 2 の本事象は回復した。

敗血症（Day 47～58）（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）（寛解導入試験）：
Day 47、Grade 4 の重篤な敗血症が発現した。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 58、Grade 4 の本事象は回復した。

その他の関連情報：大腸菌尿培養検査陽性に基づく敗血症及び代謝性アシドーシスが認められた。被験者は、prednisone 併用に伴う免疫抑制状態にあるとみなされたため、入院時に治験薬の投与が中止された。抗生剤の静脈内投与による治療が開始された。有害事象として菌血症が報告されたが、血液培養検査の結果は陰性であった。菌血症及び敗血症の要因として、潰瘍性大腸炎によるバクテリアルトランスロケーションの可能性が考えられた。被験者は結腸直腸外科を受診し、将来的な結腸切除術の可能性に備え栄養状態を最適化するよう助言された。被験者は退院し、自宅で抗生剤の静脈内投与による治療を完了した。

Medical History	
Medical History	**Resolution**
arthritis	Ongoing
chronic kidney disease	Ongoing
colitis ulcerative	Ongoing
drug hypersensitivity	Ongoing
electrolyte imbalance	Ongoing
hypertension	Ongoing
nausea	Ongoing
seasonal allergy	Ongoing
deep vein thrombosis	About -132 days
pulmonary embolism	About -132 days

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
metoprolol	HYPERTENSION	ORAL	About -8471 days	Ongoing
calcium	NUTRITIONAL	ORAL	About -2992 days	Ongoing
vitamin d nos	NUTRITIONAL	ORAL	About -2992 days	Ongoing
loratadine	SEASONAL ALLERGIES	ORAL	About -162 days	Ongoing
magnesium	NUTRITIONAL	ORAL	About -162 days	Ongoing
ondansetron	NAUSEA	ORAL	About -162 days	Ongoing
potassium	NUTRITIONAL	ORAL	About -162 days	Ongoing
prednisone	ULCERATIVE COLITIS	ORAL	About -101 days	Ongoing
sodium bicarbonate	ELECTROLYTE INBALANCE	ORAL	About -70 days	Ongoing

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
mesalazine	ULCERATIVE COLITIS	ORAL	About -6845 days	About -6280 days
mercaptopurine	ULCERATIVE COLITIS	ORAL	About -1166 days	About -802 days
adalimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	About -801 days	About -436 days
infliximab	ULCERATIVE COLITIS	INTRAVENOUS	About -801 days	About -436 days
vedolizumab	ULCERATIVE COLITIS	INTRAVENOUS	About -284 days	-83 days
lidocaine	COLONOSCOPY ANESTHESIA	INTRAVENOUS	-5 days	-5 days
propofol	COLONOSCOPY ANESTHESIA	INTRAVENOUS	-5 days	-5 days
antipropulsives	ULCERATIVE COLITIS	ORAL	About -101 days	47 days
betamethasone dipropionate	ERYTHEMA NODOSUM	TOPICAL	47 days	58 days
enoxaparin sodium	PROPHYLAXIS DVT	SUBCUTANEOUS	47 days	58 days
ertapenem sodium	SEPSIS	INTRAVENOUS	47 days	58 days
omeprazole	PROPHYLAXIS GERD	ORAL	47 days	58 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**
Bacteraemia	47	58	2	not related	dose not changed	not applicable	medication required
Erythema nodosum	47	58	2	not related	not applicable	not applicable	medication required
Metabolic acidosis	47	58	2	not related	dose not changed	not applicable	none
Sepsis	47	58	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)
-18	11.9 (N)	37 (N)	4.1 (N)	280 (N)	0.101 (N)	90 (N)
1	13.3 (N)	43 (N)	4.6 (N)	234 (N)	0.081 (N)	93 (N)
17	12.8 (N)	42 (N)	4.5 (N)	313 (N)	0.092 (N)	93 (N)
29	12.1 (N)	40 (N)	4.4 (N)	150 (N)	0.094 (N)	92 (N)
36	11.6 (N)	39 (N)	4.2 (N)	213 (N)	0.068 (N)	93 (N)
46	11 (L)	36 (N)	3.9 (N)	215 (N)	0.039 (N)	93 (N)
80	9.2 (L)	33 (L)	3.4 (L)	278 (N)	0.119 (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)
-18	12.48 (H)	10.6 (H)	1.43 (N)	0.34 (N)	0.01 (N)	0.09 (N)
1	11.61 (H)	8.54 (H)	2.18 (N)	0.7 (N)	0.02 (N)	0.17 (N)
17	14.56 (H)	10.69 (H)	2.94 (N)	0.71 (N)	0.03 (N)	0.18 (N)
29	10 (N)	9.2 (H)	0.47 (L)	0.26 (N)	0.03 (N)	0.04 (N)
36	11.09 (H)	9.62 (H)	0.92 (N)	0.39 (N)	0.02 (N)	0.15 (N)
46	13.07 (H)	11.88 (H)	0.67 (L)	0.43 (N)	0.02 (N)	0.08 (N)
80	11.64 (H)	7.42 (H)	3.32 (H)	0.71 (N)	0.1 (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	31 (N)	21 (N)	123 (N)	0.3 (N)	1.58 (H)
1	No	20 (N)	11 (N)	114 (N)	0.3 (N)	1.55 (H)
17	No	36 (H)	18 (N)	109 (N)	0.3 (N)	2.31 (H)
23	Yes					1.64 (H)
29	No	26 (N)	15 (N)	86 (N)	0.3 (N)	1.58 (H)
46	Yes	22 (N)	14 (N)	121 (N)	0.4 (N)	2.13 (H)
80	Yes	22 (N)	15 (N)	112 (N)	0.2 (N)	1.53 (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)
-18	Yes	47.4 (L)	48 (N)	95 (N)	0.7 (N)
1	No	46.8 (L)	32 (N)	86 (N)	5.89 (N)
17	No	30 (L)	49 (N)	88 (N)	17.3 (H)
23	Yes	42.2 (L)			
29	No	45.4 (L)	33 (N)	91 (N)	8.45 (N)
46	Yes	32.3 (L)	23 (L)	74 (N)	114 (H)
80	Yes	49.8 (L)	33 (N)	87 (N)	3.31 (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)
1	No	142 (L)	51 (N)	64 (N)	142 (N)
80	Yes	176 (L)	61 (N)	101 (N)	96 (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－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。

虫垂粘液嚢胞（Day 18～20）（試験治療下の重篤な有害事象）（寛解導入試験）：
Day 18、Grade 3 の重篤な虫垂粘液嚢胞が発現した。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 20、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
cryptorchism	Ongoing
intervertebral disc protrusion	Ongoing
kyphosis	Ongoing
lactose intolerance	Ongoing
lordosis	Ongoing
epilepsy	About -6116 days
traumatic renal injury	-1498 days
appendix disorder	18 days

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
infliximab	ULCERATIVE COLITIS	INTRAVENOUS	About -3924 days	Unknown
mesalazine	ULCERATIVE COLITIS	ORAL	-459 days	Ongoing
pantoprazole sodium sesquihydrate	STOMAC PROTECTION	ORAL	-213 days	Ongoing
methylprednisolone	ULCERATIVE COLITIS	ORAL	-14 days	Ongoing
budesonide	ULCERATIVE COLITIS	RECTAL	-4587 days	-4580 days
budesonide	ULCERATIVE COLITIS	RECTAL	-4573 days	-4559 days
infliximab	ULCERATIVE COLITIS	INTRAVENOUS	Unknown	About -456 days
adalimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	-480 days	About -394 days
beclometasone dipropionate	ULCERATIVE COLITIS	ORAL	-388 days	-374 days
adalimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	About -424 days	About -241 days
mesalazine	ULCERATIVE COLITIS	RECTAL	-213 days	About -182 days
vedolizumab	ULCERATIVE COLITIS	INTRAVENOUS	About -271 days	-163 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
vedolizumab	ULCERATIVE COLITIS	INTRAVENOUS	-163 days	-71 days
azathioprine	ULCERATIVE COLITIS	ORAL	-374 days	-53 days
mesalazine	ULCERATIVE COLITIS	RECTAL	-71 days	-47 days
methylprednisolone	ULCERATIVE COLITIS	ORAL	About -59 days	-37 days
methylprednisolone	ULCERATIVE COLITIS	ORAL	-36 days	-15 days
midazolam	SEDATION COLONOSCOPY	INTRAVENOUS	-4 days	-4 days
pethidine	SEDATION COLONOSCOPY	INTRAVENOUS	-4 days	-4 days
paracetamol	NECK PAIN	ORAL	10 days	10 days
anesthetics, general	APPEDECTOMY	INTRAVENOUS	19 days	19 days
enoxaparin sodium	PREVENTION THROMBOSIS	SUBCUTANEOUS	19 days	19 days
morphine	PREVENTION SURGICAL PAIN	SUBCUTANEOUS	19 days	19 days
paracetamol	PREVENTION SURGICAL PAIN	ORAL	19 days	20 days
tramadol hydrochloride	PREVENTION SURGICAL PAIN	ORAL	20 days	20 days
tramadol hydrochloride	ABDOMINAL PAIN	ORAL	21 days	24 days
influenza vaccine inactsag 3v	VACCINATION	INTRAMUSCULAR	53 days	53 days
midazolam	SEDATION FOR SIGMOIDOSCOPY	INTRAVENOUS	68 days	68 days
pethidine	SEDATION FOR SIGMOIDOSCOPY	INTRAVENOUS	68 days	68 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
Neck pain	10	10	1	not related	dose not changed	not applicable	medication required
Appendiceal mucocoele	18	20	3	not related	drug interrupted	not applicable	other treatment required
Headache	20	About 63	1	not related	dose not changed	not applicable	none
Neck pain	20	About 63	1	not related	dose not changed	not applicable	medication required
Procedural pain	21	About 33	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)
-15	14.5 (N)	45 (N)	4.6 (N)	271 (N)	0.093 (N)	97 (H)
-11	13.3 (N)	41 (N)	4.2 (L)	227 (N)	0.074 (N)	97 (H)
1	14.3 (N)	44 (N)	4.6 (N)	236 (N)	0.062 (N)	96 (N)
15	13.3 (N)	40 (N)	4.3 (L)	252 (N)	0.066 (N)	92 (N)
29	13.4 (N)	40 (N)	4.3 (L)	286 (N)	0.057 (N)	93 (N)
43	13.5 (N)	40 (N)	4.4 (L)	268 (N)	0.078 (N)	92 (N)
68	12.3 (L)	37 (L)	4 (L)	189 (N)	0.081 (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)
-15	9.94 (N)	8.83 (H)	0.61 (L)	0.42 (N)	0.03 (N)	0.04 (N)
-11	9.43 (N)	7.13 (N)	1.49 (N)	0.71 (N)	0.03 (N)	0.06 (N)
1	9.55 (N)	7.21 (N)	1.46 (N)	0.71 (N)	0.05 (N)	0.11 (N)
15	7.44 (N)	5.73 (N)	1.25 (N)	0.34 (N)	0.04 (N)	0.08 (N)
29	9.45 (N)	7.96 (H)	0.88 (L)	0.48 (N)	0.05 (N)	0.09 (N)
43	8.86 (N)	7.16 (N)	1.09 (N)	0.47 (N)	0.04 (N)	0.1 (N)
68	6.47 (N)	4.74 (N)	0.96 (N)	0.55 (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)
-15	No	12 (N)	12 (N)	63 (N)	<0.2 (L)	0.97 (N)
1	Yes	16 (N)	18 (N)	67 (N)	0.2 (N)	0.9 (N)
15	No	18 (N)	23 (N)	66 (N)	0.4 (N)	1.02 (N)
29	No	20 (N)	17 (N)	68 (N)	0.2 (N)	0.94 (N)
43	No	17 (N)	18 (N)	67 (N)	0.3 (N)	0.93 (N)
68	Yes	9 (N)	13 (N)	60 (N)	0.2 (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)
-15	No	109.8 (N)	61 (N)	91 (N)	9.25 (N)
1	Yes	114 (N)	69 (N)	81 (N)	11.5 (H)
15	No	102.6 (N)	219 (N)	115 (H)	6.19 (N)
29	No	109.2 (N)	149 (N)	98 (N)	9.54 (N)
43	No	113.4 (N)	98 (N)	86 (N)	3.04 (N)
68	Yes	119.4 (N)	84 (N)	88 (N)	1.95 (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	148 (L)	66 (H)	68 (N)	66 (N)
1	Yes	135 (L)	64 (H)	65 (N)	43 (L)
15	No	149 (L)	72 (H)	69 (N)	54 (N)
29	No	143 (L)	57 (N)	62 (N)	91 (N)
43	No	172 (N)	85 (H)	72 (N)	81 (N)
68	Yes	142 (L)	76 (H)	57 (N)	48 (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 27）；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、ベルギーからの参加であった。

腹痛（Day 26～27）（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 26、Grade 3 の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 27、Grade 3 の本事象は回復した。

潰瘍性大腸炎（Day 46～53）（TE-SAE）（寛解導入試験）：
Day 46、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。Day 53、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
arthralgia	Ongoing
arthritis	Ongoing
colitis ulcerative	Ongoing
dermatitis contact	Ongoing
headache	Ongoing
insomnia	Ongoing
myalgia	Ongoing
rash pustular	Ongoing
adenoidal hypertrophy	-6465 days
chronic sinusitis	-4911 days
nasal obstruction	-4911 days
nasal septal operation	-4911 days
sinus operation	-4911 days
joint injury	About -2527 days
cholecystectomy	-2456 days
cholecystitis	-2090 days
vitamin b12 decreased	About -1796 days
kinesiophobia	About -1431 days
photophobia	About -1431 days
haematuria	-578 days
haemorrhoids	About -457 days
blepharitis	-303 days
rash	-303 days
iron deficiency anaemia	About -62 days

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
desogestrel;ethinylestradiol	ANTI CONCEPTION	ORAL	About -3987 days	Ongoing
paracetamol	ULCERATIVE COLITIS	ORAL	About -3256 days	Ongoing
zolpidem	INSOMNIA	ORAL	About -2891 days	Ongoing
pantoprazole	STOMAC PAIN	ORAL	-73 days	Ongoing
alizapride hydrochloride	PREVENTION NAUSEA	ORAL	About 1 day	Ongoing
tramadol hydrochloride	PAIN PREVENTION	ORAL	About 32 days	Ongoing
enoxaparin sodium	PREVENTION TROMBOSE	SUBCUTANEOUS	46 days	Ongoing
infliximab	ULCERATIVE COLITIS	INTRAVENOUS	-2151 days	-1848 days
prednisolone sodium phosphate	ULCERATIVE COLITIS	INTRAVENOUS DRIP	-1780 days	-1767 days
infliximab	ULCERATIVE COLITIS	INTRAVENOUS	-1808 days	-1682 days
investigational drug	ULCERATIVE COLITIS	ORAL	-1603 days	-1536 days
investigational drug	ULCERATIVE COLITIS	ORAL	-1492 days	-1465 days
golimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	-1452 days	-1452 days
golimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	-1438 days	-1269 days
azathioprine	ULCERATIVE COLITIS	ORAL	-1459 days	About -1219 days
vedolizumab	ULCERATIVE COLITIS	INTRAVENOUS	-756 days	-715 days
investigational drug	ULCERATIVE COLITIS	INTRAVENOUS	-578 days	-520 days
mirikizumab	ULCERATIVE COLITIS	INTRAVENOUS	-484 days	-315 days
investigational drug	ULCERATIVE COLITIS	ORAL	-262 days	-99 days
ozanimod	ULCERATIVE COLITIS	ORAL	-94 days	-73 days
mesalazine	ULCERATIVE COLITIS	ORAL	About -395 days	-63 days
methylprednisolone	ULCERATIVE COLITIS	ORAL	-48 days	-42 days
methylprednisolone	ULCERATIVE COLITIS	ORAL	-41 days	-35 days
methylprednisolone	ULCERATIVE COLITIS	ORAL	-34 days	-29 days
methylprednisolone	ULCERATIVE COLITIS	ORAL	-28 days	-25 days
methylprednisolone	ULCERATIVE COLITIS	ORAL	-24 days	-23 days
methylprednisolone	ULCERATIVE COLITIS	ORAL	-22 days	-16 days
methylprednisolone	ULCERATIVE COLITIS	ORAL	-15 days	26 days
hyoscine butylbromide	SEVERE ABDOMINAL PAIN	INTRAVENOUS	26 days	26 days
pethidine	SEVERE ABDOMINAL PAIN	INTRAVENOUS	26 days	26 days
alizapride hydrochloride	SEVERE ABDOMINAL PAIN	INTRAVENOUS	26 days	27 days
tramadol	SEVERE ABDOMINAL PAIN	INTRAVENOUS	26 days	27 days
levofloxacin	SEVERE ABDOMINAL PAIN	INTRAVENOUS	27 days	27 days
methylprednisolone	SEVERE ABDOMINAL PAIN	INTRAVENOUS	27 days	27 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
morphine	SEVERE ABDOMINAL PAIN	SUBCUTANEOUS	27 days	27 days
ornidazole	SVERE ABDOMINAL PAIN	INTRAVENOUS	27 days	27 days
pantoprazole	SEVERE ABDOMINAL PAIN	ORAL	27 days	27 days
paracetamol	SEVERE ABDOMINAL PAIN	INTRAVENOUS	27 days	27 days
levofloxacin	ULCERATIVE COLITIS	ORAL	27 days	36 days
ornidazole	ULCERATIVE COLITIS	ORAL	27 days	36 days
methylprednisolone	ULCERATIVE COLITIS	ORAL	28 days	45 days
hydrocortisone sodium succinate	PREVENTION CORTISOL WITHDRAWAL SYNDROME	INTRAVENOUS	46 days	46 days
hydrocortisone sodium succinate	PREVENTION CORTISOL WITHDRAWAL SYNDROME	INTRAVENOUS	47 days	47 days
analgesics	SURGICAL PAIN	EPIDURAL	46 days	49 days
paracetamol	SURGICAL PAIN	INTRAVENOUS	46 days	50 days
morphine	PREVENTION SURGICAL PAIN	SUBCUTANEOUS	47 days	51 days
calcium carbonate;colecalciferol	PREVENTION OSTEOPOROSIS	ORAL	-63 days	52 days
alprazolam	PREVENTION ANXIETY	ORAL	46 days	52 days
methylprednisolone	ULCERATIVE COLITIS	ORAL	46 days	52 days
tramadol hydrochloride	SURGICAL PAIN	ORAL	51 days	52 days
tramadol hydrochloride	SURGICAL PAIN	ORAL	49 days	53 days
tramadol hydrochloride	ULCERATIVE COLITIS	ORAL	-55 days	About 62 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	26	27	3	not related	drug withdrawn	not applicable	medication required + permanent study discontinuation
Colitis ulcerative	46	53	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)
-16	13.1 (N)	39 (N)	4.3 (N)	465 (H)	0.126 (H)	91 (N)
-11	11.6 (N)	35 (N)	3.9 (L)	490 (H)	0.123 (H)	91 (N)
1	12.5 (N)	39 (N)	4.3 (N)	521 (H)	0.092 (N)	90 (N)
13	13.3 (N)	42 (N)	4.6 (N)	487 (H)	0.146 (H)	91 (N)
27	13.9 (N)	42 (N)	4.8 (N)	424 (H)	0.125 (H)	89 (N)
62	13 (N)	40 (N)	4.5 (N)	578 (H)	0.104 (N)	88 (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)
-16	10.27 (N)	9 (H)	0.52 (L)	0.49 (N)	0.04 (N)	0.22 (N)
-11	7.1 (N)	4.98 (N)	1.49 (N)	0.4 (N)	0.03 (N)	0.2 (N)
1	11.71 (H)	9.29 (H)	1.47 (N)	0.55 (N)	0.05 (N)	0.36 (N)
13	10.72 (H)	7.38 (H)	2.41 (N)	0.76 (N)	0.04 (N)	0.13 (N)
27	7.03 (N)	6.64 (N)	0.22 (L)	0.15 (N)	0.01 (N)	0.02 (N)
62	7.61 (N)	4.45 (N)	2.06 (N)	0.59 (N)	0.08 (N)	0.43 (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	No	15 (N)	20 (N)	77 (N)	0.2 (N)	0.84 (N)
1	Yes	16 (N)	18 (N)	74 (N)	<0.2 (L)	0.77 (N)
13	No	9 (N)	10 (N)	57 (N)	0.2 (N)	0.8 (N)
27	No	6 (N)	8 (L)	44 (N)	0.2 (N)	0.62 (N)
62	No	12 (N)	15 (N)	77 (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)
-16	No	121.2 (H)	116 (N)	84 (N)	74.4 (H)
1	Yes	128.4 (H)	104 (N)	73 (N)	18 (H)
13	No	123.6 (H)	39 (N)	68 (L)	3.32 (N)
27	No	158.4 (H)	41 (N)	98 (N)	76.6 (H)
62	No	120.6 (H)	52 (N)	77 (N)	13.2 (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)
-16	No	229 (N)	90 (H)	107 (N)	153 (N)
1	Yes	219 (N)	75 (N)	92 (N)	283 (H)
13	No	276 (H)	100 (H)	153 (H)	157 (N)
27	No	222 (N)	90 (H)	112 (N)	105 (N)
62	No	234 (N)	79 (H)	120 (N)	198 (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 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 115*）

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、ベルギーからの参加であった。

上咽頭炎（Day 39～55）（試験治療下の注目すべき有害事象）（寛解導入試験）：
Day 39、Grade 1 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ありと判断された。Day 55、Grade 1 の本事象は回復した。

潰瘍性大腸炎（Day 46～47）（試験治療下の重篤な有害事象）（寛解導入試験）：
Day 46、Grade 2 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。

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**
arthralgia	Ongoing
chest pain	Ongoing
colitis ulcerative	Ongoing
depression	Ongoing
dyspnoea	Ongoing
fatigue	Ongoing
gastrooesophageal reflux disease	Ongoing
hepatic steatosis	Ongoing
hypercholesterolaemia	Ongoing
pain	Ongoing
cataract	-3660 days
proctalgia	About -1773 days
coronary artery disease	About -222 days

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
pantoprazole sodium sesquihydrate	REFLUX OESOPHAGITIS	ORAL	About -2382 days	Ongoing
mirtazapine	DEPRESSION	ORAL	-2186 days	Ongoing
trazodone hydrochloride	DEPRESSION	ORAL	-2186 days	Ongoing
quetiapine fumarate	DEPRESSION	ORAL	-1536 days	Ongoing
duloxetine hydrochloride	DEPRESSION	ORAL	-1477 days	Ongoing
pregabalin	CHRONIC WIDESPREAD PAIN SYNDROME	ORAL	About -342 days	Ongoing

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
acetylsalicylic acid	SECUNDARY PREVENTION CORONARY ARTERY DISEASE	ORAL	About -252 days	Ongoing
bisoprolol	PREVENTION CORONARY ARTERY DISEASE	ORAL	About -252 days	Ongoing
atorvastatin	HYPERCHOLESTEROLEMY	ORAL	-225 days	Ongoing
tramadol	STERNAL PAIN AFTER CORONARY ARTERY BYPASS GRAFTING + PAIN RIGHT GROIN	ORAL	About 1 day	Ongoing
levothyroxine sodium	HYPOTHYROIDISM	ORAL	About 114 days	Ongoing
paracetamol	PAIN RIGHT GROIN	ORAL	168 days	Ongoing
infliximab	ULCERATIVE COLITIS	INTRAVENOUS	-4339 days	About -4240 days
investigational drug	ULCERATIVE COLITIS	INTRAVENOUS	-4160 days	-4104 days
investigational drug	ULCERATIVE COLITIS	INTRAVENOUS	-4076 days	-4020 days
proteins nos	ULCERATIVE COLITIS	INTRAVENOUS	-3991 days	-3628 days
investigational drug	ULCERATIVE COLITIS	INTRAVENOUS	-3481 days	-3439 days
investigational drug	ULCERATIVE COLITIS	INTRAVENOUS	-3411 days	-3411 days
azathioprine	ULCERATIVE COLITIS	ORAL	About -3904 days	-3383 days
beclometasone	ULCERATIVE COLITIS	ORAL	-3386 days	-3369 days
mesalazine	ULCERATIVE COLITIS	ORAL	About -3933 days	About -2444 days
vedolizumab	ULCERATIVE COLITIS	INTRAVENOUS	-3383 days	-1256 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
Nasopharyngitis	39	55	1	related	dose not changed	not applicable	none
Colitis ulcerative	46	47	2	not related	dose not changed	not applicable	other treatment required
Hypothyroidism	About 40*	Ongoing	2	not related	not applicable	dose not changed	medication required
Muscle strain	46*	Ongoing	1	not related	not applicable	dose not changed	none
Groin pain	69*	Ongoing	2	related	not applicable	dose not changed	medication required + other treatment required
Colitis ulcerative	About 101*	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)
-14	13.6 (N)	40 (N)	4.2 (L)	179 (N)	0.112 (N)	95 (N)
1	14.2 (N)	41 (N)	4.3 (L)	198 (N)	0.123 (N)	95 (N)
15	14 (N)	41 (N)	4.3 (L)	209 (N)	0.112 (N)	95 (N)
29	14.3 (N)	42 (N)	4.4 (L)	217 (N)	0.111 (N)	94 (N)
43	14.9 (N)	44 (N)	4.6 (N)	226 (N)	0.101 (N)	96 (N)
68	14.8 (N)	43 (N)	4.5 (N)	230 (N)	0.101 (N)	96 (N)
-7*	14.8 (N)	43 (N)	4.5 (N)	230 (N)	0.101 (N)	96 (N)
24*	14 (N)	41 (N)	4.3 (L)	207 (N)	0.107 (N)	95 (N)
66*	14.2 (N)	41 (N)	4.4 (L)	202 (N)	0.096 (N)	95 (N)
108*	14.6 (N)	43 (N)	4.4 (L)	207 (N)	0.112 (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)
-14	8.17 (N)	4.56 (N)	2.65 (N)	0.65 (N)	0.07 (N)	0.24 (N)
1	8.77 (N)	5.19 (N)	2.52 (N)	0.62 (N)	0.1 (N)	0.34 (N)
15	9.49 (N)	4.69 (N)	3.73 (N)	0.61 (N)	0.1 (N)	0.35 (N)
29	7.88 (N)	4.34 (N)	2.91 (N)	0.31 (N)	0.04 (N)	0.27 (N)
43	10.07 (N)	5.58 (N)	3.27 (N)	0.79 (N)	0.1 (N)	0.32 (N)
68	9.87 (N)	5.81 (N)	3.17 (N)	0.55 (N)	0.05 (N)	0.28 (N)
-7*	9.87 (N)	5.81 (N)	3.17 (N)	0.55 (N)	0.05 (N)	0.28 (N)
24*	9.88 (N)	6.87 (N)	2.26 (N)	0.5 (N)	0.05 (N)	0.2 (N)
66*	9 (N)	4.91 (N)	3.27 (N)	0.54 (N)	0.07 (N)	0.22 (N)
108*	9.56 (N)	6.68 (N)	2.09 (N)	0.6 (N)	0.07 (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)
-14	No	57 (H)	54 (H)	80 (N)	0.9 (N)	1.07 (N)
1	Yes	58 (H)	53 (H)	85 (N)	0.9 (N)	1.06 (N)
15	No	57 (H)	51 (H)	82 (N)	0.9 (N)	1.16 (N)
29	No	57 (H)	54 (H)	77 (N)	0.8 (N)	1.02 (N)
43	No	53 (H)	45 (H)	89 (N)	0.7 (N)	1.16 (N)
68	Yes	69 (H)	57 (H)	88 (N)	1.1 (N)	1.19 (N)
-7*	Yes	69 (H)	57 (H)	88 (N)	1.1 (N)	1.19 (N)
24*	No	48 (H)	46 (H)	79 (N)	1.1 (N)	1.16 (N)
66*	Yes	40 (N)	41 (H)	80 (N)	1.2 (N)	1.13 (N)
108*	No	48 (H)	41 (H)	75 (N)	0.9 (N)	1.2 (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	117 (N)	245 (N)	103 (H)	8.54 (N)
1	Yes	118.8 (N)	202 (N)	96 (N)	7.23 (N)
15	No	110.4 (N)	307 (N)	121 (H)	5.04 (N)
29	No	126 (H)	234 (N)	186 (H)	3.35 (N)
43	No	109.8 (N)	232 (N)	103 (H)	13.3 (H)
68	Yes	106.2 (N)	333 (H)	114 (H)	2.17 (N)
-7*	Yes	106.2 (N)	333 (H)	114 (H)	2.17 (N)
24*	No	109.8 (N)	455 (H)	163 (H)	1.86 (N)
66*	Yes	112.8 (N)	341 (H)	106 (H)	2.73 (N)
108*	No	108 (N)	428 (H)	145 (H)	4.08 (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)
-14	No	138 (L)	37 (N)	55 (N)	327 (H)
1	Yes	160 (L)	39 (N)	59 (N)	355 (H)
68	Yes	175 (N)	60 (N)	96 (N)	205 (N)
-7*	Yes	175 (N)	60 (N)	96 (N)	205 (N)

Lipid Panel					
Study Day	Fasting	Total Cholesterol (mg/dL)	HDL Cholesterol (mg/dL)	LDL Cholesterol (mg/dL)	Triglycerides (mg/dL)
108*	No	166 (L)	53 (N)	80 (N)	270 (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 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、米国からの参加であった。

肺腫瘤（左肺底部の結節影）（Day 62*～380*）（試験治療下の重篤な有害事象［TE-SAE］）（寛解維持試験）：
Day 62*、Grade 2 の重篤な肺腫瘤が発現した。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 380*、Grade 2 の本事象は回復した。

肺腫瘤（右肺底部の結節影）（Day 62*～380*）（TE-SAE）（寛解維持試験）：
Day 62*、Grade 2 の重篤な肺腫瘤が発現した。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 380*、Grade 2 の本事象は回復した。

無気肺（Day 99*～380*）（TE-SAE）（寛解維持試験）：
Day 99*、Grade 3 の重篤な無気肺が発現した。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 380*、Grade 3 の本事象は回復した。

呼吸困難（Day 99*～275*頃）（TE-SAE）（寛解維持試験）：
Day 99*、Grade 3 の重篤な呼吸困難が発現した。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 275*頃に、Grade 3 の本事象は回復した。

非心臓性胸痛（Day 99*～275*頃）（TE-SAE）（寛解維持試験）：
Day 99*、Grade 3 の重篤な非心臓性胸痛が発現した。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ありと判断された。Day 275*頃に、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**
abdominal pain	Ongoing
arthralgia	Ongoing
arthralgia	Ongoing
back pain	Ongoing
colitis ulcerative	Ongoing
diverticulum	Ongoing
drug hypersensitivity	Ongoing
erectile dysfunction	Ongoing
gastritis	Ongoing
gastrooesophageal reflux disease	Ongoing
haemorrhoids	Ongoing
hepatic steatosis	Ongoing
hiatus hernia	Ongoing
hypertension	Ongoing
hypertriglyceridaemia	Ongoing

Medical History	
Medical History	**Resolution**
intervertebral disc protrusion	Ongoing
memory impairment	Ongoing
nausea	Ongoing
obesity	Ongoing
pseudopolyp	Ongoing
psoriasis	Ongoing
psoriatic arthropathy	Ongoing
rectal haemorrhage	Ongoing
renal cyst	Ongoing
spinal osteoarthritis	Ongoing
splenomegaly	Ongoing
umbilical hernia	Ongoing
inguinal hernia repair	About -11275 days
anal fistula	About -6892 days
fatigue	About -6892 days
intervertebral disc operation	About -6526 days
iron deficiency anaemia	About -6526 days
jaundice	About -3453 days
lipase increased	About -3453 days
basal cell carcinoma	About -2143 days
cholecystectomy	-1412 days
large intestine polyp	-433 days
sinusitis	-318 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
omeprazole	GERD	ORAL	About -4334 days	Ongoing
hydrochlorothiazide	HYPRTENSION	ORAL	-400 days	Ongoing
carvedilol phosphate hemihydrate	HYPERTENSION	ORAL	-399 days	Ongoing
fenofibrate	HYPERTRIGLYCERIDEMIA	ORAL	140 days	Ongoing
metronidazole	ULCERATIVE COLITIS	ORAL	-3483 days	-3477 days
mercaptopurine	ULCERATIVE COLITIS	ORAL	About -3572 days	About -3453 days
azathioprine	ULCERATIVE COLITIS	ORAL	-3427 days	About -3392 days
prednisone	ULCERATIVE COLITIS	ORAL	About -3695 days	About -3239 days
adalimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	About -3603 days	About -3239 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
sulfasalazine	ULCERATIVE COLITIS	ORAL	About -3483 days	About -3239 days
infliximab	ULCERATIVE COLITIS	INTRAVENOUS	About -3238 days	-104 days
mesalazine	ULCERATIVE COLITIS	ORAL	-412 days	-72 days
citric acid;magnesium oxide;sodium picosulfate	BOWEL PREP FOR COLONOSCOPY	ORAL	-5 days	-5 days
propofol	ANESTHESIA FOR COLONOSCOPY	INTRAVENOUS	-4 days	-4 days
hydrocodone	LEFT KNEE PAIN	ORAL	38 days	42 days
ibuprofen	LEFT KNEE PAIN	ORAL	38 days	54 days
magnesium sulfate;potassium sulfate;sodium sulfate	BOWEL PREP FOR SIGMOIDOSCOPY	ORAL	70 days	70 days
propofol	ANESTHESIA DURING SIGMOIDOSCOPY	INTRAVENOUS	71 days	71 days
magnesium sulfate;potassium sulfate;sodium sulfate	PREP FOR SIGMOIDOSCOPY	ORAL	409 days	409 days
propofol	ANESTHESIA DURING SIGMOIDOSCOPY	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
Osteoarthritis	38	38	2	not related	dose not changed	not applicable	medication required + other treatment required
Abdominal pain	34*	About 275*	2	not related	not applicable	dose not changed	other treatment required
Pulmonary mass	62*	380*	2	related	not applicable	dose not changed	other treatment required
Pulmonary mass	62*	380*	2	related	not applicable	dose not changed	other treatment required
Atelectasis	99*	380*	3	related	not applicable	dose not changed	other treatment required
Dyspnoea	99*	About 275*	3	related	not applicable	dose not changed	other treatment required
Non-cardiac chest pain	99*	About 275*	3	related	not applicable	dose not changed	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)
-26	15.5 (N)	48 (N)	5.7 (N)	223 (N)	0.135 (H)	84 (N)
1	15.2 (N)	47 (N)	5.5 (N)	267 (N)	0.122 (N)	85 (N)
16	15.9 (N)	48 (N)	5.7 (N)	228 (N)	0.084 (N)	83 (N)
30	15.3 (N)	49 (N)	5.7 (N)	223 (N)	0.092 (N)	87 (N)
45	15.8 (N)	48 (N)	5.7 (N)	274 (N)	0.104 (N)	84 (N)
70	15.4 (N)	47 (N)	5.6 (N)	292 (N)	0.107 (N)	83 (N)
-9*	15.4 (N)	47 (N)	5.6 (N)	292 (N)	0.107 (N)	83 (N)
21*	15.3 (N)	46 (N)	5.5 (N)	264 (N)	0.091 (N)	83 (N)
58*	15.7 (N)	47 (N)	5.6 (N)	256 (N)	0.088 (N)	84 (N)
106*	15.2 (N)	45 (N)	5.4 (N)	228 (N)	0.084 (N)	84 (N)
163*	16.4 (N)	52 (N)	5.8 (N)	192 (N)	0.087 (N)	91 (N)
218*	16.5 (N)	53 (N)	5.8 (N)	241 (N)	0.09 (N)	91 (N)
275*	16 (N)	48 (N)	5.5 (N)	200 (N)	0.08 (N)	88 (N)
332*	15.3 (N)	45 (N)	5.3 (N)	230 (N)	0.071 (N)	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)
-26	9.93 (N)	6.43 (N)	2.77 (N)	0.59 (N)	0.05 (N)	0.09 (N)
1	10.6 (N)	6.95 (N)	2.85 (N)	0.63 (N)	0.05 (N)	0.12 (N)
16	9.54 (N)	6.42 (N)	2.43 (N)	0.58 (N)	0.06 (N)	0.05 (N)
30	9.35 (N)	6.45 (N)	2.36 (N)	0.41 (N)	0.05 (N)	0.08 (N)
45	9.61 (N)	6 (N)	2.94 (N)	0.48 (N)	0.07 (N)	0.13 (N)
70	10.67 (N)	7.18 (N)	2.93 (N)	0.43 (N)	0.06 (N)	0.08 (N)
-9*	10.67 (N)	7.18 (N)	2.93 (N)	0.43 (N)	0.06 (N)	0.08 (N)
21*	10.33 (N)	6.87 (N)	2.79 (N)	0.48 (N)	0.08 (N)	0.12 (N)
58*	11.21 (H)	7.69 (H)	2.77 (N)	0.53 (N)	0.09 (N)	0.12 (N)
106*	10.27 (N)	6.64 (N)	2.99 (N)	0.48 (N)	0.06 (N)	0.1 (N)
163*	7.88 (N)	5.44 (N)	1.96 (N)	0.37 (N)	0.05 (N)	0.07 (N)
218*	8.5 (N)	5.81 (N)	2.13 (N)	0.47 (N)	0.03 (N)	0.06 (N)
275*	7.55 (N)	4.83 (N)	2.22 (N)	0.37 (N)	0.04 (N)	0.08 (N)
332*	7.39 (N)	4.63 (N)	2.34 (N)	0.32 (N)	0.03 (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)
-26	No	79 (H)	68 (H)	88 (N)	0.7 (N)	1.05 (N)
1	No	64 (H)	76 (H)	62 (N)	0.6 (N)	1.12 (N)
16	No	47 (H)	51 (H)	61 (N)	0.3 (N)	1.12 (N)
30	No	41 (N)	44 (H)	56 (N)	0.4 (N)	1.08 (N)
45	No	32 (N)	39 (H)	50 (N)	0.3 (N)	1.27 (H)
70	No	25 (N)	30 (N)	46 (N)	0.6 (N)	1.13 (N)
-9*	No	25 (N)	30 (N)	46 (N)	0.6 (N)	1.13 (N)
21*	No	44 (H)	51 (H)	45 (N)	0.5 (N)	1.17 (N)
58*	No	29 (N)	29 (N)	47 (N)	0.5 (N)	1.04 (N)
106*	No	47 (H)	43 (H)	46 (N)	0.3 (N)	1.22 (N)
163*	No	55 (H)	52 (H)	43 (N)	0.5 (N)	1.04 (N)
218*	No	42 (N)	50 (H)	40 (N)	0.6 (N)	1.2 (N)
275*	No	51 (H)	46 (H)	42 (N)	0.8 (N)	1.23 (N)
332*	Yes	70 (H)	52 (H)	41 (N)	1.2 (N)	0.96 (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)
-26	No	177.3 (H)	77 (N)	104 (H)	1.99 (N)
1	No	166.2 (H)	115 (N)	82 (N)	1.79 (N)
16	No	166.7 (H)	88 (N)	79 (N)	0.58 (N)
30	No	174.5 (H)	79 (N)	95 (N)	0.76 (N)
45	No	147.5 (H)	117 (N)	87 (N)	0.59 (N)
70	No	164.9 (H)	87 (N)	95 (N)	2.5 (N)
-9*	No	164.9 (H)	87 (N)	95 (N)	2.5 (N)
21*	No	158.3 (H)	107 (N)	95 (N)	1.09 (N)
58*	No	179.2 (H)	87 (N)	95 (N)	3.02 (N)
106*	No	150.9 (H)	89 (N)	85 (N)	0.46 (N)
163*	No	174.9 (H)	81 (N)	95 (N)	0.42 (N)
218*	No	151 (H)	81 (N)	99 (N)	0.52 (N)
275*	No	146.8 (H)	107 (N)	106 (H)	0.2 (N)
332*	Yes	187.6 (H)	73 (N)	84 (N)	0.93 (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)
1	No	151 (L)	34 (N)	93 (N)	197 (N)
70	No	150 (L)	31 (N)	95 (N)	164 (N)
-9*	No	150 (L)	31 (N)	95 (N)	164 (N)
106*	No	155 (L)	31 (N)	93 (N)	270 (N)
332*	Yes	120 (L)	25 (L)	71 (N)	185 (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－死亡により投与中止（Day 302*）

死因：Day 302*に喘息増悪のため死亡した。

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、ニュージーランドからの参加であった。

喘息（Day 298*～継続）（死亡、試験治療下の重篤な有害事象）（寛解維持試験）：
Day 298*、Grade 5 の重篤な喘息が発現した。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 293*に Grade 1 の喘息が認められた。治験責任医師によると、被験者は喘息のためかかりつけ医の診療を受け、アレルギーによる再燃と診断された。寛解維持試験 Day 302*に被験者が自宅で死亡しているのが発見され、家族により治験実施施設に死亡が報告された。死亡診断書によると死因は喘息であった。
*寛解維持試験における study day

Medical History	
Medical History	**Resolution**
ankylosing spondylitis	Ongoing
asthma	Ongoing
colitis ulcerative	Ongoing
folliculitis	Ongoing
hypertension	Ongoing
functional endoscopic sinus surgery	-3647 days
nasal polypectomy	-3647 days
seborrhoeic dermatitis	About -1248 days

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
cilazapril;hydrochlorothiazide	HYPERTENSION	ORAL	-2796 days	Ongoing
mesalazine	ULCERATIVE COLITIS	ORAL	-2187 days	Ongoing
cetirizine hydrochloride	ASTHMA	ORAL	-2181 days	Ongoing
beclometasone	ASTHMA	RESPIRATORY (INHALATION)	-1770 days	Ongoing
paracetamol	ANKYLOSING SPONDALTIS	ORAL	-1770 days	Ongoing
doxazosin mesilate	HYPERTENSION	ORAL	-1441 days	Ongoing
budesonide;formoterol fumarate	ASTHMA	RESPIRATORY (INHALATION)	-1338 days	Ongoing
celecoxib	ANKYLOSISING SPONDYLITIS	ORAL	About -577 days	Ongoing
felodipine	HYPERTENSION	ORAL	-476 days	Ongoing
metoprolol	HYPERTENSION	ORAL	-476 days	Ongoing
mesalazine	ULCERATIVE COLITIS	ORAL	-2704 days	-2393 days
azathioprine	ULCERATIVE COLITIS	ORAL	-2380 days	-2345 days
infliximab	ULCERATIVE COLITIS	INTRAVENOUS DRIP	-1969 days	-1818 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
adalimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	-1819 days	-1704 days
methotrexate sodium	ULCERATIVE COLITIS	ORAL	-1834 days	-1700 days
mesalazine	ULCERATIVE COLITIS	RECTAL	-1998 days	-1669 days
investigational drug	ULCERATIVE COLITIS	SUBCUTANEOUS	-1674 days	About -455 days
prednisone	ULCERATIVE COLITIS	ORAL	-61 days	-55 days
prednisone	ULCERATIVE COLITIS	ORAL	-54 days	-48 days
prednisone	ULCERATIVE COLITIS	ORAL	-47 days	-41 days
prednisone	ULCERATIVE COLITIS	ORAL	-40 days	-34 days
prednisone	ULCERATIVE COLITIS	ORAL	-33 days	98 days
prednisone	ULCERATIVE COLITIS	ORAL	99 days	105 days
prednisone	ULCERATIVE COLITIS	ORAL	106 days	112 days
prednisone	ULCERATIVE COLITIS	ORAL	113 days	119 days
prednisone	ULCERATIVE COLITIS	ORAL	120 days	126 days
fluticasone propionate	ASTHMA	RESPIRATORY (INHALATION)	224 days	289 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	199*	216*	2	not related	not applicable	dose not changed	none
Colitis ulcerative	281*	288*	1	not related	not applicable	dose not changed	none
Colitis ulcerative	289*	Ongoing	2	not related	not applicable	dose not changed	none
Asthma	293*	297*	1	not related	not applicable	dose not changed	none
Electrocardiogram T wave abnormal	294*	302*	1	not related	not applicable	dose not changed	none
Asthma	298*	Ongoing	5	not related	not applicable	dose not changed	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	14.4 (N)	43 (N)	4.3 (N)	252 (N)	0.142 (H)	100 (N)
1	13.8 (N)	41 (N)	4 (N)	216 (N)	0.141 (H)	102 (H)
19	14.4 (N)	43 (N)	4.3 (N)	218 (N)	0.091 (N)	102 (H)
47	14.5 (N)	43 (N)	4.4 (N)	172 (N)	0.061 (N)	97 (N)
68	16 (N)	47 (N)	4.8 (N)	174 (N)	0.06 (N)	98 (N)
-8*	16 (N)	47 (N)	4.8 (N)	174 (N)	0.06 (N)	98 (N)
23*	15.8 (N)	47 (N)	4.8 (N)	165 (N)	0.096 (N)	99 (N)
71*	16 (N)	48 (N)	4.8 (N)	171 (N)	0.091 (N)	100 (N)
113*	16.2 (N)	47 (N)	4.6 (N)	170 (N)	0.086 (N)	103 (H)
168*	16.3 (N)	48 (N)	4.5 (N)	180 (N)	0.076 (N)	106 (H)
221*	15.4 (N)	45 (N)	4.3 (N)	194 (N)	0.074 (N)	105 (H)
277*	15.7 (N)	48 (N)	4.4 (N)	193 (N)	0.097 (N)	110 (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)
-27	10.3 (N)	8.73 (H)	0.82 (N)	0.64 (N)	0.06 (N)	0.06 (N)
1	10.34 (N)	9.08 (H)	0.62 (L)	0.59 (N)	0.04 (N)	0.01 (N)
19	8.92 (N)	6.55 (N)	1.53 (N)	0.67 (N)	0.06 (N)	0.12 (N)
47	5.02 (N)	3.46 (N)	1.11 (N)	0.31 (N)	0.03 (N)	0.12 (N)
68	5.34 (N)	3.46 (N)	1.55 (N)	0.26 (N)	0.02 (N)	0.04 (N)
-8*	5.34 (N)	3.46 (N)	1.55 (N)	0.26 (N)	0.02 (N)	0.04 (N)
23*	4.7 (N)	3.26 (N)	1.03 (N)	0.33 (N)	0.02 (N)	0.06 (N)
71*	6.01 (N)	4.03 (N)	1.4 (N)	0.47 (N)	0.03 (N)	0.08 (N)
113*	6.04 (N)	4.11 (N)	1.24 (N)	0.45 (N)	0.11 (N)	0.13 (N)
168*	6.79 (N)	5.18 (N)	1.07 (N)	0.45 (N)	0.04 (N)	0.05 (N)
221*	7.06 (N)	5.58 (N)	0.92 (N)	0.56 (N)	0 (N)	0 (N)
277*	7.35 (N)	5.84 (N)	0.93 (N)	0.5 (N)	0.05 (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	19 (N)	21 (N)	82 (N)	0.5 (N)	0.93 (N)
1	No	16 (N)	19 (N)	69 (N)	0.6 (N)	0.8 (N)
19	No	19 (N)	25 (N)	73 (N)	0.5 (N)	1.06 (N)
47	No	24 (N)	32 (N)	65 (N)	0.6 (N)	0.89 (N)
68	Yes	20 (N)	25 (N)	69 (N)	0.5 (N)	0.89 (N)
-8*	Yes	20 (N)	25 (N)	69 (N)	0.5 (N)	0.89 (N)
23*	No	23 (N)	29 (N)	63 (N)	0.6 (N)	0.92 (N)
71*	No	25 (N)	29 (N)	64 (N)	0.7 (N)	0.96 (N)
113*	Yes	108 (H)	66 (H)	73 (N)	0.8 (N)	1.06 (N)
168*	No	43 (N)	40 (H)	66 (N)	0.8 (N)	0.96 (N)
221*	No	32 (N)	37 (H)	66 (N)	0.7 (N)	1.01 (N)
277*	No	30 (N)	38 (H)	77 (N)	0.6 (N)	1.09 (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	140.4 (H)	214 (N)	115 (H)	49.5 (H)
1	No	163.2 (H)	184 (N)	117 (H)	45.9 (H)
19	No	123 (N)	288 (N)	93 (N)	18.5 (H)
47	No	148.2 (H)	652 (H)	87 (N)	5.16 (N)
68	Yes	147 (H)	433 (H)	100 (N)	3.04 (N)
-8*	Yes	147 (H)	433 (H)	100 (N)	3.04 (N)
23*	No	145.2 (H)	497 (H)	124 (H)	3.15 (N)
71*	No	139.2 (H)	464 (H)	106 (H)	5.58 (N)
113*	Yes	128.4 (H)	598 (H)	98 (N)	7.18 (N)
168*	No	141.6 (H)	568 (H)	110 (H)	10.3 (H)
221*	No	132.6 (H)	517 (H)	103 (H)	6.23 (N)
277*	No	122.4 (N)	657 (H)	104 (H)	15.6 (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	180 (N)	51 (N)	109 (N)	112 (N)
68	Yes	238 (N)	79 (H)	161 (H)	94 (N)
-8*	Yes	238 (N)	79 (H)	161 (H)	94 (N)
113*	Yes	215 (N)	64 (N)	152 (H)	102 (N)
168*	No	232 (N)	71 (N)	164 (H)	90 (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－完了；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、クロアチアからの参加であった。

ウイルス性胃腸炎（Day 80～87）（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 80、Grade 3 の重篤なウイルス性胃腸炎が発現した。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。
Day 87、Grade 3 の本事象は回復した。

その他の関連情報：急性発症した発熱及び下痢が認められ、被験者は同日に入院した。入院時に抗生剤による経験的治療が開始され、臨床的改善が認められた。便培養検査及びクロストリジウム・ディフィシレ毒素検査を含む感染に関する精密検査の結果は陰性であった。被験者はウイルス性胃腸炎を発症したと考えられた。

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

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
calcium	CALCIUM SUPPLEMENTATION	ORAL	About -654 days	Ongoing
colecalciferol	VITAMIN D SUPPLEMENTATION	ORAL	About -654 days	Ongoing
infliximab	ULCERATIVE COLITIS	INTRAVENOUS	About -807 days	About -443 days
vedolizumab	ULCERATIVE COLITIS	INTRAVENOUS	-420 days	-147 days
ciprofloxacin	GASTEROENTERITIS OF VIRAL INFECTION	INTRAVENOUS	80 days	87 days
metronidazole	GASTEROENTERITIS OF VIRAL INFECTION	INTRAVENOUS	80 days	87 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**
Gastroenteritis viral	80	87	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)
-77	12.4 (L)	45 (N)	4.9 (N)	590 (H)	0.056 (N)	92 (N)
-37	11.6 (L)	40 (N)	4.6 (N)	619 (H)	0.066 (N)	87 (N)
1	12 (L)	41 (N)	4.9 (N)	706 (H)	0.042 (N)	83 (N)
15	10.5 (L)	35 (L)	4.2 (L)	678 (H)	0.044 (N)	82 (N)
29	11.3 (L)	37 (L)	4.6 (N)	791 (H)	0.036 (N)	80 (N)
42	10.9 (L)	35 (L)	4.5 (N)	596 (H)	0.044 (N)	78 (L)
93	10.4 (L)	34 (L)	4.5 (N)	773 (H)	0.033 (N)	76 (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)
-77	7.14 (N)	4.16 (N)	2.06 (N)	0.27 (N)	0.12 (N)	0.55 (N)
-37	8.03 (N)	4.72 (N)	1.94 (N)	0.49 (N)	0.1 (N)	0.78 (H)
1	6.94 (N)	4.08 (N)	1.93 (N)	0.35 (N)	0.06 (N)	0.52 (N)
15	8.15 (N)	5.12 (N)	1.85 (N)	0.44 (N)	0.08 (N)	0.67 (H)
29	7.47 (N)	4.46 (N)	2.11 (N)	0.39 (N)	0.08 (N)	0.43 (N)
42	7.44 (N)	4.68 (N)	1.73 (N)	0.44 (N)	0.07 (N)	0.52 (N)
93	7.7 (N)	4.7 (N)	1.83 (N)	0.65 (N)	0.09 (N)	0.43 (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)
-77	Yes	8 (N)	11 (N)	89 (N)	0.4 (N)	0.77 (N)
-37	Yes	8 (N)	14 (N)	83 (N)	0.3 (N)	0.78 (N)
1	No	6 (N)	11 (N)	84 (N)	0.2 (N)	0.78 (N)
15	Yes	6 (N)	10 (L)	82 (N)	0.2 (N)	0.78 (N)
29	Yes	7 (N)	13 (N)	91 (N)	0.2 (N)	0.83 (N)
42	Yes	9 (N)	14 (N)	91 (N)	0.3 (N)	0.69 (N)
73	Yes					
93	Yes	16 (N)	16 (N)	90 (N)	0.4 (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)
-77	Yes	112.8 (N)	26 (L)	83 (N)	5.24 (N)
-37	Yes	112.2 (N)	72 (N)	82 (N)	12.4 (H)
1	No	112.2 (N)	32 (L)	81 (N)	5.89 (N)
15	Yes	117.6 (N)	44 (N)	84 (N)	8.17 (N)
29	Yes	109.8 (N)	55 (N)	84 (N)	3.38 (N)
42	Yes	135 (H)	53 (N)	82 (N)	5.89 (N)
73	Yes				7.55 (N)
93	Yes	140.4 (H)	42 (N)	88 (N)	2.21 (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	No	147 (N)	56 (N)	84 (N)	84 (N)
42	Yes	154 (N)	61 (N)	80 (N)	64 (N)
73	Yes	158 (N)	64 (H)	89 (N)	
93	Yes	152 (N)	50 (N)	95 (N)	63 (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 12）；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、米国からの参加であった。

敗血症（Day 13～18）（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、試験治療下の注目すべき有害事象）（寛解導入試験）：
Day 13、Grade 4 の重篤な敗血症が発現した。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なしと判断された。Day 18、Grade 4 の本事象は回復した。

その他の関連情報：発熱、悪寒及び鼻閉が認められた。被験者は白血球増加症及び高熱を認め、その後入院した。入院時に抗生剤の静脈内投与による治療が開始された。感染に関する精密検査の結果は陰性であった。広域抗生剤の静脈内投与により改善が認められ、被験者は退院した。被験者は原因が特定できない敗血症を発症したと考えられた。

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

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
mesalazine	ULCERATIVE COLITIS	ORAL	-2142 days	Ongoing
lisinopril	HIGH BLOOD PRESSURE	ORAL	-1259 days	Ongoing
prednisone	ULCERATIVE COLITIS	ORAL	-49 days	Ongoing
infliximab	ULCERATIVE COLITIS	INTRAVENOUS	-2295 days	-2230 days
adalimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	-1989 days	-1685 days
vedolizumab	ULCERATIVE COLITIS	INTRAVENOUS	About -1624 days	About -1260 days
tofacitinib	ULCERATIVE COLITIS	ORAL	-347 days	-123 days
vitamin d nos	GENERAL HEALTH	ORAL	-132 days	-49 days
oxycodone hydrochloride;paracetamol	FEVER	ORAL	13 days	17 days
paracetamol	FEVER	ORAL	13 days	17 days
hydrocortisone	SEPSIS	INTRAVENOUS	14 days	17 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**
Sepsis	13	18	4	not related	drug withdrawn	not applicable	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)
-15	14 (N)	46 (N)	4.8 (N)	317 (N)	0.098 (N)	96 (N)
1	13.6 (N)	43 (N)	4.9 (N)	345 (N)	0.131 (H)	88 (N)
23	12.5 (L)	42 (N)	4.5 (N)	454 (H)	0.081 (N)	94 (N)
45	12.4 (L)	40 (N)	4.5 (N)	264 (N)	0.152 (H)	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)
-15	10.63 (N)	8.81 (H)	1.16 (N)	0.52 (N)	0.05 (N)	0.09 (N)
1	13.86 (H)	11.66 (H)	1.26 (N)	0.69 (N)	0.06 (N)	0.2 (N)
23	14.23 (H)	10.11 (H)	2.3 (N)	1.01 (H)	0.05 (N)	0.77 (H)
45	9.82 (N)	6.85 (N)	2.13 (N)	0.66 (N)	0.03 (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)
-15	Yes	27 (N)	24 (N)	91 (N)	0.3 (N)	1.04 (N)
1	Yes	25 (N)	24 (N)	100 (N)	0.5 (N)	0.96 (N)
23	Yes	47 (H)	33 (N)	93 (N)	0.3 (N)	1.25 (H)
45	Yes	17 (N)	19 (N)	109 (N)	0.4 (N)	0.99 (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	Yes	137.6 (H)	47 (N)	127 (H)	11.5 (H)
1	Yes	148.6 (H)	57 (N)	136 (H)	15.9 (H)
23	Yes	108.9 (N)	31 (L)	83 (N)	16.3 (H)
45	Yes	139.9 (H)	75 (N)	78 (N)	10.2 (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)
1	Yes	147 (L)	27 (L)	84 (N)	204 (N)
45	Yes	171 (N)	35 (N)	98 (N)	203 (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 3）；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 2～18）（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 2、Grade 2 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 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**
anaemia	Ongoing
anxiety	Ongoing
colitis ulcerative	Ongoing
gastrooesophageal reflux disease	Ongoing
pyoderma	Ongoing
haematochezia	-3047 days
pneumomediastinum	-250 days

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
folic acid	NUTRITIONAL SUPPLEMENT	ORAL	-482 days	Ongoing
vitamins nos	NUTRITIONAL SUPPLEMENT	ORAL	-482 days	Ongoing
escitalopram oxalate	ANXIETY	ORAL	-22 days	Ongoing
ferrous gluconate	ANEMIA	ORAL	2 days	Ongoing
pantoprazole	GERD	ORAL	2 days	Ongoing
oxycodone;paracetamol	ULCERATIVE COLITIS	ORAL	9 days	Ongoing
levofloxacin	ACNE WITH MILD CELLULITIS RIGHT CHEST WALL	ORAL	85 days	Ongoing
prednisone	ULCERATIVE COLITIS	ORAL	-1118 days	About -1019 days
infliximab	ULCERATIVE COLITIS	INTRAVENOUS	About -865 days	-438 days
ferrous sulfate	ANEMIA	ORAL	-482 days	-149 days
pantoprazole	GERD	ORAL	-482 days	-134 days
prednisone	ULCERATIVE COLITIS	ORAL	-161 days	-114 days
prednisone	ULCERATIVE COLITIS	ORAL	-114 days	-107 days
prednisone	ULCERATIVE COLITIS	ORAL	-106 days	-99 days
prednisone	ULCERATIVE COLITIS	ORAL	-98 days	-91 days
vedolizumab	ULCERATIVE COLITIS	INTRAVENOUS	-132 days	-86 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
mesalazine	ULCERATIVE COLITIS	ORAL	About -499 days	-85 days
prednisone	ULCERATIVE COLITIS	ORAL	-90 days	-83 days
mesalazine	ULCERATIVE COLITIS	RECTAL	-482 days	About -45 days
red blood cells, concentrated	ANEMIA DUE TO ACUTE BLOOD LOSS	INTRAVENOUS	2 days	2 days
methylprednisolone sodium succinate	ULCERATIVE COLITIS	INTRAVENOUS	3 days	8 days
prednisone	ULCERATIVE COLITIS	ORAL	-82 days	13 days
prednisone	ULCERATIVE COLITIS	ORAL	14 days	About 78 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	2	18	2	not related	drug withdrawn	not applicable	medication required + permanent study discontinuation
Cellulitis	83	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)
-22	8.3 (L)	33 (L)	4.9 (N)	612 (H)	0.159 (H)	67 (L)
1	7.3 (L)	29 (L)	4.4 (L)	560 (H)	0.151 (H)	66 (L)
25	9.4 (L)	37 (L)	4.8 (N)	645 (H)	0.147 (H)	76 (L)
85	9.1 (L)	37 (L)	5.3 (N)	492 (H)	0.128 (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)
-22	11.94 (H)	8.36 (H)	2.39 (N)	0.36 (N)	0.24 (H)	0 (N)
1	9.61 (N)	7.97 (H)	0.89 (L)	0.67 (N)	0.03 (N)	0.05 (N)
25	15.07 (H)	12.54 (H)	1.59 (N)	0.82 (N)	0.03 (N)	0.09 (N)
85	9.79 (N)	6.64 (N)	1.71 (N)	1.3 (H)	0.1 (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)
-22	No	12 (N)	10 (L)	56 (N)	0.2 (N)	1.04 (N)
1	No	11 (N)	12 (N)	54 (N)	0.3 (N)	0.85 (N)
25	Yes	20 (N)	11 (N)	67 (N)	0.2 (N)	0.71 (N)
85	No	21 (N)	17 (N)	59 (N)	0.3 (N)	0.98 (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	139.4 (H)	23 (L)	114 (H)	3.06 (N)
1	No	168.5 (H)	<18 (L)	102 (H)	8.44 (N)
25	Yes	195.1 (H)	<18 (L)	92 (N)	5.38 (N)
85	No	143 (H)	33 (L)	125 (H)	35.2 (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)
1	No	96 (L)	49 (N)	37 (N)	106 (N)
25	Yes	107 (L)	58 (N)	40 (N)	91 (N)
85	No	94 (L)	47 (N)	41 (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－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 47*）

ベースライン特性：本被験者は 2[redacted] 歳の南アフリカカラード女性であった。その他の特性として、民族は非ヒスパニック／ラテン系、南アフリカからの参加であった。

蜂巣炎（Day 45*～55*）（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、試験治療下の注目すべき有害事象［TE-AEI］）（寛解維持試験）：
Day 45*、Grade 3 の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ありと判断された。Day 55*、Grade 3 の本事象は回復した。

爪囲炎（Day 45*～55*）（TE-SAE、投与中止に至った有害事象、TE-AEI）（寛解維持試験）：
Day 45*、Grade 3 の重篤な爪囲炎が発現した。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ありと判断された。Day 55*、Grade 3 の本事象は回復した。

その他の関連情報：被験者は、右人差し指の爪囲炎及び蜂巣炎のため入院した。抗生剤による治療が行われ、膿瘍ドレナージ術が実施された。
*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	About -2383 days	Ongoing
norethisterone enantate	CONTRACEPTION	INTRAMUSCULAR	About -1652 days	Ongoing
azathioprine	ULCERATIVE COLITIS	ORAL	-63 days	Ongoing
fentanyl	SEDATION	INTRAVENOUS	-8 days	-8 days
midazolam	SEDATION	INTRAVENOUS	-8 days	-8 days
propofol	SEDATION	INTRAVENOUS	-8 days	-8 days
fentanyl	SEDATION	INTRAVENOUS	69 days	69 days
midazolam	SEDATION	INTRAVENOUS	69 days	69 days
propofol	SEDATION	INTRAVENOUS	69 days	69 days
prednisone	ULCERATIVE COLITIS	ORAL	-51 days	99 days
prednisone	ULCERATIVE COLITIS	ORAL	100 days	106 days
prednisone	ULCERATIVE COLITIS	ORAL	107 days	113 days
prednisone	ULCERATIVE COLITIS	ORAL	114 days	120 days
analgesics	PAIN RELIEF	INTRAVENOUS	125 days	125 days
dexamethasone	SAE PARONYCHIA, CELLULITIS	INTRAVENOUS	125 days	125 days
lidocaine	ANAESTHETIC	INTRAVENOUS	125 days	125 days
morphine	PAIN RELIEF	INTRAVENOUS	125 days	125 days
parecoxib sodium	PERI-OPERATIVE TREATMENT	INTRAVENOUS	125 days	125 days
propafenone	ANAESTHETIC	INTRAVENOUS	125 days	125 days
loprazolam mesilate	INSOMNIA	ORAL	125 days	126 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
paracetamol	PAIN RELIEF	INTRAVENOUS	125 days	126 days
amoxicillin trihydrate;clavulanate potassium	PARONYCHIA & CELLULITIS	INTRAVENOUS	125 days	128 days
paracetamol	PAIN RELIEF	ORAL	127 days	128 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	45*	55*	3	related	not applicable	drug withdrawn	medication required + permanent study discontinuation
Paronychia	45*	55*	3	related	not applicable	drug withdrawn	medication required + other treatment required + permanent study discontinuation
Insomnia	47*	48*	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)
-35	9.9 (L)	33 (L)	3.7 (L)	532 (H)	0.113 (N)	90 (N)
-15	9.6 (L)	33 (L)	3.8 (L)	715 (H)	0.152 (H)	89 (N)
1	9.7 (L)	34 (N)	3.9 (L)	375 (N)	0.138 (H)	86 (N)
15	9.5 (L)	35 (N)	3.9 (L)	430 (H)	0.116 (N)	90 (N)
29	11.2 (L)	40 (N)	4.6 (N)	406 (H)	0.129 (H)	88 (N)
43	11.8 (N)	41 (N)	4.7 (N)	325 (N)	0.123 (H)	86 (N)
69	12.3 (N)	40 (N)	4.7 (N)	267 (N)	0.055 (N)	87 (N)
-10*	12.3 (N)	40 (N)	4.7 (N)	267 (N)	0.055 (N)	87 (N)
21*	13.7 (N)	43 (N)	4.9 (N)	293 (N)	0.065 (N)	87 (N)
49*	12 (N)	37 (N)	4.1 (N)	241 (N)	0.038 (N)	89 (N)
75*	12.6 (N)	38 (N)	4.2 (N)	266 (N)	0.061 (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)
-35	4.77 (N)	3.78 (N)	0.7 (L)	0.16 (N)	0.01 (N)	0.12 (N)
-15	8.16 (N)	6.4 (N)	1.44 (N)	0.27 (N)	0.02 (N)	0.02 (N)
1	7.82 (N)	4.55 (N)	2.82 (N)	0.3 (N)	0.04 (N)	0.11 (N)
15	8.25 (N)	4.91 (N)	2.86 (N)	0.3 (N)	0.05 (N)	0.12 (N)
29	7.13 (N)	3.17 (N)	3.57 (N)	0.28 (N)	0.05 (N)	0.06 (N)
43	6.94 (N)	4.06 (N)	2.44 (N)	0.31 (N)	0.03 (N)	0.1 (N)
69	5.95 (N)	4.48 (N)	1.28 (N)	0.14 (N)	0.02 (N)	0.03 (N)
-10*	5.95 (N)	4.48 (N)	1.28 (N)	0.14 (N)	0.02 (N)	0.03 (N)
21*	6.29 (N)	2.8 (N)	3.13 (N)	0.29 (N)	0.02 (N)	0.06 (N)
49*	4.77 (N)	2.6 (N)	1.81 (N)	0.22 (N)	0.02 (N)	0.12 (N)
75*	6.28 (N)	3.97 (N)	1.8 (N)	0.28 (N)	0.07 (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)
-35	No	12 (N)	10 (N)	83 (N)	<0.2 (L)	0.71 (N)
1	No	15 (N)	12 (N)	42 (N)	0.2 (N)	0.74 (N)
15	Yes	13 (N)	12 (N)	37 (N)	0.2 (N)	0.75 (N)
29	Yes	16 (N)	15 (N)	40 (N)	<0.2 (L)	0.78 (N)
43	No	17 (N)	13 (N)	36 (N)	<0.2 (L)	0.77 (N)
69	No	24 (N)	16 (N)	44 (N)	<0.2 (L)	0.74 (N)
-10*	No	24 (N)	16 (N)	44 (N)	<0.2 (L)	0.74 (N)
21*	No	13 (N)	14 (N)	42 (N)	0.2 (N)	0.85 (N)
49*	Yes	13 (N)	12 (N)	45 (N)	<0.2 (L)	0.63 (N)
75*	No	50 (H)	28 (N)	77 (N)	0.4 (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)
-35	No	106.8 (N)	51 (N)	87 (N)	73 (H)
1	No	112.8 (N)	49 (N)	90 (N)	2.2 (N)
15	Yes	115.2 (N)	47 (N)	72 (N)	2.21 (N)
29	Yes	112.2 (N)	71 (N)	69 (L)	0.63 (N)
43	No	117 (H)	90 (N)	75 (N)	0.7 (N)
69	No	121.2 (H)	125 (N)	100 (H)	5.54 (N)
-10*	No	121.2 (H)	125 (N)	100 (H)	5.54 (N)
21*	No	109.2 (N)	90 (N)	87 (N)	0.99 (N)
49*	Yes	144.6 (H)	60 (N)	79 (N)	27 (H)
75*	No	154.8 (H)	90 (N)	97 (N)	5.48 (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	189 (N)	47 (N)	127 (N)	112 (N)
69	No	174 (N)	48 (N)	113 (N)	79 (N)
-10*	No	174 (N)	48 (N)	113 (N)	79 (N)

Lipid Panel					
Study Day	Fasting	Total Cholesterol (mg/dL)	HDL Cholesterol (mg/dL)	LDL Cholesterol (mg/dL)	Triglycerides (mg/dL)
49*	Yes	172 (N)	33 (L)	134 (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 200 mg 群（コホート B）

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、民族に関する情報は取得できず、フランスからの参加であった。

潰瘍性大腸炎（Day 35～46）（試験治療下の重篤な有害事象）（寛解導入試験）：
Day 35、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 46、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	About -1529 days	About -1074 days
adalimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	About -1073 days	-907 days
prednisone	ULCERATIVE COLITIS	ORAL	About -1529 days	-879 days
etrolizumab	ULCERATIVE COLITIS	SUBCUTANEOUS	-879 days	-456 days
vedolizumab	ULCERATIVE COLITIS	INTRAVENOUS	-465 days	-93 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	35	46	3	not related	dose not changed	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)
-25	14.3 (N)	44 (N)	5.5 (N)	249 (N)	0.066 (N)	79 (N)
1	15.1 (N)	46 (N)	5.7 (N)	237 (N)	0.07 (N)	82 (N)
14	14.8 (N)	44 (N)	5.6 (N)	245 (N)	0.045 (N)	79 (N)
28	14.4 (N)	46 (N)	5.8 (N)	282 (N)	0.071 (N)	80 (N)
42	16 (N)	49 (N)	6.1 (N)	323 (N)	0.09 (N)	80 (N)
63	14.2 (N)	43 (N)	5.4 (N)	231 (N)	0.114 (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	6.72 (N)	3.98 (N)	2 (N)	0.38 (N)	0.05 (N)	0.3 (N)
1	8.26 (N)	5.37 (N)	2.07 (N)	0.47 (N)	0.04 (N)	0.31 (N)
14	6.75 (N)	4.21 (N)	1.95 (N)	0.33 (N)	0.05 (N)	0.21 (N)
28	7.19 (N)	3.68 (N)	2.72 (N)	0.55 (N)	0.05 (N)	0.2 (N)
42	12.41 (H)	8.41 (H)	2.65 (N)	1.01 (H)	0.07 (N)	0.27 (N)
63	13.46 (H)	10.13 (H)	2.11 (N)	0.84 (N)	0.04 (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)
-25	Yes	8 (N)	13 (N)	93 (N)	0.5 (N)	0.72 (N)
1	Yes	7 (N)	9 (L)	93 (N)	0.4 (N)	0.63 (N)
14	Yes	9 (N)	10 (L)	90 (N)	0.4 (N)	0.77 (N)
28	Yes	10 (N)	18 (N)	90 (N)	0.5 (N)	0.8 (N)
42	Yes	6 (N)	10 (L)	105 (N)	0.3 (N)	0.87 (N)
63	Yes	15 (N)	9 (L)	88 (N)	0.4 (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)
-25	Yes	148.2 (H)	77 (N)	85 (N)	4 (N)
1	Yes	166.8 (H)	54 (N)	92 (N)	5.67 (N)
14	Yes	135.6 (H)	58 (N)	77 (N)	1.54 (N)
28	Yes	132 (H)	275 (N)	83 (N)	2.32 (N)
42	Yes	114 (N)	46 (N)	94 (N)	104 (H)
63	Yes	159.6 (H)	29 (L)	67 (L)	5.46 (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	196 (N)	44 (N)	130 (N)	76 (N)
42	Yes	144 (N)	34 (N)	81 (N)	116 (N)
63	Yes	180 (N)	63 (N)	106 (N)	90 (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 120*）

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、ポーランドからの参加であった。

潰瘍性大腸炎（Day 40～48）（試験治療下の重篤な有害事象［TE-SAE］）（寛解導入試験）：
Day 40、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 48、Grade 3 の本事象は回復した。

潰瘍性大腸炎（Day 71*～72*）（TE-SAE、投与中止に至った有害事象）（寛解維持試験）：
Day 71*、Grade 2 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 72*、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**
anaemia	Ongoing
colitis ulcerative	Ongoing
dental caries	Ongoing
visual impairment	Ongoing
varicella	About -8223 days
forearm fracture	About -5666 days
tonsillectomy	About -5666 days
tonsillectomy	About -4205 days

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
ascorbic acid;ferrous sulfate	ANEMIA	ORAL	About -278 days	Ongoing
mesalazine	ULCERATIVE COLITIS	ORAL	About -278 days	Ongoing
lactulose	CONSTIPATION	ORAL	131 days	Ongoing
methylprednisolone	ULCERATIVE COLITIS	ORAL	190 days	Ongoing
methylprednisolone	ULCERATIVE COLITIS	ORAL	About -217 days	40 days
methylprednisolone	ULCERATIVE COLITIS	ORAL	41 days	41 days
methylprednisolone	ULCERATIVE COLITIS	ORAL	42 days	44 days
saccharomyces boulardii	ULCERATIVE COLITIS	ORAL	41 days	45 days
amoxicillin trihydrate;clavulanate potassium	EXACERBATION OF THE DISEASE ULCERATIVE COLITIS	ORAL	41 days	47 days
metronidazole	FEVER	ORAL	41 days	47 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
saccharated iron oxide	ANEMIA	INTRAVENOUS	41 days	47 days
methylprednisolone	ULCERATIVE COLITIS	ORAL	45 days	72 days
methylprednisolone	ULCERATIVE COLITIS	ORAL	73 days	73 days
lactulose	CONSTIPATION	ORAL	73 days	75 days
methylprednisolone	ULCERATIVE COLITIS	ORAL	74 days	82 days
methylprednisolone	ULCERATIVE COLITIS	ORAL	83 days	110 days
methylprednisolone	ULCERATIVE COLITIS	ORAL	About 88 days	189 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	40	48	3	not related	dose not changed	not applicable	none
Constipation	73	75	2	not related	dose not changed	not applicable	medication required
Pyrexia	16*	18*	1	not related	not applicable	dose not changed	none
Constipation	50*	Ongoing	1	not related	not applicable	dose not changed	medication required
Colitis ulcerative	71*	72*	2	not related	not applicable	drug withdrawn	other treatment required + permanent study discontinuation
Face oedema	110*	Ongoing	1	not related	not applicable	dose not changed	none
Oedema peripheral	110*	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)
-28	12.1 (L)	40 (N)	4.9 (N)	475 (H)	0.097 (N)	82 (N)
1	12.7 (N)	41 (N)	5 (N)	380 (N)	0.105 (N)	83 (N)
12	12.9 (N)	43 (N)	5 (N)	416 (H)	0.09 (N)	86 (N)
26	13.4 (N)	47 (N)	5.3 (N)	378 (N)	0.13 (N)	89 (N)
40	12.8 (N)	43 (N)	5.2 (N)	385 (N)	0.093 (N)	84 (N)
68	13.7 (N)	43 (N)	5.1 (N)	389 (N)	0.09 (N)	86 (N)
-14*	13.7 (N)	43 (N)	5.1 (N)	389 (N)	0.09 (N)	86 (N)
22*	13.3 (N)	42 (N)	5 (N)	375 (N)	0.099 (N)	83 (N)
64*	13.2 (N)	40 (N)	5.1 (N)	392 (N)	0.117 (N)	80 (N)
106*	12.4 (L)	38 (L)	5 (N)	407 (H)	0.14 (H)	77 (L)
121*	10.8 (L)	35 (L)	4.5 (N)	432 (H)	0.141 (H)	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	8.85 (N)	7.27 (H)	1.07 (N)	0.44 (N)	0.03 (N)	0.04 (N)
1	10.73 (H)	8.99 (H)	0.86 (L)	0.77 (N)	0.06 (N)	0.04 (N)
12	8.32 (N)	6.03 (N)	1.53 (N)	0.61 (N)	0.06 (N)	0.09 (N)
26	8.4 (N)	5.65 (N)	1.95 (N)	0.74 (N)	0.03 (N)	0.04 (N)
40	6.71 (N)	4.67 (N)	1.3 (N)	0.69 (N)	0.02 (N)	0.02 (N)
68	9.25 (N)	5.86 (N)	2.43 (N)	0.88 (N)	0.04 (N)	0.05 (N)
-14*	9.25 (N)	5.86 (N)	2.43 (N)	0.88 (N)	0.04 (N)	0.05 (N)
22*	12.29 (H)	9.37 (H)	2.1 (N)	0.74 (N)	0.03 (N)	0.06 (N)
64*	10.21 (N)	8.36 (H)	1.05 (N)	0.68 (N)	0.08 (N)	0.04 (N)
106*	12.26 (H)	10.02 (H)	1.27 (N)	0.92 (N)	0.02 (N)	0.03 (N)
121*	7.21 (N)	5.79 (N)	0.67 (L)	0.69 (N)	0.05 (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)
-28	Yes	9 (N)	9 (L)	58 (N)	0.3 (N)	0.84 (N)
1	Yes	9 (N)	8 (L)	61 (N)	0.2 (N)	0.83 (N)
12	Yes	10 (N)	13 (N)	66 (N)	0.3 (N)	0.83 (N)
26	Yes	11 (N)	10 (L)	60 (N)	0.4 (N)	0.74 (N)
40	Yes	9 (N)	8 (L)	55 (N)	0.3 (N)	0.8 (N)
68	Yes	9 (N)	9 (L)	59 (N)	0.3 (N)	0.64 (N)
-14*	Yes	9 (N)	9 (L)	59 (N)	0.3 (N)	0.64 (N)
22*	Yes	15 (N)	10 (L)	53 (N)	0.4 (N)	0.62 (N)
64*	No	13 (N)	9 (L)	57 (N)	0.3 (N)	0.68 (N)
106*	Yes	7 (N)	7 (L)	52 (N)	0.3 (N)	0.68 (N)
121*	Yes	12 (N)	8 (L)	63 (N)	<0.2 (L)	0.55 (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	144 (H)	<18 (L)	83 (N)	18.3 (H)
1	Yes	143.4 (H)	19 (L)	87 (N)	9.43 (N)
12	Yes	144.6 (H)	38 (L)	106 (H)	9.82 (N)
26	Yes	157.8 (H)	<18 (L)	101 (H)	26.7 (H)
40	Yes	139.8 (H)	19 (L)	97 (N)	15.3 (H)
68	Yes	182.4 (H)	<18 (L)	95 (N)	17.9 (H)
-14*	Yes	182.4 (H)	<18 (L)	95 (N)	17.9 (H)
22*	Yes	185.4 (H)	<18 (L)	82 (N)	7.93 (N)
64*	No	163.2 (H)	<18 (L)	99 (N)	27.7 (H)
106*	Yes	158.4 (H)	<18 (L)	88 (N)	16.3 (H)
121*	Yes	202.2 (H)	<18 (L)	132 (H)	16.2 (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)
-28	Yes	141 (N)	33 (N)	86 (N)	90 (N)
1	Yes	142 (N)	39 (N)	82 (N)	97 (N)
12	Yes	126 (L)	42 (N)	70 (N)	106 (N)
26	Yes	137 (N)	43 (N)	86 (N)	70 (N)
40	Yes	133 (N)	33 (N)	79 (N)	99 (N)
68	Yes	136 (N)	44 (N)	84 (N)	50 (N)
-14*	Yes	136 (N)	44 (N)	84 (N)	50 (N)
22*	Yes	145 (N)	42 (N)	91 (N)	65 (N)
64*	No	138 (N)	37 (N)	77 (N)	136 (N)
106*	Yes	133 (N)	36 (N)	81 (N)	90 (N)
121*	Yes	139 (N)	51 (N)	77 (N)	76 (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 19）；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 20～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）（寛解導入試験）：
Day 20、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。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**
colecalciferol	OSTEOPOROSIS PROPHYLAXIS	ORAL	About -1296 days	Ongoing
amino acids nos;carbohydrates nos;electrolytes nos	PARENTERAL NUTRITION	INTRAVENOUS	20 days	Ongoing
calcium acetate;magnesium acetate;potassium acetate;sodium acetate;sodium chloride	HYDRATION	INTRAVENOUS	20 days	Ongoing
metamizole	ABDOMINAL PAIN	ORAL	20 days	Ongoing
pantoprazole sodium sesquihydrate	GASTRIC ULCER PROPHYLAXIS	ORAL	20 days	Ongoing
tramadol	ABDOMINAL PAIN	ORAL	20 days	Ongoing
prednisolone	ULCERATIVE COLITIS	INTRAVENOUS	21 days	Ongoing
mesalazine	ULCERATIVE COLITIS	ORAL	About -2272 days	About -1266 days
infliximab	ULCERATIVE COLITIS	INTRAVENOUS	About -1237 days	About -1054 days
vedolizumab	ULCERATIVE COLITIS	INTRAVENOUS	About -1084 days	About -993 days
azathioprine	ULCERATIVE COLITIS	ORAL	About -1023 days	About -415 days
infliximab	ULCERATIVE COLITIS	INTRAVENOUS	About -445 days	About -385 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
golimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	About -384 days	About -354 days
mesalazine	ULCERATIVE COLITIS	ORAL	About -200 days	About -142 days
prednisolone	ULCERATIVE COLITIS	ORAL	-388 days	19 days
blood, whole	SIGNIFICANT HGB DECREASE IN LOCAL LAB FROM 11 TO 8.6 G/DL	INTRAVENOUS	21 days	21 days
prednisolone	ULCERATIVE COLITIS	ORAL	20 days	22 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	20	Ongoing	3	not related	drug withdrawn	not applicable	medication required + permanent study discontinuation
Haemoglobin decreased	21	21	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	16 (N)	50 (H)	5.3 (N)	359 (N)	0.104 (N)	96 (N)
1	12.5 (N)	40 (N)	4.2 (N)	484 (H)	0.13 (H)	96 (N)
20	11.6 (N)	38 (N)	3.8 (L)	659 (H)	0.304 (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)
-16	13.69 (H)	11.22 (H)	1.03 (N)	0.7 (N)	0.14 (N)	0.61 (H)
1	13.33 (H)	10.57 (H)	1.3 (N)	0.82 (N)	0.08 (N)	0.55 (N)
20	11.35 (H)	7.88 (H)	1.54 (N)	0.3 (N)	0.06 (N)	1.57 (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	No	19 (N)	13 (N)	99 (N)	0.6 (N)	0.64 (N)
1	Yes	13 (N)	9 (N)	80 (N)	0.2 (N)	0.54 (N)
20	Yes	14 (N)	11 (N)	115 (H)	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)
-16	No	108.6 (N)	57 (N)	87 (N)	9.56 (N)
1	Yes	129 (H)	29 (N)	108 (H)	30.3 (H)
20	Yes	110.4 (N)	28 (N)	77 (N)	36.2 (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)
-16	No	222 (H)	61 (N)	114 (N)	221 (H)
1	Yes	189 (N)	45 (N)	77 (N)	296 (H)
20	Yes	214 (N)	68 (N)	102 (N)	200 (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 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 48）；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、フランスからの参加であった。

潰瘍性大腸炎（Day 31～80）（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 31、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 80、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	Ongoing
asthenia	Ongoing
colitis ulcerative	Ongoing

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
azathioprine	ULCERATIVE COLITIS	ORAL	-168 days	Ongoing
calcium carbonate;colecalciferol	ULCERATIVE COLITIS	ORAL	-71 days	Ongoing
prednisolone	ULCERATIVE COLITIS	ORAL	-40 days	Ongoing
mesalazine	ULCERATIVE COLITIS	RECTAL	About -5748 days	-5063 days
ciclosporin	ULCERATIVE COLITIS	ORAL	-4975 days	-4930 days
mesalazine	ULCERATIVE COLITIS	ORAL	-4975 days	-3551 days
azathioprine	ULCERATIVE COLITIS	ORAL	-4930 days	About -3314 days
infliximab	ULCERATIVE COLITIS	INTRAVENOUS	-3551 days	About -1215 days
methotrexate	ULCERATIVE COLITIS	SUBCUTANEOUS	About -2096 days	About -1062 days
adalimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	About -1245 days	About -1062 days
vedolizumab	ULCERATIVE COLITIS	INTRAVENOUS	-1059 days	-141 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
infliximab	ULCERATIVE COLITIS	INTRAVENOUS	-110 days	-71 days
ascorbic acid;macrogol 3350;potassium chloride;sodium ascorbate;sodium chloride;sodium sulfate	ENDOSCOPY	ORAL	-7 days	-7 days
calcium phosphate monobasic;magnesium glycerophosphate;phosphoric acid;sodium phosphate dibasic	DECREASE PHOPHORUS	ORAL	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
Blood phosphorus decreased	1	Ongoing	3	not related	dose not changed	not applicable	medication required
Colitis ulcerative	31	80	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)
-15	12.9 (N)	40 (N)	4.3 (N)	329 (N)	0.089 (N)	92 (N)
1	12.8 (N)	38 (N)	4.3 (N)	320 (N)	0.162 (H)	89 (N)
13	12.5 (N)	38 (N)	4.1 (N)	374 (N)	0.119 (N)	93 (N)
24	12.8 (N)	38 (N)	4.1 (N)	335 (N)	0.122 (H)	91 (N)
49	12.6 (N)	38 (N)	4.1 (N)	430 (H)	0.1 (N)	94 (N)
79	11.1 (L)	32 (L)	3.6 (L)	438 (H)	0.088 (N)	88 (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	8.05 (N)	4.47 (N)	2.79 (N)	0.51 (N)	0.05 (N)	0.24 (N)
1	8.73 (N)	5.06 (N)	2.65 (N)	0.71 (N)	0.04 (N)	0.27 (N)
13	12.15 (H)	9.36 (H)	2.02 (N)	0.58 (N)	0.05 (N)	0.15 (N)
24	7.26 (N)	4.81 (N)	1.73 (N)	0.54 (N)	0.05 (N)	0.13 (N)
49	11.63 (H)	7.99 (H)	2.99 (N)	0.5 (N)	0.05 (N)	0.11 (N)
79	7.81 (N)	4.95 (N)	1.52 (N)	0.7 (N)	0.06 (N)	0.58 (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)
-15	Yes	10 (N)	11 (N)	73 (N)	0.5 (N)	0.93 (N)
1	Yes	14 (N)	12 (N)	72 (N)	0.4 (N)	0.76 (N)
13	Yes	11 (N)	14 (N)	75 (N)	0.6 (N)	0.78 (N)
24	Yes	10 (N)	13 (N)	83 (N)	0.8 (N)	0.77 (N)
49	Yes	11 (N)	17 (N)	77 (N)	0.5 (N)	0.84 (N)
79	No	48 (H)	23 (N)	85 (N)	0.4 (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)
-15	Yes	76.8 (N)	61 (N)	82 (N)	4.69 (N)
1	Yes	91.8 (N)	42 (N)	77 (N)	25.3 (H)
13	Yes	90 (N)	103 (N)	75 (N)	4.17 (N)
24	Yes	90 (N)	65 (N)	76 (N)	19 (H)
49	Yes	82.8 (N)	137 (N)	84 (N)	2.94 (N)
79	No	108 (N)	39 (N)	101 (H)	17.7 (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)
-15	Yes	152 (L)	55 (N)	83 (N)	89 (N)
1	Yes	146 (L)	50 (N)	70 (N)	112 (N)
13	Yes	162 (L)	59 (N)	82 (N)	136 (N)
24	Yes	159 (L)	57 (N)	88 (N)	97 (N)
49	Yes	173 (N)	55 (N)	96 (N)	124 (N)
79	No	110 (L)	22 (L)	56 (N)	176 (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] 歳の女性であり、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、民族に関する情報は取得できず、フランスからの参加であった。

腎仙痛（Day 2～5）（試験治療下の重篤な有害事象［TE-SAE］）（寛解導入試験）：
Day 2、Grade 3 の重篤な腎仙痛が発現した。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 5、Grade 3 の本事象は回復した。

潰瘍性大腸炎（Day 14～22）（TE-SAE、投与中止に至った有害事象）（寛解導入試験）：
Day 14、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 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**
abdominal pain	Ongoing
asthenia	Ongoing
cholelithiasis	Ongoing
colitis ulcerative	Ongoing
rectal haemorrhage	Ongoing

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
ethinylestradiol;levonorgestrel	CONTRACEPTION	ORAL	About -543 days	Ongoing
paracetamol	ABDOMINAL PAIN	ORAL	14 days	Ongoing
phloroglucinol	ABDOMINAL PAIN	ORAL	14 days	Ongoing
sulfamethoxazole;trimethoprim	PREVENTION OF PULMONARY INFECTION UNDER THE TREATMENT OF NEORAL	ORAL	15 days	Ongoing
ciclosporin	ULCERATIVE COLITIS	ORAL	19 days	Ongoing
prednisolone	ULCERATIVE COLITIS	ORAL	36 days	Ongoing
mesalazine	ULCERATIVE COLITIS	ORAL	About -3465 days	About -2370 days
infliximab	ULCERATIVE COLITIS	INTRAVENOUS DRIP	About -1852 days	About -1093 days
azathioprine	ULCERATIVE COLITIS	ORAL	About -2583 days	-973 days
vedolizumab	ULCERATIVE COLITIS	INTRAVENOUS DRIP	-1020 days	-939 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
adalimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	-918 days	-116 days
morphine	NEPHRITIC COLIC	INTRAVENOUS	2 days	2 days
paracetamol	NEPHRITIC COLIC	INTRAVENOUS	2 days	3 days
paracetamol	NEPHRITIC COLIC	ORAL	4 days	5 days
prednisolone	ULCERATIVE COLITIS	ORAL	-18 days	14 days
ferric carboxymaltose	ANEMIA	INTRAVENOUS	15 days	15 days
ciclosporin	ULCERATIVE COLITIS	INTRAVENOUS	15 days	18 days
prednisolone	ULCERATIVE COLITIS	INTRAVENOUS	14 days	21 days
enoxaparin sodium	PREVENTION OF VENOUS THROMBOEMBOLISM	SUBCUTANEOUS	14 days	22 days
prednisolone	ULCERATIVE COLITIS	ORAL	22 days	28 days
prednisolone	ULCERATIVE COLITIS	ORAL	29 days	35 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
Renal colic	2	5	3	not related	dose not changed	not applicable	medication required
Anaemia	About 5	Ongoing	2	not related	dose not changed	not applicable	medication required
Colitis ulcerative	14	22	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)
-19	12.4 (N)	36 (N)	4 (L)	318 (N)	0.077 (N)	91 (N)
14	8.6 (L)	27 (L)	3.1 (L)	448 (H)	0.1 (N)	86 (N)
39	12.3 (N)	39 (N)	4.1 (N)	210 (N)	0.164 (H)	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)
-19	11.35 (H)	8.78 (H)	1.59 (N)	0.83 (N)	0.05 (N)	0.09 (N)
14	11.67 (H)	9.84 (H)	1.13 (N)	0.66 (N)	0.02 (N)	0.01 (N)
39	8.66 (N)	5.59 (N)	2.26 (N)	0.72 (N)	0.04 (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	No	18 (N)	13 (N)	55 (N)	0.4 (N)	0.89 (N)
1	No	96 (H)	26 (N)	41 (N)	0.2 (N)	0.75 (N)
14	No	63 (H)	31 (N)	50 (N)	0.3 (N)	0.86 (N)
39	No	26 (N)	14 (N)	62 (N)	0.4 (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)
-19	No	110.4 (N)	30 (N)	86 (N)	42.4 (H)
1	No	127.2 (H)	23 (L)	93 (N)	41.7 (H)
14	No	106.2 (N)	21 (L)	130 (H)	85.7 (H)
39	No	130.2 (H)	23 (L)	117 (H)	0.59 (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)
-19	No	177 (N)	46 (N)	101 (N)	130 (N)
1	No	177 (N)	55 (N)	99 (N)	125 (N)
14	No	169 (N)	43 (N)	82 (N)	163 (H)
39	No	243 (H)	77 (N)	143 (H)	114 (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－完了；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、フランスからの参加であった。

上咽頭炎（Day 18～23）（試験治療下の注目すべき有害事象［TE-AEI］）（寛解導入試験）：
Day 18、Grade 1 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 23、Grade 1 の本事象は回復した。

せつ（Day 81～継続）（TE-AEI）（寛解導入試験）：
Day 81、Grade 1 の非重篤なせつが発現した。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。

口腔真菌感染（Day 81～継続）（TE-AEI）（寛解導入試験）：
Day 81、Grade 1 の非重篤な口腔真菌感染が発現した。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。

外陰部腟カンジダ症（Day 81～継続）（TE-AEI）（寛解導入試験）：
Day 81、Grade 1 の非重篤な外陰部腟カンジダ症が発現した。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 85～95）（試験治療下の重篤な有害事象）（寛解導入試験）：
Day 85、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ありと判断された。Day 95、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	Ongoing
abdominal pain upper	Ongoing
anaemia	Ongoing
arthralgia	Ongoing
asthenia	Ongoing
colitis ulcerative	Ongoing
cough	Ongoing
hypothyroidism	Ongoing
mouth ulceration	Ongoing
proctalgia	Ongoing
infarction	About -288 days
bronchitis	About 17 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
golimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	Unknown	Unknown
infliximab	ULCERATIVE COLITIS	INTRAVENOUS	Unknown	Unknown
methotrexate	ULCERATIVE COLITIS	SUBCUTANEOUS	Unknown	Unknown
levothyroxine sodium	HYPOTHYROIDIE	ORAL	About -3695 days	Ongoing
etonogestrel	CONTRACEPTIVE	INTRADERMAL	About -2234 days	Ongoing
paracetamol;tramadol hydrochloride	RECTAL PAIN	ORAL	About -407 days	Ongoing
acetylsalicylic acid	INFARCT	ORAL	About -317 days	Ongoing
atorvastatin calcium	INFARCTUS	ORAL	About -317 days	Ongoing
bisoprolol fumarate	INFARCTUS	ORAL	About -317 days	Ongoing
pantoprazole	DOULEUR EPIGASTRIQUE	ORAL	About -317 days	Ongoing
prednisolone	ULCERATIVE COLITIS	ORAL	About -73 days	Ongoing
calcium phosphate monobasic;magnesium glycerophosphate;phosphoric acid;sodium phosphate dibasic	HYPOPHOSPHATEMIA	ORAL	73 days	Ongoing
prednisolone	ULCERATIVE COLITIS	ORAL	95 days	Ongoing
aminosalicylate sodium	ULCERATIVE COLITIS	ORAL	About -6251 days	About -5522 days
mesalazine	ULCERATIVE COLITIS	ORAL	About -5886 days	About -5522 days
azathioprine	ULCERATIVE COLITIS	ORAL	About -5156 days	About -4791 days
vedolizumab	ULCERATIVE COLITIS	INTRAVENOUS	About -407 days	About -165 days
adalimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	About -195 days	-77 days
paracetamol	RHINOPHARYNGITE	ORAL	18 days	23 days
fluticasone propionate;salmeterol xinafoate	ULCERATIVE COLITIS	RESPIRATORY (INHALATION)	-4 days	25 days
salbutamol	BROCHITE	RESPIRATORY (INHALATION)	-4 days	25 days
ferric carboxymaltose	ANEMIA	INTRAVENOUS	44 days	44 days
ferric carboxymaltose	ANEMIA	INTRAVENOUS	72 days	72 days
econazole nitrate	VAGINAL THRUSH	VAGINAL	81 days	82 days
econazole	VAGINAL THRUSH	VAGINAL	81 days	84 days
amphotericin b	ORAL MYCOSIS	ORAL	81 days	86 days
fusidic acid	BOIL IN THE SCALP	TOPICAL	81 days	86 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
methylprednisolone	ULCERATIVE COLITIS	INTRAVENOUS	85 days	94 days
diosmectite	DIARREHA	ORAL	94 days	94 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
Stomatitis	About 1	About 17	2	not related	dose not changed	not applicable	none
Basophil count increased	15	72	1	not related	dose not changed	not applicable	none
Chest pain	About 18	72	1	not related	dose not changed	not applicable	none
Myalgia	About 18	72	1	not related	dose not changed	not applicable	none
Nasopharyngitis	18	23	1	not related	dose not changed	not applicable	medication required
Nocturia	About 18	72	1	not related	dose not changed	not applicable	none
Visual acuity reduced	44	72	1	not related	dose not changed	not applicable	none
Hypokalaemia	72	81	1	not related	dose not changed	not applicable	none
Hypophosphataemia	72	Ongoing	3	related	dose not changed	not applicable	medication required
Sterile pyuria	73	Ongoing	1	related	not applicable	not applicable	none
Furuncle	81	Ongoing	1	related	not applicable	not applicable	medication required
Oral fungal infection	81	Ongoing	1	related	not applicable	not applicable	medication required
Vulvovaginal candidiasis	81	Ongoing	1	related	not applicable	not applicable	medication required
Colitis ulcerative	85	95	3	related	not applicable	not applicable	medication required
Diarrhoea	94	95	2	related	not applicable	not applicable	medication required
Rectal haemorrhage	98	Ongoing	2	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)
-19	11 (L)	35 (N)	3.9 (L)	336 (N)	0.083 (N)	90 (N)
15	10.1 (L)	32 (L)	3.7 (L)	383 (N)	0.056 (N)	86 (N)
72	11.4 (L)	37 (N)	3.8 (L)	294 (N)	0.09 (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)
-19	12.3 (H)	8.78 (H)	2.09 (N)	0.78 (N)	0.18 (N)	0.46 (N)
15	11.58 (H)	8.74 (H)	1.33 (N)	0.75 (N)	0.3 (H)	0.46 (N)
72	12.85 (H)	10.89 (H)	1.35 (N)	0.42 (N)	0.03 (N)	0.15 (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	9 (N)	12 (N)	76 (N)	<0.2 (L)	0.63 (N)
1	No	12 (N)	12 (N)	81 (N)	<0.2 (L)	0.64 (N)
15	No	18 (N)	17 (N)	86 (N)	<0.2 (L)	0.67 (N)
31	No	22 (N)	17 (N)	74 (N)	0.2 (N)	0.78 (N)
44	No	23 (N)	17 (N)	79 (N)	<0.2 (L)	0.61 (N)
72	Yes	19 (N)	17 (N)	82 (N)	0.4 (N)	0.6 (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	78 (N)	31 (N)	89 (N)	12.1 (H)
1	No	78 (N)	25 (L)	165 (H)	9.92 (N)
15	No	76.2 (N)	44 (N)	129 (H)	24.9 (H)
31	No	63.6 (L)	29 (N)	172 (H)	12.2 (H)
44	No	81 (N)	37 (N)	114 (H)	5.44 (N)
72	Yes	81.6 (N)	48 (N)	95 (N)	8.44 (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)
-19	No	137 (L)	42 (N)	75 (N)	104 (N)
1	No	141 (L)	44 (N)	77 (N)	114 (N)
15	No	131 (L)	43 (N)	67 (N)	133 (N)
72	Yes	129 (L)	45 (N)	68 (N)	73 (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 12）；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、民族に関する情報は取得できず、フランスからの参加であった。

大腸出血（Day 12～15）（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 12、Grade 3 の重篤な大腸出血が発現した。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ありと判断された。Day 15、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**
asthma	Ongoing
colitis ulcerative	Ongoing

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
fluticasone propionate;salmeterol xinafoate	ASTHME	RESPIRATORY (INHALATION)	Unknown	Ongoing
folic acid	ANEMIA	ORAL	18 days	Ongoing
mercaptopurine	ULCERATIVE COLITIS	ORAL	18 days	Ongoing
prednisone	ULCERATIVE COLITIS	ORAL	18 days	Ongoing
azathioprine	ULCERATIVE COLITIS	ORAL	About -2817 days	About -2729 days
infliximab	ULCERATIVE COLITIS	INTRAVENOUS	About -2728 days	About -2210 days
mercaptopurine	ULCERATIVE COLITIS	INTRAVENOUS	About -2239 days	About -1449 days
vedolizumab	ULCERATIVE COLITIS	INTRAVENOUS	-1404 days	-64 days
codeine;paracetamol	ABDOMINAL PAIN PROPHYLAXIS	ORAL	-10 days	1 day
blood, whole	COLONIC HEMORRHAGE AND ANEMIA	INTRAVENOUS	12 days	12 days
blood, whole	COLONIC HEMMORHAGE AND ANEMIA	INTRAVENOUS	14 days	14 days
prednisone	ULCERATIVE COLITIS	ORAL	-35 days	17 days
ferric carboxymaltose	ANEMIA	INTRAVENOUS DRIP	35 days	35 days
enoxaparin	UPPER LIMB PHLEBITIS	SUBCUTANEOUS	27 days	41 days
glucose 1-phosphate disodium	HYPOPHOSPHOREMIA	ORAL	47 days	62 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	12	Ongoing	3	related	dose not changed	not applicable	medication required
Large intestinal haemorrhage	12	15	3	related	drug withdrawn	not applicable	medication required + permanent study discontinuation
Phlebitis	27	41	2	related	not applicable	not applicable	medication required
Hypophosphataemia	43	Ongoing	4	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)
-10	14.7 (N)	45 (N)	4.9 (N)	463 (H)	0.111 (N)	91 (N)
1	13.8 (N)	42 (N)	4.6 (N)	424 (H)	0.133 (H)	91 (N)
12	7.9 (L)	25 (L)	2.7 (L)	443 (H)		94 (N)
43	12 (L)	38 (L)	3.8 (L)	395 (N)	0.206 (H)	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)
-10	12.76 (H)	11.09 (H)	0.99 (N)	0.53 (N)	0.05 (N)	0.1 (N)
1	13.8 (H)	9.79 (H)	2.79 (N)	0.87 (N)	0.09 (N)	0.26 (N)
12	16.34 (H)	13.89 (H)	1.95 (N)	0.43 (N)	0.04 (N)	0.03 (N)
43	10.45 (N)	7.9 (H)	1.89 (N)	0.56 (N)	0.04 (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)
-10	No	14 (N)	12 (N)	59 (N)	0.4 (N)	1.06 (N)
1	Yes	11 (N)	8 (L)	55 (N)	0.4 (N)	1.04 (N)
12	No	11 (N)	9 (L)	45 (N)	<0.2 (L)	1.1 (N)
43	Yes	30 (N)	13 (N)	39 (N)	<0.2 (L)	0.78 (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)
-10	No	109.8 (N)	40 (N)	98 (N)	25.4 (H)
1	Yes	110.4 (N)	26 (L)	89 (N)	23.2 (H)
12	No	105.6 (N)	34 (L)	114 (H)	
43	Yes	156 (H)	55 (N)	78 (N)	1.96 (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	158 (L)	54 (N)	91 (N)	86 (N)
12	No	163 (N)	53 (N)	98 (N)	105 (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 78*）

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。

歯嚢胞（Day 74*～77*）（試験治療下の重篤な有害事象［TE-SAE］）（寛解維持試験）：
Day 74*、Grade 4 の重篤な歯嚢胞が発現した。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 77*、Grade 4 の本事象は回復した。

過剰歯（Day 74*～77*）（TE-SAE）（寛解維持試験）：
Day 74*、Grade 4 の重篤な過剰歯が発現した。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 77*、Grade 4 の本事象は回復した。

肺炎（Day 78*～131*）（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）（寛解維持試験）：
Day 78*、Grade 4 の重篤な肺炎が発現した。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 131*、Grade 4 の本事象は回復した。

その他の関連情報：被験者は過剰歯の外科的抜歯術のため入院した。被験者は退院し、自宅で抗生剤による治療を継続したが、発熱及び呼吸困難を訴え、退院日と同日に再来院した。被験者は、誤嚥性肺炎が疑われ、気管挿管及び人工呼吸器装着を要する呼吸不全のため集中治療室へ入院した。入院中に、敗血症性ショック、右肺の多発性膿瘍及び急性呼吸窮迫症候群を合併した。気管切開術及び開胸肺膿瘍ドレナージ術が実施された。被験者は手術後に回復し、気管切開チューブが除去された。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

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
drospirenone;ethinylestradiol	CONTRACEPTION	ORAL	About -1337 days	Ongoing
sulfasalazine	ULCERATIVE COLITIS	ORAL	165 days	Ongoing
prednisone	ULCERATIVE COLITIS	ORAL	About -2798 days	About -2434 days
mesalazine	ULCERATIVE COLITIS	RECTAL	About -1337 days	About -973 days
prednisone	ULCERATIVE COLITIS	ORAL	About -1337 days	About -973 days
mesalazine	ULCERATIVE COLITIS	ORAL	About -972 days	About -608 days

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
citric acid;magnesium oxide;sodium picosulfate	COLONOSCOPY PREPARATION	ORAL	-3 days	-2 days
citric acid;magnesium oxide;sodium picosulfate	COLONOSCOPY PREPARATION	ORAL	68 days	69 days
amoxicillin trihydrate;clavulanate potassium	CYSTECTOMY AND RETAINED TOOTH EXTRACTION-ANTIBIOTIC THERAPY AFTER SURGERY	ORAL	153 days	156 days
mesalazine	ULCERATIVE COLITIS	ORAL	-123 days	157 days
amiodarone hydrochloride	ARRHYTHMIA	INTRAVENOUS	About 156 days	About 157 days
dopamine	CIRCULATORY FAILURE IN THE COURSE OF PNEUMONIA	INTRAVENOUS	About 156 days	About 157 days
furosemide	CIRCULATORY FAILURE	INTRAVENOUS	About 156 days	About 157 days
norepinephrine bitartrate	CIRCULATORY FAILURE IN THE COURSE OF PNEUMONIA	INTRAVENOUS	About 156 days	About 157 days
voriconazole	PNEUMONIA	INTRAVENOUS	About 156 days	About 157 days
meropenem trihydrate	PNEUMONIA	INTRAVENOUS	157 days	About 157 days
vancomycin hydrochloride	PNEUMONIA	INTRAVENOUS	157 days	About 157 days
clindamycin	PNEUMONIA	INTRAVENOUS	161 days	165 days
caspofungin acetate	PNEUMONIA	INTRAVENOUS	165 days	About 183 days
linezolid	PNEUMONIA	INTRAVENOUS	165 days	About 183 days
colistin	PNEUMONIA	INTRAVENOUS	181 days	About 214 days
ampicillin sodium;sulbactam sodium	PNEUMONIA	INTRAVENOUS	About 184 days	About 214 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
Dental cyst	74*	77*	4	not related	not applicable	dose not changed	medication required + other treatment required
Supernumerary teeth	74*	77*	4	not related	not applicable	dose not changed	medication required + other treatment required
Pneumonia	78*	131*	4	not related	not applicable	drug withdrawn	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)
-16	12.6 (N)	40 (N)	4.2 (N)	234 (N)	0.089 (N)	95 (N)
1	11.3 (L)	36 (N)	3.7 (L)	168 (N)	0.065 (N)	96 (N)
15	12.8 (N)	40 (N)	4.3 (N)	300 (N)	0.092 (N)	93 (N)
27	11.6 (N)	35 (N)	3.9 (L)	233 (N)	0.09 (N)	91 (N)
41	12.1 (N)	37 (N)	4.1 (N)	296 (N)	0.048 (N)	90 (N)
69	12.6 (N)	38 (N)	4.3 (N)	275 (N)	0.09 (N)	90 (N)
-11*	12.6 (N)	38 (N)	4.3 (N)	275 (N)	0.09 (N)	90 (N)
18*	11.2 (L)	35 (N)	4 (L)	224 (N)	0.041 (N)	88 (N)
60*	11.4 (L)	35 (N)	4.1 (N)	201 (N)	0.064 (N)	86 (N)
384*	12.6 (N)	38 (N)	4.1 (N)	215 (N)	0.057 (N)	92 (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)
-16	7.56 (N)	4.7 (N)	2.32 (N)	0.39 (N)	0.04 (N)	0.11 (N)
1	6.95 (N)	4.71 (N)	1.72 (N)	0.29 (N)	0.12 (N)	0.11 (N)
15	13.32 (H)	9.74 (H)	2.29 (N)	0.58 (N)	0.08 (N)	0.63 (H)
27	9.91 (N)	6.63 (N)	2.22 (N)	0.54 (N)	0.05 (N)	0.47 (N)
41	11.61 (H)	8.86 (H)	1.93 (N)	0.47 (N)	0.05 (N)	0.3 (N)
69	5.36 (N)	3.73 (N)	1.34 (N)	0.18 (N)	0.06 (N)	0.06 (N)
-11*	5.36 (N)	3.73 (N)	1.34 (N)	0.18 (N)	0.06 (N)	0.06 (N)
18*	3.82 (N)	2.03 (N)	1.46 (N)	0.24 (N)	0.03 (N)	0.06 (N)
60*	5.41 (N)	2.98 (N)	1.96 (N)	0.34 (N)	0.03 (N)	0.1 (N)
384*	5.27 (N)	2.74 (N)	1.88 (N)	0.29 (N)	0.04 (N)	0.32 (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	20 (N)	16 (N)	55 (N)	0.6 (N)	0.89 (N)
1	Yes	10 (N)	13 (N)	44 (N)	0.4 (N)	0.76 (N)
15	Yes	15 (N)	15 (N)	54 (N)	0.2 (N)	0.76 (N)
27	Yes	13 (N)	14 (N)	56 (N)	0.4 (N)	0.77 (N)
41	Yes	18 (N)	14 (N)	66 (N)	0.4 (N)	0.81 (N)
69	Yes	17 (N)	20 (N)	64 (N)	1.4 (H)	1.02 (N)
-11*	Yes	17 (N)	20 (N)	64 (N)	1.4 (H)	1.02 (N)
18*	Yes	14 (N)	15 (N)	54 (N)	0.4 (N)	0.78 (N)
60*	Yes	30 (N)	25 (N)	52 (N)	0.5 (N)	0.72 (N)
384*	Yes	19 (N)	12 (N)	44 (N)	0.5 (N)	0.81 (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	73.2 (L)	64 (N)	97 (N)	1.6 (N)
1	Yes	86.4 (N)	82 (N)	101 (H)	13.2 (H)
15	Yes	87 (N)	51 (N)	91 (N)	1.52 (N)
27	Yes	85.2 (N)	66 (N)	93 (N)	4.13 (N)
41	Yes	79.2 (N)	55 (N)	82 (N)	2.21 (N)
69	Yes	60 (L)	76 (N)	78 (N)	0.48 (N)
-11*	Yes	60 (L)	76 (N)	78 (N)	0.48 (N)
18*	Yes	81 (N)	82 (N)	85 (N)	0.35 (N)
60*	Yes	89.4 (N)	236 (H)	98 (N)	1.24 (N)
384*	Yes	81 (N)	59 (N)	97 (N)	0.3 (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)
-16	Yes	231 (N)	85 (N)	135 (H)	76 (N)
1	Yes	180 (N)	60 (N)	111 (N)	79 (N)
15	Yes	212 (N)	50 (N)	125 (N)	252 (H)
27	Yes	212 (N)	63 (N)	135 (H)	92 (N)

Lipid Panel					
Study Day	Fasting	Total Cholesterol (mg/dL)	HDL Cholesterol (mg/dL)	LDL Cholesterol (mg/dL)	Triglycerides (mg/dL)
41	Yes	217 (N)	52 (N)	126 (N)	210 (N)
69	Yes	262 (N)	75 (N)	179 (H)	84 (N)
-11*	Yes	262 (N)	75 (N)	179 (H)	84 (N)
18*	Yes	228 (N)	71 (N)	134 (H)	113 (N)
60*	Yes	225 (N)	80 (N)	126 (N)	120 (N)
384*	Yes	188 (N)	56 (N)	127 (N)	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－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、イタリアからの参加であった。

毛包炎（Day 34～195）（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 1 の非重篤な毛包炎が発現した。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変更なし。本事象は治験薬と関連なしと判断された。Day 195、Grade 1 の本事象は回復した。

交通事故（Day 34～40）（試験治療下の重篤な有害事象）（寛解導入試験）：
Day 34、Grade 3 の重篤な交通事故に遭った。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 40、Grade 3 の本事象は回復した。

咽頭扁桃炎（Day 38*～39*）（TE-AEI）（寛解維持試験）：
Day 38*、Grade 2 の非重篤な咽頭扁桃炎が発現した。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 39*、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**
autoimmune thyroiditis	Ongoing
colitis ulcerative	Ongoing
headache	Ongoing
psoriasis	Ongoing
tympanoplasty	About -8860 days
megacolon	About -3169 days

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
metamizole	CHRONIC INTERMITTENT HEADACHE	ORAL	Unknown	Unknown
paracetamol	CHRONIC INTERMITTENT HEADACHE	ORAL	Unknown	Unknown
mesalazine	ULCERATIVE COLITIS	ORAL	-3201 days	Ongoing
levothyroxine	HASHIMOTO THYROIDITIS	ORAL	About -3199 days	Ongoing
prednisone	ULCERATIVE COLITIS	ORAL	About -3229 days	About -3138 days
ciclosporin	ULCERATIVE COLITIS	INTRAVENOUS	About -3199 days	About -3108 days
ciclosporin	ULCERATIVE COLITIS	ORAL	About -3199 days	About -3108 days
prednisone	ULCERATIVE COLITIS	ORAL	About -1554 days	About -1190 days

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
azathioprine	ULCERATIVE COLITIS	ORAL	About -3137 days	About -428 days
budesonide	ULCERATIVE COLITIS	ORAL	About -185 days	About -125 days
prednisone	ULCERATIVE COLITIS	ORAL	About -93 days	-16 days
bisacodyl	ENDOSCOPIC PREPARATION	ORAL	-15 days	-14 days
fentanyl	ENDOSCOPIC SEDATION	INTRAVENOUS	-14 days	-14 days
midazolam	ENDOSCOPIC SEDATION	INTRAVENOUS	-14 days	-14 days
sodium chloride	IDRATATION DURING ENDOSCOPY	INTRAVENOUS	-14 days	-14 days
analgesics	BIKE ACCIDENT	INTRAVENOUS	34 days	40 days
antibiotics	BIKE ACCIDENT	INTRAVENOUS	34 days	40 days
i.v. solutions	BIKE ACCIDENT	INTRAVENOUS	34 days	40 days
calcium carbonate	PROPHYLAXIS STEROID THERAPY	ORAL	-77 days	54 days
prednisone	ULCERATIVE COLITIS	ORAL	-15 days	97 days
prednisone	ULCERATIVE COLITIS	ORAL	98 days	104 days
colecalciferol	BIKE ACCIDENT	ORAL	55 days	111 days
prednisone	ULCERATIVE COLITIS	ORAL	105 days	111 days
paracetamol	PHARYNGO TONSILLITIS	ORAL	114 days	115 days
prednisone	ULCERATIVE COLITIS	ORAL	112 days	118 days
amoxicillin trihydrate;clavulanate potassium	PHARYNGO TONSILLITIS	ORAL	115 days	121 days
clodronate disodium	BIKE ACCIDENT	INTRAMUSCULAR	55 days	132 days
gentamicin sulfate	ARMS, TRUNK AND FACE FOLLICULITIS	TOPICAL	141 days	148 days
sodium phosphate dibasic;sodium phosphate monobasic	ENDOSCOPIC PREPARATION	RECTAL	407 days	408 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**
Folliculitis	34	195	1	not related	dose not changed	dose not changed	medication required
Road traffic accident	34	40	3	not related	drug interrupted	not applicable	medication required
Pharyngotonsillitis	38*	39*	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)
-29	12.8 (N)	39 (N)	4.5 (N)	311 (N)	0.072 (N)	86 (N)
1	12.4 (L)	39 (N)	4.6 (N)	360 (N)	0.046 (N)	84 (N)
16	12.5 (L)	39 (N)	4.7 (N)	311 (N)	0.05 (N)	83 (N)
30	12.1 (L)	38 (L)	4.6 (N)	321 (N)	0.026 (L)	84 (N)
69	11.6 (L)	37 (L)	4.7 (N)	290 (N)	0.05 (N)	80 (N)
-8*	11.6 (L)	37 (L)	4.7 (N)	290 (N)	0.05 (N)	80 (N)
22*	13.1 (N)	44 (N)	5.3 (N)	291 (N)	0.059 (N)	83 (N)
64*	14.2 (N)	45 (N)	5.5 (N)	262 (N)	0.069 (N)	81 (N)
108*	14.2 (N)	42 (N)	5.1 (N)	292 (N)	0.047 (N)	82 (N)
163*	14.7 (N)	43 (N)	5.1 (N)	282 (N)	0.053 (N)	85 (N)
220*	14.9 (N)	45 (N)	5.2 (N)	258 (N)	0.036 (N)	86 (N)
275*	15.1 (N)	44 (N)	5.1 (N)	271 (N)	0.037 (N)	87 (N)
332*	15.6 (N)	46 (N)	5.2 (N)	248 (N)	0.029 (L)	88 (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	8.65 (N)	5.97 (N)	2.09 (N)	0.36 (N)	0.06 (N)	0.18 (N)
1	7.91 (N)	5.1 (N)	2.15 (N)	0.47 (N)	0.07 (N)	0.13 (N)
16	7.27 (N)	4.37 (N)	2.39 (N)	0.36 (N)	0.08 (N)	0.07 (N)
30	6.62 (N)	3.87 (N)	2.28 (N)	0.32 (N)	0.05 (N)	0.1 (N)
69	7.52 (N)	4.99 (N)	2.06 (N)	0.4 (N)	0.03 (N)	0.04 (N)
-8*	7.52 (N)	4.99 (N)	2.06 (N)	0.4 (N)	0.03 (N)	0.04 (N)
22*	6.26 (N)	3.43 (N)	2.33 (N)	0.37 (N)	0.06 (N)	0.07 (N)
64*	5.29 (N)	3.4 (N)	1.4 (N)	0.38 (N)	0.03 (N)	0.08 (N)
108*	5.15 (N)	3.4 (N)	1.33 (N)	0.31 (N)	0.05 (N)	0.07 (N)
163*	5.81 (N)	4.23 (N)	1.19 (N)	0.28 (N)	0.04 (N)	0.06 (N)
220*	4.25 (N)	2.67 (N)	1.18 (N)	0.25 (N)	0.04 (N)	0.11 (N)
275*	4.82 (N)	3.09 (N)	1.27 (N)	0.29 (N)	0.03 (N)	0.13 (N)
332*	4.35 (N)	2.9 (N)	1.06 (N)	0.22 (N)	0.05 (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)
-29	Yes	14 (N)	13 (N)	38 (N)	0.5 (N)	1.01 (N)
1	Yes	15 (N)	13 (N)	37 (N)	0.3 (N)	1.02 (N)
16	Yes	13 (N)	15 (N)	32 (N)	0.6 (N)	1 (N)
30	Yes	13 (N)	16 (N)	28 (L)	0.4 (N)	1.05 (N)
69	Yes	21 (N)	17 (N)	54 (N)	0.6 (N)	1.04 (N)
-8*	Yes	21 (N)	17 (N)	54 (N)	0.6 (N)	1.04 (N)
22*	Yes	23 (N)	17 (N)	43 (N)	0.6 (N)	1.06 (N)
64*	No	21 (N)	28 (N)	52 (N)	0.6 (N)	1.18 (N)
108*	Yes	20 (N)	30 (N)	47 (N)	0.7 (N)	1.03 (N)
163*	Yes	21 (N)	27 (N)	43 (N)	0.6 (N)	1.1 (N)
220*	Yes	38 (N)	67 (H)	42 (N)	0.5 (N)	0.93 (N)
275*	Yes	24 (N)	27 (N)	40 (N)	0.7 (N)	1.06 (N)
332*	Yes	26 (N)	30 (N)	38 (N)	0.8 (N)	0.98 (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	97.2 (N)	47 (N)	92 (N)	1.09 (N)
1	Yes	97.8 (N)	62 (N)	82 (N)	0.37 (N)
16	Yes	100.8 (N)	87 (N)	92 (N)	0.56 (N)
30	Yes	95.4 (N)	73 (N)	94 (N)	0.77 (N)
69	Yes	95.4 (N)	168 (N)	86 (N)	0.25 (N)
-8*	Yes	95.4 (N)	168 (N)	86 (N)	0.25 (N)
22*	Yes	93 (N)	110 (N)	93 (N)	0.25 (N)
64*	No	86.4 (N)	247 (N)	84 (N)	1.04 (N)
108*	Yes	97.8 (N)	486 (H)	97 (N)	1.18 (N)
163*	Yes	91.8 (N)	210 (N)	99 (N)	0.92 (N)
220*	Yes	107.4 (N)	2998 (H)	91 (N)	0.6 (N)
275*	Yes	94.8 (N)	213 (N)	89 (N)	0.56 (N)
332*	Yes	102.6 (N)	294 (N)	86 (N)	0.48 (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)
-29	Yes	179 (N)	75 (H)	97 (N)	69 (N)
1	Yes	198 (N)	77 (H)	108 (N)	76 (N)
69	Yes	183 (N)	80 (H)	100 (N)	67 (N)
-8*	Yes	183 (N)	80 (H)	100 (N)	67 (N)
108*	Yes	162 (L)	63 (N)	94 (N)	43 (L)
163*	Yes	174 (N)	62 (N)	107 (N)	49 (L)
220*	Yes	172 (N)	66 (N)	104 (N)	53 (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）；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 36*）

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、イタリアからの参加であった。

大腿骨骨折（Day 35～76）（試験治療下の重篤な有害事象）（寛解導入試験）：
Day 35、Grade 3 の重篤な大腿骨骨折が発現した。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。

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**
asthenia	Ongoing
colitis ulcerative	Ongoing
hypercholesterolaemia	Ongoing
hypertension	Ongoing
musculoskeletal disorder	Ongoing
cerebral haemorrhage	About -13090 days
mycobacterium tuberculosis complex test positive	About -186 days
blastocystis infection	-17 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
calcium;colecalciferol	OSTEOPROTECTION PROPHYLAXIS DURING STEROID TREATMENT	ORAL	Unknown	Ongoing
telmisartan	HYPERTENSION	ORAL	About -5784 days	Ongoing
latanoprost	GLAUCOMA	OPHTHALMIC	65 days	Ongoing
timolol maleate	GLAUCOMA	OPHTHALMIC	65 days	Ongoing
prednisone	ULCERATIVE COLITIS	ORAL	110 days	Ongoing
azathioprine	ULCERATIVE COLITIS	ORAL	About -611 days	About -459 days
mesalazine	ULCERATIVE COLITIS	ORAL	About -489 days	About -367 days
golimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	-395 days	-323 days
isoniazid	POSITIVE QUANTIFERON	ORAL	About -458 days	About -186 days
pyridoxine hydrochloride	POSITIVE QUANTIFERON	ORAL	About -458 days	About -186 days
infliximab	ULCERATIVE COLITIS	INTRAVENOUS	-253 days	-150 days
metronidazole	BLASTOCYSTIS HOMINIS	ORAL	-44 days	-34 days
prednisone	ULCERATIVE COLITIS	ORAL	-78 days	-24 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
sodium phosphate dibasic;sodium phosphate monobasic	ENDOSCOPY PREPARATION	RECTAL	-9 days	-8 days
midazolam	ENDOSCOPY SEDATION	INTRAVENOUS	-8 days	-8 days
anesthetics	LEFT HIP REPLACEMENT	OTHER	36 days	36 days
pantoprazole	FRACTURE OF THE LEFT FEMORAL HEAD	ORAL	37 days	65 days
sodium phosphate dibasic;sodium phosphate monobasic	ENDOSCOPY PREPARATION	RECTAL	69 days	70 days
midazolam	ENDOSCOPY SEDATION	INTRAVENOUS	70 days	70 days
parnaparin sodium	FRACTURE OF THE LEFT FEMORAL HEAD	SUBCUTANEOUS	36 days	74 days
prednisone	ULCERATIVE COLITIS	ORAL	-23 days	96 days
prednisone	ULCERATIVE COLITIS	ORAL	About 92 days	About 112 days
prednisone	ULCERATIVE COLITIS	ORAL	97 days	About 112 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
Femur fracture	35	76	3	not related	dose not changed	not applicable	medication required + other treatment required
Glaucoma	About 61	Ongoing	1	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)
-59	14 (N)	43 (N)	5 (N)	226 (N)	0.103 (N)	85 (N)
-56	13.6 (N)	42 (N)	4.9 (N)	236 (N)	0.091 (N)	86 (N)
-17	14 (N)	43 (N)	5 (N)	256 (N)	0.088 (N)	87 (N)
1	14.1 (N)	42 (N)	5 (N)	261 (N)	0.091 (N)	85 (N)
13	14.6 (N)	42 (N)	5.1 (N)	291 (N)	0.114 (N)	83 (N)
26	14.1 (N)	43 (N)	5.1 (N)	239 (N)	0.111 (N)	85 (N)
62	12.9 (N)	40 (N)	4.7 (N)	249 (N)	0.044 (N)	84 (N)
70	13.6 (N)	40 (N)	4.9 (N)	371 (N)	0.126 (N)	83 (N)
-7*	13.6 (N)	40 (N)	4.9 (N)	371 (N)	0.126 (N)	83 (N)
21*	13.7 (N)	42 (N)	5 (N)	288 (N)	0.113 (N)	85 (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)
-59	12.82 (H)	11.6 (H)	0.72 (L)	0.42 (N)	0.04 (N)	0.04 (N)
-56	10.31 (N)	9.05 (H)	0.87 (N)	0.29 (N)	0.05 (N)	0.05 (N)
-17	9.76 (N)	8.34 (H)	1.02 (N)	0.33 (N)	0.02 (N)	0.05 (N)
1	13.11 (H)	11.94 (H)	0.76 (L)	0.32 (N)	0.02 (N)	0.06 (N)
13	10.73 (H)	8.97 (H)	0.81 (N)	0.35 (N)	0.15 (N)	0.46 (N)
26	8.36 (N)	5.71 (N)	1.63 (N)	0.52 (N)	0.18 (N)	0.32 (N)
62	9.24 (N)	7.85 (H)	1.01 (N)	0.34 (N)	0.01 (N)	0.03 (N)
70	8.9 (N)	5.66 (N)	2.29 (N)	0.55 (N)	0.19 (N)	0.22 (N)
-7*	8.9 (N)	5.66 (N)	2.29 (N)	0.55 (N)	0.19 (N)	0.22 (N)
21*	11.13 (H)	9.71 (H)	0.74 (L)	0.4 (N)	0.1 (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)
-59	Yes	27 (N)	20 (N)	62 (N)	0.5 (N)	0.81 (N)
-17	Yes	28 (N)	24 (N)	60 (N)	0.6 (N)	0.83 (N)
1	Yes	26 (N)	20 (N)	62 (N)	0.5 (N)	0.83 (N)
13	No	19 (N)	20 (N)	58 (N)	0.3 (N)	0.85 (N)
26	Yes	22 (N)	20 (N)	62 (N)	0.5 (N)	0.88 (N)
62	Yes	19 (N)	16 (N)	87 (N)	0.3 (N)	0.78 (N)
70	Yes	20 (N)	14 (N)	89 (N)	0.5 (N)	0.87 (N)
-7*	Yes	20 (N)	14 (N)	89 (N)	0.5 (N)	0.87 (N)
21*	Yes	15 (N)	16 (N)	65 (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)
-59	Yes	120 (N)	88 (N)	149 (H)	4.57 (N)
-17	Yes	117.6 (N)	202 (N)	167 (H)	2.52 (N)
1	Yes	117.6 (N)	72 (N)	148 (H)	4.36 (N)
13	No	114.6 (N)	87 (N)	147 (H)	
26	Yes	109.8 (N)	57 (N)	111 (H)	2.7 (N)
62	Yes	121.8 (N)	30 (L)	122 (H)	5.2 (N)
70	Yes	109.2 (N)	41 (N)	91 (N)	1.01 (N)
-7*	Yes	109.2 (N)	41 (N)	91 (N)	1.01 (N)
21*	Yes	108.6 (N)	40 (N)	139 (H)	2.91 (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)
-59	Yes	300 (H)	116 (H)	163 (H)	131 (N)
-17	Yes	300 (H)	96 (H)	181 (H)	112 (N)
1	Yes	300 (H)	97 (H)	177 (H)	147 (N)
13	No	309 (H)	119 (H)	172 (H)	128 (N)
26	Yes	311 (H)	120 (H)	169 (H)	250 (N)
62	Yes	253 (N)	81 (H)	158 (H)	159 (N)

Lipid Panel					
Study Day	Fasting	Total Cholesterol (mg/dL)	HDL Cholesterol (mg/dL)	LDL Cholesterol (mg/dL)	Triglycerides (mg/dL)
70	Yes	302 (H)	94 (H)	179 (H)	266 (H)
-7*	Yes	302 (H)	94 (H)	179 (H)	266 (H)
21*	Yes	309 (H)	107 (H)	180 (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 8）；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、イタリアからの参加であった。

鉄欠乏性貧血（Day 1～6）（試験治療下の重篤な有害事象）（寛解導入試験）：
Day 1、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 6、Grade 3 の本事象は回復した。

貧血（Day 7～14）（投与中止に至った有害事象）（寛解導入試験）：
Day 7、Grade 2 の非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なしと判断された。Day 14、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**
abdominal pain upper	Ongoing
chronic gastritis	Ongoing
colitis ulcerative	Ongoing
fibromyalgia	Ongoing
folate deficiency	Ongoing
hepatic steatosis	Ongoing
iron deficiency anaemia	Ongoing
thyroidectomy	Unknown
type 2 diabetes mellitus	Ongoing

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
insulin lispro	DIABETES MELLITUS TYPE 2	SUBCUTANEOUS	About -403 days	Ongoing
folic acid	FOLIC ACID DEFICIENCY	ORAL	About -313 days	Ongoing
insulin glargine	DIABETES MELLITUS TYPE 2	SUBCUTANEOUS	About -313 days	Ongoing
mesalazine	ULCERATIVE COLITIS	ORAL	About -283 days	Ongoing
calcium carbonate;colecalciferol	STEROID PROPHYLAXIS	ORAL	-69 days	Ongoing
prednisone	ULCERATIVE COLITIS	ORAL	-69 days	Ongoing
infliximab	ULCERATIVE COLITIS	INTRAVENOUS	-285 days	About -192 days
sodium phosphate dibasic;sodium phosphate monobasic	ENDOSCOPY PREPARATION	RECTAL	-9 days	-8 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
midazolam	ENDOSCOPY SEDATION	INTRAVENOUS	-8 days	-8 days
ferric carboxymaltose	WORSENING OF ANEMIA (IRON-DEFICIENCY RELATED)	INTRAVENOUS	1 day	1 day
blood, whole	WORSENING OF ANEMIA (IRON-DEFICIENCY RELATED)	INTRAVENOUS	5 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
Iron deficiency anaemia	1	6	3	not related	drug interrupted	not applicable	medication required
Anaemia	7	14	2	not related	drug withdrawn	not applicable	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	8.7 (L)	27 (L)	3.7 (L)	446 (H)	0.127 (H)	73 (L)
1	7.1 (L)	25 (L)	3.5 (L)	435 (H)	0.093 (N)	72 (L)
15	10.1 (L)	32 (L)	4.5 (N)	374 (N)	0.074 (N)	72 (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)
-21	7.17 (N)	4.05 (N)	2.46 (N)	0.52 (N)	0.02 (N)	0.13 (N)
1	7.41 (N)	3.68 (N)	3.05 (N)	0.5 (N)	0.03 (N)	0.15 (N)
15	8.25 (N)	4.23 (N)	3.23 (N)	0.56 (N)	0.02 (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)
-21	Yes	20 (N)	11 (N)	64 (N)	0.3 (N)	0.76 (N)
1	Yes	14 (N)	10 (N)	57 (N)	<0.2 (L)	0.59 (N)
15	Yes	16 (N)	10 (N)	61 (N)	0.4 (N)	0.6 (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	106.2 (N)	39 (N)	125 (H)	27.2 (H)
1	Yes	139.2 (H)	28 (N)	98 (N)	19.5 (H)
15	Yes	133.2 (H)	35 (N)	113 (H)	22.8 (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)
-21	Yes	206 (N)	60 (N)	118 (N)	163 (N)
1	Yes	194 (N)	61 (N)	111 (N)	143 (N)
15	Yes	185 (N)	65 (N)	103 (N)	121 (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－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、イタリアからの参加であった。

乳癌（Day 53～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 53、Grade 2 の重篤な乳癌が発現した。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：両側マンモグラム検査が行われ、異常所見が認められた。右胸の嚢胞性病変に対し超音波ガイド下の生検が実施された。細胞診の結果、偽乳頭状凝集体中に小さな腫瘍性上皮細胞が認められ、癌と考えられた。被験者は外科を受診し、治療のため手術（詳細不明）が計画された。

Medical History	
Medical History	**Resolution**
colitis ulcerative	Ongoing
drug hypersensitivity	Ongoing
fibromyalgia	Ongoing
menopause	Ongoing
vitamin d deficiency	Ongoing
tonsillectomy	About -17505 days
abscess drainage	About -948 days
abscess drainage	-552 days
abscess drainage	-313 days

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
colecalciferol	VITAMIN D INSUFFICIENCY	ORAL	About -1068 days	Ongoing
mesalazine	ULCERATIVE COLITIS	ORAL	77 days	Ongoing
mesalazine	ULCERATIVE COLITIS	RECTAL	77 days	Ongoing
azathioprine	ULCERATIVE COLITIS	ORAL	About -3259 days	About -1253 days
golimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	-743 days	-644 days
infliximab	ULCERATIVE COLITIS	INTRAVENOUS	-595 days	-573 days
mesalazine	ULCERATIVE COLITIS	ORAL	About -3259 days	About -338 days
vedolizumab	ULCERATIVE COLITIS	INTRAVENOUS	-529 days	-200 days
prednisone	ULCERATIVE COLITIS	ORAL	-92 days	-79 days
prednisone	ULCERATIVE COLITIS	ORAL	-78 days	-65 days
prednisone	ULCERATIVE COLITIS	ORAL	-64 days	-51 days
adalimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	-117 days	-47 days

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
sodium phosphate dibasic;sodium phosphate monobasic	PREPARATION (ENDOSCOPY EXAM)	RECTAL	-9 days	-8 days
midazolam	SEDATIVE (ENDOSCOPIC EXAM)	INTRAVENOUS	-8 days	-8 days
sodium phosphate dibasic;sodium phosphate monobasic	ENDOSCOPY PREPARATION	RECTAL	69 days	70 days
mesalazine	ULCERATIVE COLITIS	ORAL	About -337 days	76 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**
Breast cancer	53	Ongoing	2	not related	drug withdrawn	not applicable	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)
-26	12.3 (N)	38 (N)	4.6 (N)	303 (N)	0.073 (N)	81 (N)
1	12.4 (N)	37 (N)	4.7 (N)	315 (N)	0.078 (N)	78 (L)
15	12 (N)	36 (N)	4.7 (N)	305 (N)	0.042 (N)	77 (L)
30	12.1 (N)	38 (N)	4.5 (N)	268 (N)	0.016 (L)	83 (N)
43	12.3 (N)	37 (N)	4.8 (N)	280 (N)	0.069 (N)	77 (L)
70	13.4 (N)	40 (N)	5.2 (N)	297 (N)	0.07 (N)	78 (L)
77	13 (N)	38 (N)	4.9 (N)	284 (N)	0.04 (N)	78 (L)
100	13.4 (N)	41 (N)	5.1 (N)	283 (N)	0.086 (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)
-26	5 (N)	3.14 (N)	1.3 (N)	0.25 (N)	0.03 (N)	0.28 (N)
1	4.57 (N)	2.59 (N)	1.45 (N)	0.18 (N)	0.02 (N)	0.33 (N)
15	3.82 (N)	1.93 (L)	1.47 (N)	0.13 (N)	0.03 (N)	0.26 (N)
30	5 (N)	3.22 (N)	1.34 (N)	0.16 (N)	0.15 (N)	0.13 (N)
43	3.88 (N)	1.96 (N)	1.51 (N)	0.17 (N)	0.05 (N)	0.19 (N)
70	5.42 (N)	3.72 (N)	1.27 (N)	0.27 (N)	0.02 (N)	0.14 (N)
77	3.76 (L)	2.26 (N)	1.13 (N)	0.21 (N)	0.02 (N)	0.13 (N)
100	4.78 (N)	3.03 (N)	1.22 (N)	0.3 (N)	0.04 (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)
-26	Yes	18 (N)	18 (N)	58 (N)	0.4 (N)	0.62 (N)
1	Yes	17 (N)	17 (N)	60 (N)	0.4 (N)	0.63 (N)
15	Yes	15 (N)	16 (N)	57 (N)	0.3 (N)	0.72 (N)
30	Yes	16 (N)	17 (N)	55 (N)	0.4 (N)	0.76 (N)
43	Yes	18 (N)	15 (N)	55 (N)	0.4 (N)	0.74 (N)
70	Yes	13 (N)	17 (N)	57 (N)	0.5 (N)	0.83 (N)
77	No	14 (N)	15 (N)	57 (N)	0.4 (N)	0.69 (N)
100	Yes	16 (N)	15 (N)	61 (N)	0.4 (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)
-26	Yes	135.6 (H)	50 (N)	87 (N)	5.66 (N)
1	Yes	133.2 (H)	68 (N)	84 (N)	5.31 (N)
15	Yes	116.4 (H)	84 (N)	86 (N)	1.92 (N)
30	Yes	109.8 (N)	95 (N)	86 (N)	2.13 (N)
43	Yes	113.4 (N)	74 (N)	89 (N)	1.65 (N)
70	Yes	100.8 (N)	92 (N)	92 (N)	1.75 (N)
77	No	122.4 (H)	58 (N)	93 (N)	7.34 (N)
100	Yes	130.8 (H)	64 (N)	88 (N)	5.87 (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)	59 (N)	115 (N)	76 (N)
30	Yes	207 (N)	86 (N)	122 (N)	58 (N)
43	Yes	211 (N)	96 (H)	116 (N)	51 (L)
70	Yes	216 (N)	92 (N)	124 (N)	58 (N)
77	No	207 (N)	80 (N)	125 (N)	50 (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 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 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、英国からの参加であった。

胃腸炎（Day 72～76）（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 72、Grade 4 の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 76、Grade 4 の本事象は回復した。

その他の関連情報：結腸内視鏡検査のため腸管の前処置薬の服用を開始した後に嘔吐及び下痢が発現した。経口投与困難で、腹痛が悪化したため、被験者は入院した。治療として輸液及び抗生剤の静脈内投与が行われた。便培養検体は採取されなかった。臨床的改善が認められ、被験者は症状が回復した後に退院した。

Medical History	
Medical History	**Resolution**
colitis ulcerative	Ongoing
gastrooesophageal reflux disease	Ongoing
nephrolithiasis	About -3445 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
amitriptyline	ABDOMINAL PAIN SECONDARY TO UC	ORAL	Unknown	Ongoing
dihydrocodeine	ABDOMINAL PAIN SECONDARY TO UC	ORAL	Unknown	Ongoing
prochlorperazine	NAUSEA AND VOMITING SECONDARY TO ULCERATIVE COLITIS.	ORAL	Unknown	Ongoing
azathioprine	ULCERATIVE COLITIS	ORAL	About -67 days	Ongoing
mesalazine	ULCERATIVE COLITIS	ORAL	About -67 days	Ongoing
desogestrel	CONTRACEPTION	ORAL	7 days	Ongoing
esomeprazole	GASTEOESOPHAGEAL RELFUX	ORAL	17 days	Ongoing
ibuprofen;phenylephrine	COLD	ORAL	112 days	Ongoing
prednisolone	ULCERATIVE COLITIS	ORAL	-171 days	-165 days
omeprazole	REFLUX	ORAL	Unknown	16 days
dalteparin	PROPHLACTIC ANTICOAGULANT	SUBCUTANEOUS	72 days	73 days
hydrocortisone sodium succinate	ULCERATIVE COLITIS	RECTAL	72 days	73 days
methylprednisolone	ULCERATIVE COLITIS	INTRAVENOUS	72 days	73 days
paracetamol	MILD TO MODERATE PAIN SECONDARY TO SEVERE GASTROENTERITIS.	INTRAVENOUS	72 days	73 days
paracetamol	MILD PAIN SECONDARY TO SEVERE GASTROENTERITIS.	ORAL	72 days	74 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
sodium chloride	RESPIRATORY SECRETIONS SECONDARY TO WORSENING ULCERATIVE COLITIS	RESPIRATORY (INHALATION)	74 days	74 days
ondansetron	NAUSEA AND VOMITING	INTRAVENOUS	72 days	75 days
amoxicillin trihydrate;clavulanate potassium	INTRA ABDOMINAL INFECTION	INTRAVENOUS	72 days	76 days
calcium chloride;potassium chloride;sodium chloride;sodium lactate	DEHYDRATION SECONDARY TO WORSENING UC	INTRAVENOUS	72 days	76 days
cyclizine	NAUSEA AND VOMITING	INTRAVENOUS	72 days	76 days
oxycodone	MODERATE PAIN	ORAL	74 days	76 days
paracetamol	MILD TO MODERATE PAIN	INTRAVENOUS	74 days	76 days
prednisolone	ULCERATIVE COLITIS	ORAL	74 days	80 days
potassium chloride	LOW POTASSIUM SECONDARY TO GASTROENTERITIS	ORAL	76 days	87 days
prednisolone	ULCERATIVE COLITIS	ORAL	81 days	87 days
prednisolone	ULCERATIVE COLITIS	ORAL	88 days	94 days
calcium carbonate;colecalciferol	PREVENTION OF BONE DAMAGE	ORAL	72 days	97 days
prednisolone	ULCERATIVE COLITIS	ORAL	95 days	97 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
Adenomyosis	15	Ongoing	2	not related	dose not changed	not applicable	none
Gastroenteritis	72	76	4	not related	drug withdrawn	not applicable	medication required + permanent study discontinuation
Headache	72	86	1	not related	dose not changed	not applicable	none
Oropharyngeal pain	72	83	1	not related	dose not changed	not applicable	none
Nasopharyngitis	111	Ongoing	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)
-15	12.6 (N)	37 (N)	3.8 (L)	542 (H)	0.093 (N)	98 (N)
1	12 (N)	37 (N)	3.7 (L)	711 (H)	0.103 (N)	99 (H)
15	11.4 (L)	36 (N)	3.6 (L)	644 (H)	0.084 (N)	100 (H)
28	12.2 (N)	36 (N)	3.7 (L)	490 (H)	0.097 (N)	98 (N)
43	11.3 (L)	35 (N)	3.4 (L)	491 (H)	0.057 (N)	103 (H)
70	10.5 (L)	34 (N)	3.4 (L)	537 (H)	0.1 (N)	98 (N)
113	8.7 (L)	28 (L)	3 (L)	520 (H)	0.075 (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)
-15	6.05 (N)	4.27 (N)	1.4 (N)	0.31 (N)	0.02 (N)	0.05 (N)
1	9.63 (N)	7.95 (H)	1.11 (N)	0.36 (N)	0.03 (N)	0.18 (N)
15	5.85 (N)	4.29 (N)	1.14 (N)	0.25 (N)	0.01 (N)	0.15 (N)
28	6.54 (N)	4.95 (N)	1.28 (N)	0.23 (N)	0.02 (N)	0.06 (N)
43	5.05 (N)	3.15 (N)	1.57 (N)	0.28 (N)	0.01 (N)	0.06 (N)
70	6.95 (N)	5.55 (N)	0.95 (N)	0.41 (N)	0.01 (N)	0.03 (N)
113	5.09 (N)	3.58 (N)	1.08 (N)	0.34 (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)
-15	No	7 (N)	10 (N)	48 (N)	<0.2 (L)	0.67 (N)
1	Yes	8 (N)	10 (N)	53 (N)	<0.2 (L)	0.69 (N)
15	No	8 (N)	10 (N)	46 (N)	<0.2 (L)	0.8 (N)
28	No	6 (N)	11 (N)	42 (N)	<0.2 (L)	0.85 (N)
43	No	6 (N)	10 (N)	40 (N)	<0.2 (L)	0.77 (N)
70	Yes	8 (N)	12 (N)	42 (N)	0.2 (N)	0.75 (N)
113	No	5 (L)	10 (N)	34 (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)
-15	No	120.6 (H)	34 (N)	110 (H)	3.5 (N)
1	Yes	112.8 (N)	35 (N)	99 (N)	6.15 (N)
15	No	97.8 (N)	44 (N)	99 (N)	0.75 (N)
28	No	94.2 (N)	54 (N)	98 (N)	4.72 (N)
43	No	104.4 (N)	49 (N)	109 (H)	1.06 (N)
70	Yes	105 (N)	63 (N)	101 (H)	2.44 (N)
113	No	114.6 (N)	64 (N)	115 (H)	3.9 (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	216 (N)	51 (N)	109 (N)	288 (H)
70	Yes	255 (N)	56 (N)	173 (H)	200 (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 10）；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、英国からの参加であった。

潰瘍性大腸炎（Day 7～19）（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 7、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 19、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
drug dependence	Ongoing

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
buprenorphine hydrochloride	OPOID DEPENDENCE	SUBLINGUAL	Unknown	Ongoing
mesalazine	ULCERATIVE COLITIS	ORAL	About -1665 days	Ongoing
calcium	ULCERATIVE COLITIS	ORAL	-81 days	Ongoing
vitamin d nos	ULCERATIVE COLITIS	ORAL	-81 days	Ongoing
infliximab	ULCERATIVE COLITIS	INTRAVENOUS	14 days	Ongoing
prednisolone	ULCERATIVE COLITIS	ORAL	About 1 day	6 days
prednisolone	ULCERATIVE COLITIS	ORAL	About -53 days	About 8 days
prednisolone	ULCERATIVE COLITIS	ORAL	7 days	9 days
prednisolone	ULCERATIVE COLITIS	ORAL	10 days	11 days
chlorphenamine	PROPHILACTIC TREATMENT FOR INFLIXIMAB INFUSION	INTRAVENOUS	14 days	14 days
paracetamol	PROPHILACTIC TREATMENT FOR INFLIXIMAB INFUSION	ORAL	14 days	14 days
hydrocortisone	ULCERATIVE COLITIS	RECTAL	11 days	17 days
methylprednisolone	ULCERATIVE COLITIS	INTRAVENOUS BOLUS	11 days	17 days
dalteparin	THROMBOEMBOLISM PROPHYLAXIS	SUBCUTANEOUS	11 days	19 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	19	3	not related	drug withdrawn	not applicable	medication required + permanent study discontinuation
Skin papilloma	About 9	122	1	not related	not applicable	not applicable	other treatment required
Skin papilloma	About 9	122	1	not related	not applicable	not applicable	other treatment required
Pyrexia	33	34	1	not related	not applicable	not applicable	none
Vomiting	33	34	1	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)
-19	14.7 (N)	43 (N)	4.6 (N)	205 (N)	0.064 (N)	93 (N)
1	14.4 (N)	43 (N)	4.6 (N)	220 (N)	0.081 (N)	94 (N)
53	13 (N)	42 (N)	4.6 (N)	324 (N)	0.102 (N)	92 (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)
-19	9.89 (N)	7.6 (H)	1.56 (N)	0.47 (N)	0.1 (N)	0.16 (N)
1	15.12 (H)	12.46 (H)	1.72 (N)	0.81 (N)	0.04 (N)	0.09 (N)
53	10.16 (N)	6.78 (N)	2.62 (N)	0.65 (N)	0.05 (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)
-19	No	17 (N)	16 (N)	58 (N)	0.7 (N)	1.07 (N)
1	No	12 (N)	16 (N)	50 (N)	0.6 (N)	0.88 (N)
53	No	23 (N)	21 (N)	51 (N)	0.6 (N)	0.97 (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	118.2 (N)	104 (N)	96 (N)	0.84 (N)
1	No	139.8 (H)	107 (N)	90 (N)	1.92 (N)
53	No	130.2 (H)	90 (N)	80 (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	No	188 (N)	53 (N)	103 (N)	184 (N)
53	No	236 (N)	69 (H)	151 (H)	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－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 44*）

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、イスラエルからの参加であった。

腎結石症（Day 69～70）（試験治療下の重篤な有害事象）（寛解導入試験）：
Day 69、Grade 1 の重篤な腎結石症が発現した。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 70、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**
chronic inflammatory demyelinating polyradiculoneuropathy	Ongoing
colitis ulcerative	Ongoing
hypertension	Ongoing
myocardial ischaemia	Ongoing
sleep apnoea syndrome	Ongoing

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
clopidogrel bisulfate	HIGH BLOOD PRESSURE	ORAL	About -6928 days	Ongoing
prednisone	ULCERATIVE COLITIS	ORAL	-79 days	Ongoing
mesalazine	ULCERATIVE COLITIS	ORAL	About 1 day	Ongoing
vedolizumab	ULCERATIVE COLITIS	INTRAVENOUS	About -1145 days	About -1116 days
infliximab	ULCERATIVE COLITIS	INTRAVENOUS	About -718 days	About -111 days
fentanyl	SEDATION FOR COLONOSCOPY	INTRAVENOUS	-4 days	-4 days
midazolam	SEDATION FOR COLONOSCOPY	INTRAVENOUS	-4 days	-4 days
propofol	SEDATION FOR COLONOSCOPY	INTRAVENOUS	-4 days	-4 days
fentanyl	SEDATION FOR COLONOSCOPY	INTRAVENOUS	74 days	74 days
midazolam	SEDATION FOR COLONOSCOPY	INTRAVENOUS	74 days	74 days
propofol	SEDATION FOR 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
Leukopenia	32	88	1	related	drug interrupted	dose not changed	none
Nephrolithiasis	69	70	1	not related	dose not changed	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)
-28	13.9 (N)	41 (N)	4.4 (N)	144 (N)	0.127 (N)	94 (N)
1	15.2 (N)	43 (N)	4.8 (N)	173 (N)	0.138 (H)	89 (N)
18	15.3 (N)	44 (N)	4.8 (N)	196 (N)	0.13 (N)	91 (N)
32	16 (N)	46 (N)	5 (N)	102 (L)	0.165 (H)	92 (N)
40	14 (N)	39 (N)	4.4 (N)	102 (L)		88 (N)
43	15.6 (N)	43 (N)	4.9 (N)	128 (L)	0.163 (H)	88 (N)
50	14.4 (N)	40 (N)	4.5 (N)	150 (N)	0.157 (H)	90 (N)
88	14.8 (N)	44 (N)	4.5 (N)	143 (N)	0.219 (H)	98 (N)
1*	14.8 (N)	44 (N)	4.5 (N)	143 (N)	0.219 (H)	98 (N)
22*	14.8 (N)	44 (N)	4.4 (N)	145 (N)	0.114 (N)	99 (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	6.17 (N)	4 (N)	1.71 (N)	0.38 (N)	0.02 (N)	0.05 (N)
1	8.38 (N)	6.24 (N)	1.61 (N)	0.42 (N)	0.02 (N)	0.09 (N)
18	7.93 (N)	4.56 (N)	2.72 (N)	0.5 (N)	0.04 (N)	0.11 (N)
32	2.84 (L)	1.3 (L)	1.13 (N)	0.36 (N)	0.01 (N)	0.04 (N)
40	2.08 (L)	0.89 (L)	0.91 (N)	0.24 (N)	0.01 (N)	0.04 (N)
43	3.05 (L)	1.32 (L)	1.41 (N)	0.27 (N)	0.01 (N)	0.04 (N)
50	2.87 (L)	1.35 (L)	1.21 (N)	0.27 (N)	0.02 (N)	0.02 (N)
88	4.74 (N)	3.25 (N)	1.11 (N)	0.33 (N)	0.02 (N)	0.03 (N)
1*	4.74 (N)	3.25 (N)	1.11 (N)	0.33 (N)	0.02 (N)	0.03 (N)
22*	4.26 (N)	2.24 (N)	1.69 (N)	0.27 (N)	0.03 (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	17 (N)	15 (N)	50 (N)	0.6 (N)	0.87 (N)
1	Yes	19 (N)	14 (N)	54 (N)	0.7 (N)	0.7 (N)
18	Yes			55 (N)	0.5 (N)	0.84 (N)
32	Yes	24 (N)	14 (N)	57 (N)	1.1 (N)	0.68 (N)
43	Yes	25 (N)	18 (N)	53 (N)	1.1 (N)	0.74 (N)
88	Yes	23 (N)	19 (N)	50 (N)	1 (N)	0.7 (N)
1*	Yes	23 (N)	19 (N)	50 (N)	1 (N)	0.7 (N)
22*	Yes			47 (N)	1 (N)	0.83 (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	121.2 (N)	52 (N)	79 (N)	0.66 (N)
1	Yes	148.2 (H)	37 (L)	92 (N)	0.82 (N)
18	Yes	122.4 (N)		70 (L)	0.34 (N)
32	Yes	155.4 (H)	46 (N)	102 (H)	
43	Yes	144.6 (H)	43 (N)	86 (N)	1.57 (N)
88	Yes	152.4 (H)	40 (N)	96 (N)	0.63 (N)
1*	Yes	152.4 (H)	40 (N)	96 (N)	0.63 (N)
22*	Yes	129 (H)		82 (N)	0.22 (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)
-28	Yes	159 (L)	49 (N)	93 (N)	139 (N)
1	Yes	161 (L)	51 (N)	102 (N)	128 (N)
18	Yes	176 (N)	75 (H)	92 (N)	146 (N)
74	Yes	176 (N)	66 (N)	100 (N)	
88	Yes	175 (N)	65 (N)	93 (N)	151 (N)
1*	Yes	175 (N)	65 (N)	93 (N)	151 (N)
22*	Yes	174 (L)	64 (N)	92 (N)	168 (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 45）；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、フランスからの参加であった。

カンピロバクター胃腸炎（Day 43～54）（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 43、Grade 3 の重篤なカンピロバクター胃腸炎が発現した。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。Day 54、Grade 3 の本事象は回復した。

その他の関連情報：被験者は、重度の血液が混じった下痢及び発熱のため入院した。便培養検査の結果、カンピロバクターが検出された。抗生剤投与により容体は改善し、被験者は退院した。

Medical History	
Medical History	**Resolution**
colitis ulcerative	Ongoing
drug hypersensitivity	Ongoing
parkinson's disease	Ongoing
cerebral venous thrombosis	About -10115 days
anal fissure excision	About -4636 days
hysterectomy	About -3601 days
pulmonary embolism	About -2445 days
anal fissure	About -437 days
pulmonary embolism	About -163 days
headache	-13 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
mesalazine	ULCERATIVE COLITIS	ORAL	About -10479 days	Ongoing
rasagiline mesylate	PARKINSON DISEASE	ORAL	About -2840 days	Ongoing
benserazide hydrochloride;levodopa	PARKINSON DISEASE	ORAL	About -983 days	Ongoing
prednisolone	ULCERATIVE COLITIS	ORAL	About -71 days	Ongoing
fluindione	PULMONARY EMBOLISM	ORAL	2 days	Ongoing
rotigotine	PARKINSON DISEASE	TRANSDERMAL	24 days	Ongoing
ustekinumab	ULCERATIVE COLITIS	INTRAVENOUS	61 days	Ongoing
betamethasone sodium phosphate	ULCERATIVE COLITIS	RECTAL	About -10328 days	About -10237 days
mesalazine	ULCERATIVE COLITIS	RECTAL	About -10479 days	About -10115 days
azathioprine	ULCERATIVE COLITIS	ORAL	About -2931 days	About -2445 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
infliximab	ULCERATIVE COLITIS	INTRAVENOUS	About -2444 days	-1062 days
golimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	-1062 days	-70 days
paracetamol	HEADACHE	ORAL	-13 days	-13 days
fluindione	PULMONARY EMBOLISM	ORAL	About -193 days	-11 days
paracetamol	HEADACHE	ORAL	-1 day	-1 day
enoxaparin sodium	PREVENTION OF PULMONARY EMBOLISM	SUBCUTANEOUS	-10 days	1 day
paracetamol	HEADACHE	ORAL	7 days	7 days
paracetamol	HEADACHE	ORAL	15 days	21 days
pramipexole dihydrochloride	PARKINSON DISEASE	ORAL	About -2840 days	24 days
phloroglucinol	ABDOMINAL PAIN	ORAL	34 days	34 days
tramadol hydrochloride	ABDOMINAL PAIN SECONDARY TO CAMPYLOBACTER GASTROENTERITIS	ORAL	45 days	45 days
ciprofloxacin	SUSPECTED INFECTIOUS COLITIS	ORAL	46 days	50 days
metronidazole	SUSPECTED INFECTIOUS COLITIS	ORAL	46 days	50 days
paracetamol	PAIN	ORAL	46 days	61 days
phloroglucinol	ABDOMINAL PAIN	ORAL	46 days	61 days
azithromycin	CAMPYLOBACTER GASTROENTERITIS	ORAL	50 days	61 days
saccharomyces boulardii	CONCOMITANT TREATMENT OF ANTIBIOTIC THERAPY	ORAL	54 days	68 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
General physical health deterioration	-6	-1	1	not related	not applicable	not applicable	none
Nausea	-6	9	1	not related	not applicable	not applicable	none
Hepatic function abnormal	1	15	2	not related	not applicable	not applicable	none
Headache	7	7	1	not related	dose not changed	not applicable	medication required
Pain in extremity	11	14	1	not related	dose not changed	not applicable	none
Headache	15	21	1	not related	dose not changed	not applicable	medication required
Parkinson's disease	15	Ongoing	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
Campylobacter gastroenteritis	43	54	3	related	drug withdrawn	not applicable	medication required + permanent study discontinuation
Atrioventricular block first degree	52	61	1	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)
-11	12.6 (N)	38 (N)	4.4 (N)	282 (N)	0.065 (N)	88 (N)
1	11.8 (N)	37 (N)	4 (L)	246 (N)	0.088 (N)	91 (N)
15	11.9 (N)	36 (N)	4 (L)	309 (N)	0.083 (N)	90 (N)
29	11 (L)	35 (N)	4 (L)	390 (N)	0.071 (N)	88 (N)
40	10.8 (L)	34 (N)	3.9 (L)	348 (N)	0.1 (N)	88 (N)
52	11.6 (N)	36 (N)	4.1 (N)	375 (N)	0.098 (N)	87 (N)
78	10.3 (L)	32 (L)	3.9 (L)	434 (H)	0.03 (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)
-11	8.21 (N)	6.55 (N)	1.06 (N)	0.53 (N)	0.03 (N)	0.03 (N)
1	9.12 (N)	6.94 (N)	1.53 (N)	0.49 (N)	0.04 (N)	0.11 (N)
15	8.9 (N)	6.78 (N)	1.29 (N)	0.69 (N)	0.03 (N)	0.11 (N)
29	11.91 (H)	9.51 (H)	1.52 (N)	0.67 (N)	0.04 (N)	0.17 (N)
40	8.27 (N)	5.77 (N)	1.54 (N)	0.59 (N)	0.02 (N)	0.34 (N)
52	12.71 (H)	9.51 (H)	2.16 (N)	0.82 (N)	0.04 (N)	0.17 (N)
78	8.59 (N)	7.14 (N)	0.86 (L)	0.45 (N)	0.11 (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)
-11	No	16 (N)	15 (N)	61 (N)	0.2 (N)	0.85 (N)
1	Yes	206 (H)	95 (H)	163 (H)	<0.2 (L)	0.84 (N)
15	No	19 (N)	15 (N)	94 (N)	0.3 (N)	0.9 (N)
29	No	23 (N)	19 (N)	92 (N)	0.3 (N)	0.96 (N)
40	No	17 (N)	15 (N)	81 (N)	0.3 (N)	0.96 (N)
52	No	14 (N)	11 (N)	80 (N)	0.2 (N)	0.87 (N)
78	No	21 (N)	20 (N)	76 (N)	<0.2 (L)	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)
-11	No	58.8 (L)	108 (N)	100 (H)	4.54 (N)
1	Yes	60 (L)	74 (N)	100 (N)	13.7 (H)
15	No	53.4 (L)	67 (N)	91 (N)	23.2 (H)
29	No	51 (L)	84 (N)	93 (N)	13.2 (H)
40	No	51 (L)	79 (N)	75 (N)	4.21 (N)
52	No	56.4 (L)	54 (N)	83 (N)	4.73 (N)
78	No	51 (L)	82 (N)	97 (N)	3.62 (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)
1	Yes	229 (N)	72 (N)	145 (H)	101 (N)
52	No	198 (N)	64 (N)	107 (N)	123 (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－有害事象により投与中止（Day 287*）

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、フランスからの参加であった。

ウイルス性胃腸炎（Day 75～80）（試験治療下の注目すべき有害事象［TE-AEI］）（寛解導入試験）：
Day 75、Grade 1 の非重篤なウイルス性胃腸炎が発現した。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 80、Grade 1 の本事象は回復した。

上咽頭炎（Day 42*～47*）（TE-AEI）（寛解維持試験）：
Day 42*、Grade 1 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 47*、Grade 1 の本事象は回復した。

腹痛（Day 216*～222*）（試験治療下の重篤な有害事象［TE-SAE］）（寛解維持試験）：
Day 216*、Grade 2 の重篤な腹痛が発現した。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投与中断であった。本事象は治験薬と関連ありと判断された。Day 222*、Grade 2 の本事象は回復した。

胆石症（Day 287*～301*）（TE-SAE、投与中止に至った有害事象）（寛解維持試験）：
Day 287*、Grade 3 の重篤な胆石症が発現した。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ありと判断された。Day 301*、Grade 3 の本事象は回復した。

虫垂炎（Day 301*～305*）（TE-SAE、TE-AEI）（寛解維持試験）：
Day 301*、Grade 3 の重篤な虫垂炎が発現した。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ありと判断された。Day 305*、Grade 3 の本事象は回復した。

急性膵炎（Day 305*～351*）（TE-SAE）（寛解維持試験）：
Day 305*、Grade 4 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ありと判断された。Day 351*、Grade 4 の本事象は回復した。

ダグラス窩膿瘍（Day 308*～351*）（TE-AEI）（寛解維持試験）：
Day 308*、Grade 2 の非重篤なダグラス窩膿瘍が発現した。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 351*、Grade 2 の本事象は回復した。

その他の関連情報：急性の右下腹部痛が認められた。コンピューター断層撮影検査の結果、単純性虫垂炎を示唆する所見が認められた。虫垂切除術が実施され、術後の経過は良好であった。その後、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**
cholangitis sclerosing	Ongoing
crohn's disease	Ongoing
oral herpes	-108 days
blepharitis	1 day

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
ursodeoxycholic acid	MICROLITHIASIS	ORAL	374 days	Ongoing
mesalazine	ULCERATIVE COLITIS	ORAL	386 days	Ongoing
nutrients nos	ULCERATIVE COLITIS	ORAL	397 days	Ongoing
mesalazine	ULCERATIVE COLITIS	ORAL	-1547 days	-1515 days
adalimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	-1280 days	-1270 days
vedolizumab	ULCERATIVE COLITIS	INTRAVENOUS	-1228 days	About -879 days
prednisone	ULCERATIVE COLITIS	ORAL	About -1547 days	About -361 days
azathioprine	ULCERATIVE COLITIS	ORAL	-1498 days	-216 days
infliximab	ULCERATIVE COLITIS	INTRAVENOUS	-451 days	-82 days
mesalazine	ULCERATIVE COLITIS	RECTAL	About -117 days	About -57 days
retinol	BLEPHARITIS	INTRAOCULAR	-21 days	1 day
sodium chloride	BLEPHARITIS	INTRAOCULAR	-21 days	1 day
influenza vaccine inact split virion 3v	FLU PREVENTION	SUBCUTANEOUS	28 days	28 days
metopimazine	VIRAL GASTROENTERITIS	ORAL	75 days	78 days
racecadotril	VIRAL GASTROENTERITIS	ORAL	75 days	80 days
valaciclovir hydrochloride	HERPES LABIA PREVENTION	ORAL	-108 days	126 days
nefopam	ABDOMINAL PAIN	ORAL	294 days	296 days
ceftriaxone	SUSPICION OF INFECTIOUS COLITIS	INTRAVENOUS	295 days	300 days
metronidazole	SUSPICION OF INFECTIOUS COLITIS	ORAL	295 days	300 days
paracetamol	LOWER BACK PAIN	ORAL	339 days	342 days
phloroglucinol	ABDOMINAL PAIN	ORAL	364 days	364 days
paracetamol	ABDOMINAL PAIN	ORAL	363 days	365 days
alverine citrate;simeticone	ABDOMINAL PAIN	ORAL	365 days	366 days
atracurium	APPENDICITIS	INTRAVENOUS	379 days	379 days
calcium chloride;potassium chloride;sodium lactate	APPENDICITIS	INTRAVENOUS	379 days	379 days
dexamethasone	APPENDICITIS	INTRAVENOUS	379 days	379 days
oxycodone hydrochloride	APPENDICITIS	INTRAVENOUS	379 days	379 days
propofol	APPENDICITIS	INTRAVENOUS	379 days	379 days
ropivacaine	APPENDICITIS	INTRAPERITONEAL	379 days	379 days
sufentanil	APPENDICITIS	INTRAVENOUS	379 days	379 days
tramadol	APPENDICITIS	INTRAVENOUS	379 days	379 days
amoxicillin trihydrate;clavulanate potassium	APPENDICITIS	INTRAVENOUS	379 days	380 days
glucose;potassium chloride;sodium chloride	APPENDICITIS	INTRAVENOUS	379 days	380 days
paracetamol	APPENDICITIS	INTRAVENOUS	379 days	380 days
phloroglucinol	APPENDICITIS	INTRAVENOUS	379 days	380 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
paracetamol	APPENDICITIS	ORAL	380 days	383 days
phloroglucinol	APPENDICITIS	ORAL	380 days	383 days
tramadol hydrochloride	APPENDICITIS	ORAL	380 days	383 days
ceftriaxone	ABCESS OF POUCH OF DOUGLAS	INTRAVENOUS	384 days	385 days
ondansetron	ACUTE PANCREATITIS	ORAL	386 days	386 days
nefopam	ACUTE PANCREATITIS	INTRAVENOUS	388 days	388 days
paracetamol	ACUTE PANCREATITIS	INTRAVENOUS	388 days	388 days
phloroglucinol	ACUTE PANCREATITIS	INTRAVENOUS	388 days	388 days
saccharomyces boulardii	ACUTE PANCREATITIS	ORAL	387 days	390 days
metoclopramide	ACUTE PANCREATITIS	INTRAVENOUS	388 days	390 days
morphine hydrochloride	ACUTE PANCREATITIS	INTRAVENOUS	389 days	390 days
nefopam	ACUTE PANCREATITIS	INTRAVENOUS	390 days	390 days
glucose;potassium chloride;sodium chloride	ACUTE PANCREATITIS	INTRAVENOUS	388 days	392 days
metronidazole	ABCESS OF POUCH OF DOUGLAS	INTRAVENOUS	384 days	393 days
ciprofloxacin	ABCESS OF POUCH OF DOUGLAS	INTRAVENOUS	388 days	393 days
calcium chloride;potassium chloride;sodium lactate	ACUTE PANCREATITIS	INTRAVENOUS	389 days	393 days
enoxaparin sodium	ACUTE PANCREATITIS	SUBCUTANEOUS	384 days	396 days
alginic acid;aluminium hydroxide;sodium bicarbonate	ACUTE PANCREATITIS	ORAL	393 days	397 days
paracetamol	ACUTE PANCREATITIS	ORAL	384 days	407 days
phloroglucinol;trimethylphloroglucinol	ACUTE PANCREATITIS	ORAL	384 days	407 days
ciprofloxacin	ABCESS OF POUCH OF DOUGLAS	ORAL	386 days	407 days
metronidazole	ABCESS OF POUCH OF DOUGLAS	ORAL	386 days	407 days
pantoprazole	ACUTE PANCREATITIS	ORAL	388 days	407 days
racecadotril	ULCERATIVE COLITIS	ORAL	397 days	407 days
prednisolone	ULCERATIVE COLITIS	ORAL	397 days	415 days
mesalazine	ULCERATIVE COLITIS	ORAL	379 days	About 432 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
Blood alkaline phosphatase increased	15	44	1	related	dose not changed	not applicable	none
Gastroenteritis viral	75	80	1	related	dose not changed	not applicable	medication required
Nasopharyngitis	42*	47*	1	related	not applicable	dose not changed	none
Abdominal pain	216*	222*	2	related	not applicable	drug interrupted	medication required
Back pain	261*	274*	1	related	not applicable	dose not changed	medication required
Abdominal pain	284*	288*	2	not related	not applicable	dose not changed	medication required
Cholelithiasis	287*	301*	3	related	not applicable	drug withdrawn	medication required + permanent study discontinuation
Appendicitis	301*	305*	3	related	not applicable	not applicable	medication required + other treatment required
Pancreatitis acute	305*	351*	4	related	not applicable	not applicable	medication required + other treatment required
Douglas' abscess	308*	351*	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)
-21	14 (N)	42 (N)	4.8 (N)	222 (N)	0.051 (N)	88 (N)
1	13.9 (N)	40 (N)	4.8 (N)	228 (N)	0.052 (N)	84 (N)
15	13.2 (N)	40 (N)	4.7 (N)	261 (N)	0.057 (N)	84 (N)
32	13.6 (N)	40 (N)	4.8 (N)	247 (N)	0.047 (N)	82 (N)
44	12.9 (N)	38 (L)	4.7 (N)	221 (N)	0.06 (N)	81 (N)
71	14.1 (N)	42 (N)	5.2 (N)	218 (N)	0.043 (N)	80 (N)
-8*	14.1 (N)	42 (N)	5.2 (N)	218 (N)	0.043 (N)	80 (N)
17*	13.3 (N)	41 (N)	5 (N)	273 (N)	0.05 (N)	82 (N)
66*	13.1 (N)	40 (N)	5.1 (N)	232 (N)	0.037 (N)	78 (L)
106*	13.6 (N)	41 (N)	5.2 (N)	212 (N)	0.072 (N)	78 (L)
157*	13.4 (N)	42 (N)	5 (N)	197 (N)	0.053 (N)	83 (N)
213*	13.3 (N)	41 (N)	5 (N)	212 (N)	0.046 (N)	83 (N)
274*	14.1 (N)	41 (N)	5.1 (N)	225 (N)	0.058 (N)	81 (N)
290*	14.1 (N)	42 (N)	5.1 (N)	197 (N)	0.047 (N)	84 (N)
319*	13.3 (N)	41 (N)	4.9 (N)	507 (H)	0.074 (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	6.15 (N)	4.18 (N)	1.4 (N)	0.43 (N)	0.04 (N)	0.09 (N)
1	6.85 (N)	4.75 (N)	1.3 (N)	0.61 (N)	0.03 (N)	0.17 (N)
15	6.3 (N)	4.26 (N)	1.41 (N)	0.44 (N)	0.05 (N)	0.14 (N)
32	3.51 (L)	1.91 (L)	0.97 (N)	0.25 (N)	0.05 (N)	0.32 (N)
44	4.49 (N)	2.6 (N)	1.33 (N)	0.35 (N)	0.02 (N)	0.18 (N)
71	4.65 (N)	2.92 (N)	1.26 (N)	0.32 (N)	0.02 (N)	0.12 (N)
-8*	4.65 (N)	2.92 (N)	1.26 (N)	0.32 (N)	0.02 (N)	0.12 (N)
17*	4.92 (N)	3.24 (N)	1.2 (N)	0.34 (N)	0.03 (N)	0.11 (N)
66*	3.67 (L)	2.16 (N)	1.16 (N)	0.23 (N)	0.02 (N)	0.1 (N)
106*	4.54 (N)	2.75 (N)	1.3 (N)	0.31 (N)	0.03 (N)	0.15 (N)
157*	4.01 (N)	2.33 (N)	1.22 (N)	0.32 (N)	0.03 (N)	0.1 (N)
213*	4.37 (N)	2.88 (N)	1.09 (N)	0.28 (N)	0.03 (N)	0.1 (N)
274*	5.23 (N)	3.26 (N)	1.44 (N)	0.36 (N)	0.03 (N)	0.15 (N)
290*	4.55 (N)	3.18 (N)	0.89 (L)	0.31 (N)	0.07 (N)	0.11 (N)
319*	8.48 (N)	6.88 (N)	0.72 (L)	0.55 (N)	0.08 (N)	0.25 (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	11 (N)	13 (N)	159 (H)	0.4 (N)	0.81 (N)
1	Yes	14 (N)	16 (N)	160 (H)	0.4 (N)	0.81 (N)
15	No	29 (N)	16 (N)	188 (H)	0.5 (N)	0.89 (N)
32	Yes	16 (N)	22 (N)	161 (H)	0.4 (N)	0.84 (N)
44	No	19 (N)	17 (N)	149 (H)	0.5 (N)	0.81 (N)
71	Yes	13 (N)	16 (N)	148 (H)	0.5 (N)	0.84 (N)
-8*	Yes	13 (N)	16 (N)	148 (H)	0.5 (N)	0.84 (N)
17*	No	15 (N)	18 (N)	145 (H)	0.5 (N)	0.85 (N)
66*	No	22 (N)	19 (N)	132 (H)	0.2 (N)	0.84 (N)
106*	Yes	15 (N)	15 (N)	124 (N)	0.6 (N)	0.87 (N)
157*	No	11 (N)	13 (N)	113 (N)	0.5 (N)	0.76 (N)
213*	No	13 (N)	16 (N)	131 (H)	0.8 (N)	0.79 (N)
274*	No	27 (N)	20 (N)	119 (N)	0.5 (N)	0.87 (N)
290*	No	286 (H)	63 (H)	216 (H)	1.4 (H)	0.9 (N)
319*	No	11 (N)	14 (N)	141 (H)	0.2 (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)
-21	No	118.2 (N)	70 (N)	89 (N)	0.53 (N)
1	Yes	120.6 (N)	67 (N)	81 (N)	4.08 (N)
15	No	111.6 (N)	85 (N)	87 (N)	0.66 (N)
32	Yes	118.2 (N)	526 (H)	93 (N)	0.92 (N)
44	No	124.2 (N)	86 (N)	77 (N)	0.43 (N)
71	Yes	117.6 (N)	87 (N)	96 (N)	<0.20 (N)
-8*	Yes	117.6 (N)	87 (N)	96 (N)	<0.20 (N)
17*	No	117.6 (N)	215 (N)	83 (N)	<0.20 (N)
66*	No	117.6 (N)	88 (N)	89 (N)	0.31 (N)
106*	Yes	113.4 (N)	82 (N)	95 (N)	<0.20 (N)
157*	No	130.2 (H)	89 (N)	62 (L)	<0.20 (N)
213*	No	122.4 (N)	141 (N)	95 (N)	0.37 (N)
274*	No	113.4 (N)	110 (N)	92 (N)	<0.20 (N)
290*	No	109.2 (N)	196 (N)	116 (H)	1.2 (N)
319*	No	107.4 (N)	29 (L)	97 (N)	2.94 (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	159 (N)	45 (N)	103 (N)	47 (N)
71	Yes	175 (N)	66 (H)	116 (N)	28 (L)
-8*	Yes	175 (N)	66 (H)	116 (N)	28 (L)
106*	Yes	176 (N)	56 (N)	122 (N)	40 (L)
290*	No	193 (N)	65 (H)	108 (N)	55 (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－有害事象により投与中止（Day 141*）

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、英国からの参加であった。

ウイルス性胃腸炎（Day 137*～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）（寛解維持試験）：
Day 137*、Grade 3 の重篤なウイルス性胃腸炎が発現した。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 141*、Grade 3 の本事象は回復した。

その他の関連情報：急性発症した発熱及び下痢が認められた。被験者は脱水のため入院した。便培養検体が採取されたが、検査結果は得られなかった。被験者はウイルス性胃腸炎と診断され、入院した 2 日後に退院した。
*寛解維持試験における study day

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

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
tofacitinib	ULCERATIVE COLITIS	ORAL	224 days	Ongoing
azathioprine	ULCERATIVE COLITIS	ORAL	-821 days	-727 days
infliximab	ULCERATIVE COLITIS	INTRAVENOUS DRIP	-724 days	-570 days
mercaptopurine	ULCERATIVE COLITIS	ORAL	-726 days	About -555 days
vedolizumab	ULCERATIVE COLITIS	INTRAVENOUS	-505 days	-380 days
vedolizumab	ULCERATIVE COLITIS	INTRAVENOUS	-379 days	-236 days
adalimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	-236 days	-84 days
adalimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	-176 days	-84 days
ferric carboxymaltose	ANAEMIA	INTRAVENOUS	15 days	15 days
ferric carboxymaltose	ANAEMIA	INTRAVENOUS	29 days	29 days
sodium glycerophosphate	HYPOPHOSPHATAEMIA	INTRAVENOUS	44 days	44 days
sodium phosphate monobasic (anhydrous)	HYPOPHOSPHATAEMIA	ORAL	42 days	50 days
i.v. solutions	TREATMENT OF DEHYDRATION CAUSED BY VIRAL GASTROENTERITIS	INTRAVENOUS	217 days	218 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**
Hypophosphataemia	34	49	3	not related	dose not changed	not applicable	medication required
Limb injury	42	49	1	not related	dose not changed	not applicable	none
Gastroenteritis viral	137*	141*	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)
-15	12.2 (L)	39 (N)	5.6 (N)	288 (N)	0.074 (N)	70 (L)
1	12.2 (L)	40 (N)	5.6 (N)	332 (N)	0.07 (N)	71 (L)
15	12.3 (L)	40 (N)	5.7 (N)	301 (N)	0.069 (N)	70 (L)
29	14.1 (N)	43 (N)	5.9 (N)	271 (N)	0.101 (N)	73 (L)
42	15 (N)	46 (N)	5.9 (N)	209 (N)	0.06 (N)	79 (N)
70	16 (N)	47 (N)	6 (N)	192 (N)	0.044 (N)	79 (N)
-8*	16 (N)	47 (N)	6 (N)	192 (N)	0.044 (N)	79 (N)
22*	16.5 (N)	48 (N)	5.9 (N)	229 (N)	0.042 (N)	81 (N)
64*	16.7 (N)	46 (N)	5.5 (N)	261 (N)	0.063 (N)	85 (N)
111*	16.7 (N)	49 (N)	5.6 (N)	195 (N)	0.055 (N)	87 (N)
147*	16.1 (N)	47 (N)	5.4 (N)	280 (N)	0.036 (N)	87 (N)
169*	16.7 (N)	47 (N)	5.6 (N)	223 (N)	0.051 (N)	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)
-15	7.3 (N)	4.93 (N)	1.84 (N)	0.4 (N)	0.04 (N)	0.09 (N)
1	6.28 (N)	4.19 (N)	1.48 (N)	0.5 (N)	0.03 (N)	0.06 (N)
15	7.16 (N)	5.06 (N)	1.61 (N)	0.34 (N)	0.04 (N)	0.11 (N)
29	4.53 (N)	2.46 (N)	1.51 (N)	0.4 (N)	0.03 (N)	0.11 (N)
42	6.5 (N)	4.28 (N)	1.64 (N)	0.4 (N)	0.04 (N)	0.15 (N)
70	6.71 (N)	4.04 (N)	1.94 (N)	0.43 (N)	0.09 (N)	0.21 (N)
-8*	6.71 (N)	4.04 (N)	1.94 (N)	0.43 (N)	0.09 (N)	0.21 (N)
22*	6.8 (N)	4.49 (N)	1.61 (N)	0.4 (N)	0.07 (N)	0.23 (N)
64*	8.37 (N)	6.49 (N)	1.29 (N)	0.42 (N)	0.06 (N)	0.1 (N)
111*	3.05 (L)	1.39 (L)	1.19 (N)	0.28 (N)	0.07 (N)	0.13 (N)
147*	10.05 (N)	7.51 (H)	1.83 (N)	0.51 (N)	0.05 (N)	0.14 (N)
169*	7.41 (N)	5.11 (N)	1.73 (N)	0.42 (N)	0.05 (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)
-15	No	25 (N)	21 (N)	109 (N)	0.3 (N)	0.81 (N)
1	Yes	39 (N)	26 (N)	116 (N)	0.4 (N)	0.84 (N)
15	Yes	21 (N)	21 (N)	107 (N)	0.6 (N)	0.89 (N)
29	Yes	26 (N)	23 (N)	101 (N)	0.5 (N)	0.8 (N)
42	No	23 (N)	17 (N)	93 (N)	0.4 (N)	0.77 (N)
70	Yes	32 (N)	23 (N)	108 (N)	0.6 (N)	0.7 (N)
-8*	Yes	32 (N)	23 (N)	108 (N)	0.6 (N)	0.7 (N)
22*	No	29 (N)	21 (N)	102 (N)	0.8 (N)	0.84 (N)
64*	No	63 (H)	39 (H)	98 (N)	0.9 (N)	0.87 (N)
111*	Yes	55 (H)	28 (N)	103 (N)	0.5 (N)	0.8 (N)
147*	No	48 (H)	34 (N)	91 (N)	0.2 (N)	0.79 (N)
169*	No	33 (N)	25 (N)	92 (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)
-15	No	159 (H)	125 (N)	88 (N)	1.2 (N)
1	Yes	153 (H)	116 (N)	96 (N)	1.5 (N)
15	Yes	145.2 (H)	132 (N)	91 (N)	0.58 (N)
29	Yes	159 (H)	145 (N)	91 (N)	0.28 (N)
42	No	163.8 (H)	135 (N)	100 (H)	0.98 (N)
70	Yes	180 (H)	197 (N)	81 (N)	5.1 (N)
-8*	Yes	180 (H)	197 (N)	81 (N)	5.1 (N)
22*	No	154.8 (H)	134 (N)	95 (N)	0.85 (N)
64*	No	145.8 (H)	676 (H)	99 (N)	3.99 (N)
111*	Yes	156 (H)	126 (N)	94 (N)	4.07 (N)
147*	No	165.6 (H)	133 (N)	92 (N)	2.26 (N)
169*	No	147.6 (H)	128 (N)	102 (H)	0.69 (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)
1	Yes	150 (N)	36 (N)	111 (N)	56 (N)
70	Yes	166 (N)	42 (N)	114 (N)	52 (N)
-8*	Yes	166 (N)	42 (N)	114 (N)	52 (N)
111*	Yes	172 (N)	41 (N)	120 (N)	61 (N)
147*	No	153 (N)	38 (N)	119 (N)	51 (N)
169*	No	193 (N)	48 (N)	137 (H)	73 (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－有害事象により投与中止（Day 67*）

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、ウクライナからの参加であった。

自己免疫性肝炎（Day 64*～87*）（投与中止に至った有害事象）（寛解維持試験）：
Day 64*、Grade 2 の非重篤な自己免疫性肝炎が発現した。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 87*、Grade 2 の本事象は回復した。

自己免疫性肝炎（Day 87*～継続）（試験治療下の重篤な有害事象）（寛解維持試験）：
Day 87*、Grade 3 の重篤な自己免疫性肝炎が発現した。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：寛解維持試験 Day 64*以降、アスパラギン酸アミノトランスフェラーゼ（AST）値及びアラニンアミノトランスフェラーゼ（ALT）値の変動が認められた（それぞれ 37～184 U/L 及び 52～159 U/L）。寛解維持試験 Day 87*、AST 値及び ALT 値が上昇し（それぞれ 189 U/L 及び 263 U/L）、治験薬の投与が中止された。被験者は試験の早期中止来院と同日に入院し、その後慢性自己免疫性肝炎と診断された。抗核抗体検査の結果は陽性であった。また、被験者は入院中に代償性門脈圧亢進症と診断された。
*寛解維持試験における study day

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

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
mesalazine	ULCERATIVE COLITIS	ORAL	-250 days	Ongoing
ferrous sulfate	ANEMIA	ORAL	-32 days	Ongoing
pancreas extract	ENZYMATIC SUPPORT	ORAL	-32 days	Ongoing
bismuth subcitrate	PREVENTION OF ULCEROGENIC ACTION OF STEROIDS, GASTRITIS	ORAL	173 days	Ongoing
methylprednisolone	ULCERATIVE COLITIS	ORAL	173 days	Ongoing
pantoprazole	PREVENTION OF ULCEROGENIC ACTION OF STEROIDS, GASTRITIS	ORAL	173 days	Ongoing
macrogol 4000	BOWEL PREPERATION	ORAL	-4 days	-4 days
drotaverine hydrochloride	UROLITHIASIS. STONE OF THE LOWER THIRD OF THE URETER	ORAL	57 days	71 days
tamsulosin hydrochloride	UROLITHIASIS. STONE OF THE LOWER THIRD OF THE URETER	ORAL	57 days	71 days
unspecified herbal and traditional medicine	UROLITHIASIS. STONE OF THE LOWER THIRD OF THE URETER	ORAL	57 days	71 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
macrogol 4000	BOWEL PREPERATION	ORAL	72 days	72 days
methylprednisolone	ULCERATIVE COLITIS	ORAL	-101 days	100 days
methylprednisolone	ULCERATIVE COLITIS	ORAL	101 days	107 days
methylprednisolone	ULCERATIVE COLITIS	ORAL	108 days	114 days
methylprednisolone	ULCERATIVE COLITIS	ORAL	115 days	172 days
phthalylsulfathiazole	ULCERATIVE COLITIS	ORAL	165 days	172 days
ademetionine	SAE "CHRONIC AUTOIMMUNE HEPATITIS', PORTAL HYPERTENSION PREVENTION	INTRAVENOUS	165 days	179 days
cysteine hydrochloride;glycine;glycyrrhizic acid	SAE "CHRONIC AUTOIMMUNE HEPATITIS', PORTAL HYPERTENSION PREVENTION	INTRAVENOUS	165 days	179 days
ornithine aspartate	SAE "CHRONIC AUTOIMMUNE HEPATITIS', PORTAL HYPERTENSION PREVENTION	INTRAVENOUS	165 days	179 days
sodium thiosulfate	SAE "CHRONIC AUTOIMMUNE HEPATITIS', PORTAL HYPERTENSION PREVENTION	INTRAVENOUS	165 days	179 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
Ureterolithiasis	57	Ongoing	2	not related	dose not changed	not applicable	medication required
Colitis ulcerative	32*	64*	2	not related	not applicable	dose not changed	medication required
Autoimmune hepatitis	64*	87*	2	not related	not applicable	drug withdrawn	permanent study discontinuation
Autoimmune hepatitis	87*	Ongoing	3	not related	not applicable	not applicable	medication required
Portal hypertension	92*	Ongoing	2	not related	not applicable	not applicable	medication required
Gastritis	98*	Ongoing	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)
-21	7.9 (L)	30 (L)	4.4 (L)	328 (N)	0.094 (N)	69 (L)
-7	8.1 (L)	30 (L)	4.2 (L)	322 (N)		72 (L)
1	9.4 (L)	36 (L)	4.7 (N)	334 (N)	0.113 (N)	78 (L)
15	11.2 (L)	41 (N)	4.8 (N)	246 (N)	0.099 (N)	85 (N)
29	11.3 (L)	39 (N)	4.6 (N)	271 (N)	0.057 (N)	86 (N)
43	11.7 (L)	40 (N)	4.7 (N)	252 (N)	0.054 (N)	87 (N)
73	12.7 (N)	40 (N)	4.8 (N)	267 (N)	0.043 (N)	83 (N)
-6*	12.7 (N)	40 (N)	4.8 (N)	267 (N)	0.043 (N)	83 (N)
22*	12 (L)	38 (L)	4.6 (N)	315 (N)	0.052 (N)	83 (N)
37*	12.2 (L)	37 (L)	4.6 (N)	360 (N)	0.056 (N)	80 (N)
64*	10.5 (L)	33 (L)	4 (L)	355 (N)	0.073 (N)	81 (N)
87*	10.3 (L)	33 (L)	4.3 (L)	304 (N)	0.051 (N)	77 (L)
101*	10.4 (L)	34 (L)	4.5 (N)	349 (N)	0.064 (N)	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)
-21	5.06 (N)	2.59 (N)	1.79 (N)	0.52 (N)	0.06 (N)	0.1 (N)
-7	3.74 (L)	1.54 (L)	1.75 (N)	0.29 (N)	0.05 (N)	0.11 (N)
1	4.41 (N)	2.08 (N)	1.82 (N)	0.35 (N)	0.03 (N)	0.13 (N)
15	6.37 (N)	3.63 (N)	1.96 (N)	0.5 (N)	0.06 (N)	0.22 (N)
29	4.68 (N)	2.43 (N)	1.79 (N)	0.27 (N)	0.05 (N)	0.13 (N)
43	5.45 (N)	2.83 (N)	2.04 (N)	0.46 (N)	0.02 (N)	0.1 (N)
73	5.17 (N)	3.02 (N)	1.6 (N)	0.38 (N)	0.06 (N)	0.11 (N)
-6*	5.17 (N)	3.02 (N)	1.6 (N)	0.38 (N)	0.06 (N)	0.11 (N)
22*	5.77 (N)	3.29 (N)	1.93 (N)	0.42 (N)	0.04 (N)	0.09 (N)
37*	7.76 (N)	4.49 (N)	2.59 (N)	0.53 (N)	0.04 (N)	0.1 (N)
64*	6.04 (N)	3.52 (N)	2 (N)	0.41 (N)	0.02 (N)	0.09 (N)
87*	5.65 (N)	2.93 (N)	2.17 (N)	0.38 (N)	0.03 (N)	0.14 (N)
101*	6.93 (N)	5.66 (N)	1.05 (N)	0.16 (N)	0.01 (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)
-21	Yes	41 (N)	40 (H)	250 (H)	0.4 (N)	0.78 (N)
1	Yes	76 (H)	138 (H)	403 (H)	0.4 (N)	0.85 (N)
15	Yes	73 (H)	47 (H)	246 (H)	0.5 (N)	0.92 (N)
29	Yes	48 (H)	25 (N)	243 (H)	0.4 (N)	0.88 (N)
43	Yes	56 (H)	37 (H)	207 (H)	0.4 (N)	0.86 (N)
73	Yes	159 (H)	117 (H)	228 (H)	0.5 (N)	0.93 (N)
79	Yes	185 (H)	184 (H)	204 (H)	0.4 (N)	0.85 (N)
-6*	Yes					
1*	Yes	185 (H)	184 (H)	204 (H)	0.4 (N)	0.85 (N)
22*	Yes	82 (H)	42 (H)	241 (H)	0.6 (N)	0.88 (N)
37*		52 (H)	37 (H)	192 (H)	0.6 (N)	0.9 (N)
64*	Yes	263 (H)	189 (H)	392 (H)	0.9 (N)	0.85 (N)
73*	Yes	404 (H)	542 (H)	453 (H)	0.6 (N)	0.76 (N)
87*	Yes	222 (H)	161 (H)	354 (H)	0.5 (N)	0.69 (N)
101*	Yes	223 (H)	173 (H)	256 (H)	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)
-21	Yes	147.6 (H)	84 (N)	97 (N)	13 (H)
1	Yes	137.4 (H)	85 (N)	93 (N)	5.07 (N)
15	Yes	129 (H)	85 (N)	88 (N)	13.4 (H)
29	Yes	135 (H)	97 (N)	90 (N)	2.94 (N)
43	Yes	139.8 (H)	109 (N)	89 (N)	3.7 (N)
73	Yes	129 (H)	97 (N)	90 (N)	1.92 (N)
79	Yes	141.6 (H)	102 (N)	86 (N)	
-6*	Yes				1.92 (N)
1*	Yes	141.6 (H)	102 (N)	86 (N)	
22*	Yes	136.8 (H)	118 (N)	88 (N)	6.08 (N)
37*		133.2 (H)	72 (N)	96 (N)	7.94 (N)
64*	Yes	141.6 (H)	94 (N)	93 (N)	2.32 (N)
73*	Yes	158.4 (H)	91 (N)	95 (N)	
87*	Yes	174 (H)	102 (N)	93 (N)	1.7 (N)
101*	Yes	189 (H)	46 (N)	119 (H)	0.57 (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	Yes	150 (N)	55 (N)	84 (N)	69 (N)
73	Yes	161 (N)	70 (H)	82 (N)	73 (N)
79	Yes	157 (N)	68 (H)	88 (N)	49 (N)
1*	Yes	157 (N)	68 (H)	88 (N)	49 (N)
37*		177 (N)	64 (H)	113 (N)	62 (N)
73*	Yes	172 (N)	70 (H)	103 (N)	50 (N)
87*	Yes	183 (N)	76 (H)	111 (N)	41 (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 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 11）；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、ウクライナからの参加であった。

虫垂炎（Day 3～8）（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 3、Grade 3 の重篤な虫垂炎が発現した。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 8、Grade 3 の本事象は回復した。

その他の関連情報：急性発症した右下腹部痛が認められた。被験者は急性虫垂炎と診断され、同日に虫垂切除術を受けた。被験者は手術後に回復した。

Medical History	
Medical History	Resolution
colitis ulcerative	Ongoing

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
mesalazine	ULCERATIVE COLITIS	ORAL	-123 days	Ongoing
macrogol	PREPARATION FOR COLONOSCOPY	ORAL	-4 days	-4 days
atropine	ANESTHESIA	INTRAVENOUS	3 days	3 days
calcium chloride dihydrate;potassium chloride;sodium chloride	PERFUSION DURING OPERATION	INTRAVENOUS	3 days	3 days
dexamethasone	ANESTHESIA	INTRAVENOUS	3 days	3 days
diphenhydramine hydrochloride	ANESTHESIA	INTRAVENOUS	3 days	3 days
lidocaine	LOCAL ANESTHESIA	SUBCUTANEOUS	3 days	3 days
metoclopramide	ANESTHESIA	INTRAVENOUS	3 days	3 days
sodium chloride	PERFUSION DURING OPERATION	INTRAVENOUS	3 days	3 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
Appendicitis	3	8	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)
-8	13.8 (N)	42 (N)	5 (N)	335 (N)	0.103 (N)	84 (N)
1	13.8 (N)	41 (N)	5 (N)	317 (N)	0.147 (H)	82 (N)
15	13.5 (N)	44 (N)	5 (N)	446 (H)	0.125 (H)	89 (N)
38	13.7 (N)	41 (N)	4.8 (N)	294 (N)	0.134 (H)	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)
-8	7.56 (N)	4.27 (N)	2.9 (N)	0.3 (N)	0.04 (N)	0.05 (N)
1	4.48 (N)	2.91 (N)	1.39 (N)	0.13 (N)	0 (N)	0.04 (N)
15	9.92 (N)	6.72 (N)	2.93 (N)	0.2 (N)	0.04 (N)	0.02 (N)
38	6.42 (N)	4.02 (N)	2.13 (N)	0.19 (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)
-33	Yes	14 (N)	13 (N)	54 (N)	0.4 (N)	0.75 (N)
-22	Yes	15 (N)	15 (N)	43 (N)	0.2 (N)	0.76 (N)
1	Yes	16 (N)	16 (N)	43 (N)	0.4 (N)	0.76 (N)
15	Yes	24 (N)	18 (N)	49 (N)	0.2 (N)	0.64 (N)
38	Yes	14 (N)	15 (N)	47 (N)	0.3 (N)	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)
-33	Yes	102 (N)	59 (N)	96 (N)	5.29 (N)
-22	Yes	100.2 (N)	74 (N)	97 (N)	0.52 (N)
1	Yes	100.2 (N)	66 (N)	99 (N)	0.33 (N)
15	Yes	115.8 (H)	105 (N)	100 (N)	0.9 (N)
38	Yes	112.2 (N)	71 (N)	108 (H)	0.55 (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	252 (H)	87 (H)	134 (H)	108 (N)
1	Yes	217 (N)	85 (H)	125 (N)	62 (N)
15	Yes	258 (H)	80 (H)	149 (H)	194 (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）；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 112*）

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

半月板損傷（Day 71*～126*）（試験治療下の重篤な有害事象）（寛解維持試験）：
Day 71*、Grade 3 の重篤な半月板損傷が発現した。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ありと判断された。Day 126*、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
rhinitis allergic	Ongoing

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
mesalazine	ULCERATIVE COLITIS	ORAL	-63 days	Ongoing
mesalazine	ULCERATIVE COLITIS	ORAL	About -1762 days	About -1398 days
infliximab	ULCERATIVE COLITIS	INTRAVENOUS	About -1032 days	-941 days
adalimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	-906 days	-768 days
azathioprine	ULCERATIVE COLITIS	ORAL	-1341 days	About -424 days
tacrolimus	ULCERATIVE COLITIS	ORAL	-509 days	About -424 days
sodium picosulfate	PRETREATMENT FOR COLONOSCOPY	ORAL	-5 days	-5 days
ascorbic acid;macrogol 3350;potassium chloride;sodium ascorbate;sodium chloride;sodium sulfate	PRETREATMENT FOR COLONOSCOPY	ORAL	-4 days	-4 days
sodium picosulfate	PRETREATMENT FOR COLONOSCOPY	ORAL	73 days	73 days
ascorbic acid;macrogol 3350;potassium chloride;sodium ascorbate;sodium chloride;sodium sulfate	PRETREATMENT FOR COLONOSCOPY	ORAL	74 days	74 days
cefazolin sodium	MENISCUS INJURED	INTRAVENOUS	152 days	152 days
desflurane	MENISCUS INJURED	INTRAVENOUS	152 days	152 days
ephedrine hydrochloride	MENISCUS INJURED	INTRAVENOUS	152 days	152 days
fentanyl citrate	MENISCUS INJURED	INTRAVENOUS	152 days	152 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
hydroxyzine hydrochloride	ALLERGIC REACTION	INTRAVENOUS	152 days	152 days
paracetamol	MENISCUS INJURED	INTRAVENOUS	152 days	152 days
propofol	MENISCUS INJURED	INTRAVENOUS	152 days	152 days
remifentanil hydrochloride	MENISCUS INJURED	INTRAVENOUS	152 days	152 days
rocuronium bromide	MENISCUS INJURED	INTRAVENOUS	152 days	152 days
sevoflurane	MENISCUS INJURED	INTRAVENOUS	152 days	152 days
sugammadex sodium	MENISCUS INJURED	INTRAVENOUS	152 days	152 days
calcium chloride dihydrate;glucose;potassium chloride;sodium acetate;sodium chloride	MENISCUS INJURED	INTRAVENOUS	152 days	153 days
magnesium chloride;maltose;potassium chloride;potassium phosphate monobasic;sodium acetate;sodium chloride	MENISCUS INJURED	INTRAVENOUS	152 days	153 days
loxoprofen sodium dihydrate	MENISCUS INJURED	ORAL	153 days	153 days
rebamipide	MENISCUS INJURED	ORAL	153 days	153 days
betamethasone	ALLERGIC REACTION	TOPICAL	152 days	163 days
hydrocortisone butyrate	ALLERGIC REACTION	TOPICAL	152 days	163 days
clostridium butyricum	ULCERATIVE COLITIS	ORAL	171 days	177 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
Meniscus injury	53	151	1	related	dose not changed	drug interrupted	none
Meniscus injury	71*	126*	3	related	not applicable	not applicable	medication required + other treatment required
Hypersensitivity	72*	72*	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)
-14	15.4 (N)	48 (N)	5.1 (N)	361 (N)	0.142 (H)	95 (N)
1	14.9 (N)	46 (N)	4.9 (N)	275 (N)	0.094 (N)	94 (N)
17	14.1 (N)	44 (N)	4.7 (N)	267 (N)	0.074 (N)	93 (N)
31	15.6 (N)	47 (N)	5.1 (N)	227 (N)	0.063 (N)	91 (N)
45	15.4 (N)	46 (N)	5.1 (N)	226 (N)	0.062 (N)	90 (N)
74	16.3 (N)	50 (N)	5.5 (N)	244 (N)	0.052 (N)	91 (N)
-7*	16.3 (N)	50 (N)	5.5 (N)	244 (N)	0.052 (N)	91 (N)
21*	15.3 (N)	46 (N)	5.1 (N)	257 (N)	0.113 (N)	91 (N)
61*	15.1 (N)	47 (N)	5 (N)	279 (N)	0.096 (N)	93 (N)
98*	13.4 (N)	42 (N)	4.6 (N)	334 (N)	0.074 (N)	91 (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	6.87 (N)	4.66 (N)	1.31 (N)	0.48 (N)	0.1 (N)	0.32 (N)
1	6.28 (N)	4.37 (N)	1.23 (N)	0.38 (N)	0.09 (N)	0.22 (N)
17	5.55 (N)	3.23 (N)	1.7 (N)	0.35 (N)	0.09 (N)	0.17 (N)
31	4.94 (N)	2.57 (N)	1.84 (N)	0.27 (N)	0.09 (N)	0.16 (N)
45	5.04 (N)	2.42 (N)	2.09 (N)	0.31 (N)	0.06 (N)	0.15 (N)
74	4.22 (N)	2.44 (N)	1.27 (N)	0.29 (N)	0.06 (N)	0.16 (N)
-7*	4.22 (N)	2.44 (N)	1.27 (N)	0.29 (N)	0.06 (N)	0.16 (N)
21*	5.52 (N)	3.05 (N)	1.75 (N)	0.37 (N)	0.09 (N)	0.26 (N)
61*	6.22 (N)	3.86 (N)	1.44 (N)	0.34 (N)	0.07 (N)	0.52 (N)
98*	7.97 (N)	5.52 (N)	1.44 (N)	0.55 (N)	0.06 (N)	0.4 (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	18 (N)	16 (N)	42 (N)	0.4 (N)	0.74 (N)
1	Yes	8 (N)	12 (N)	38 (N)	0.8 (N)	0.84 (N)
17	No	7 (N)	12 (N)	32 (N)	0.7 (N)	0.83 (N)
31	No	8 (N)	11 (N)	33 (N)	0.7 (N)	0.85 (N)
45	No	8 (N)	12 (N)	31 (N)	0.5 (N)	0.88 (N)
74	Yes	15 (N)	16 (N)	41 (N)	1.1 (N)	0.89 (N)
-7*	Yes	15 (N)	16 (N)	41 (N)	1.1 (N)	0.89 (N)
21*	No	10 (N)	13 (N)	32 (N)	1.1 (N)	0.85 (N)
61*	No	10 (N)	13 (N)	33 (N)	0.5 (N)	0.94 (N)
98*	No	10 (N)	11 (N)	34 (N)	0.4 (N)	0.75 (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	141.6 (H)	40 (N)	62 (L)	1.68 (N)
1	Yes	123 (N)	60 (N)	74 (N)	0.75 (N)
17	No	126.6 (H)	65 (N)	72 (N)	<0.20 (N)
31	No	123.6 (N)	59 (N)	74 (N)	<0.20 (N)
45	No	120 (N)	64 (N)	91 (N)	<0.20 (N)
74	Yes	120.6 (N)	103 (N)	77 (N)	0.21 (N)
-7*	Yes	120.6 (N)	103 (N)	77 (N)	0.21 (N)
21*	No	129 (H)	69 (N)	60 (L)	<0.20 (N)
61*	No	115.8 (N)	70 (N)	86 (N)	0.38 (N)
98*	No	151.8 (H)	52 (N)	102 (H)	5.91 (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	189 (N)	61 (N)	136 (H)	56 (N)
74	Yes	266 (H)	111 (H)	187 (H)	49 (N)
-7*	Yes	266 (H)	111 (H)	187 (H)	49 (N)

Lipid Panel					
Study Day	Fasting	Total Cholesterol (mg/dL)	HDL Cholesterol (mg/dL)	LDL Cholesterol (mg/dL)	Triglycerides (mg/dL)
98*	No	159 (N)	49 (N)	97 (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 B）

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。

貧血（Day 36～47）（試験治療下の重篤な有害事象）（寛解導入試験）：
Day 36、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 47、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
arthralgia	Ongoing
colitis ulcerative	Ongoing
nausea	-7 days

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
clostridium butyricum	IMPROVEMENT OF INTESTINALENVIRONMENT	ORAL	-1192 days	Ongoing
loxoprofen sodium dihydrate	ARTHRALGIA	ORAL	-1177 days	Ongoing
rebamipide	PREVENTION OF GASTRIC ULCER	ORAL	-1177 days	Ongoing
rabeprazole sodium	PREVENTION OF GASTRIC ULCER	ORAL	-524 days	Ongoing
mesalazine	ULCERATIVE COLITIS	ORAL	-240 days	Ongoing
prednisolone	ULCERATIVE COLITIS	ORAL	-475 days	-469 days
infliximab	ULCERATIVE COLITIS	INTRAVENOUS	-380 days	-338 days
azathioprine	ULCERATIVE COLITIS	ORAL	-366 days	-271 days
tacrolimus	ULCERATIVE COLITIS	ORAL	-274 days	-240 days
lidocaine hydrochloride	ENDOSCOPY PREPARATION	TOPICAL	-23 days	-23 days
ferrous sodium citrate	ANEMIA	ORAL	-16 days	-9 days
lidocaine hydrochloride	ENDOSCOPY PREPARATION	TOPICAL	-6 days	-6 days
glucose	WORSENING OF ANEMIA	INTRAVENOUS	27 days	27 days
saccharated iron oxide	WORSENING OF ANEMIA	INTRAVENOUS	27 days	27 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
glucose	WORSENING OF ANEMIA	INTRAVENOUS	29 days	29 days
saccharated iron oxide	WORSENING OF ANEMIA	INTRAVENOUS	29 days	29 days
glucose	WORSENING OF ANEMIA	INTRAVENOUS	31 days	31 days
saccharated iron oxide	WORSENING OF ANEMIA	INTRAVENOUS	31 days	31 days
glucose	WORSENING OF ANEMIA	INTRAVENOUS	34 days	34 days
saccharated iron oxide	WORSENING OF ANEMIA	INTRAVENOUS	34 days	34 days
calcium chloride dihydrate;glucose;potassium chloride;sodium acetate	WORSENING OF ANEMIA	INTRAVENOUS	36 days	43 days
hydroxocobalamin acetate;pyridoxine hydrochloride;thiamine disulfide	WORSENING OF ANEMIA	INTRAVENOUS	36 days	43 days
sodium chloride	I.V. LINE KEEP	INTRAVENOUS	36 days	44 days
glucose;sodium chloride	WORSENING OF ANEMIA	INTRAVENOUS	36 days	45 days
glucose	WORSENING OF ANEMIA	INTRAVENOUS	36 days	46 days
saccharated iron oxide	WORSENING OF ANEMIA	INTRAVENOUS	36 days	46 days
lidocaine hydrochloride	ENDOSCOPY PREPARATION	TOPICAL	69 days	69 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	13	35	3	not related	dose not changed	not applicable	medication required
Anaemia	36	47	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)
-20	7.8 (L)	28 (L)	4.1 (L)		0.123 (N)	67 (L)
-9	8 (L)	28 (L)	4 (L)	538 (H)		70 (L)
1	8.7 (L)	30 (L)	4.2 (L)	581 (H)	0.131 (H)	71 (L)
13	7.7 (L)	26 (L)	3.8 (L)	467 (H)	0.088 (N)	70 (L)
27	7 (L)	24 (L)	3.4 (L)	471 (H)	0.106 (N)	69 (L)
42	10.2 (L)	36 (L)	4.6 (N)	529 (H)	0.221 (H)	79 (N)
69	11.6 (L)	38 (L)	4.6 (N)	369 (N)	0.088 (N)	82 (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	10.6 (N)	7.02 (N)	2.34 (N)	0.68 (N)	0.07 (N)	0.48 (N)
-9	13.42 (H)	8.94 (H)	2.99 (N)	0.61 (N)	0.08 (N)	0.79 (H)
1	9.04 (N)	5.27 (N)	2.32 (N)	0.34 (N)	0.11 (N)	1 (H)
13	8.71 (N)	4.34 (N)	2.84 (N)	0.28 (N)	0.09 (N)	1.15 (H)
27	7.33 (N)	3.86 (N)	2.34 (N)	0.29 (N)	0.1 (N)	0.74 (H)
42	5.52 (N)	3.24 (N)	1.52 (N)	0.24 (N)	0.09 (N)	0.44 (N)
69	7.62 (N)	4.49 (N)	2.25 (N)	0.32 (N)	0.08 (N)	0.47 (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	No	10 (N)	14 (N)	79 (N)	<0.2 (L)	0.88 (N)
1	Yes	11 (N)	15 (N)	77 (N)	0.2 (N)	0.84 (N)
13	No	12 (N)	15 (N)	71 (N)	<0.2 (L)	0.94 (N)
27	No	12 (N)	15 (N)	69 (N)	<0.2 (L)	0.89 (N)
42	Yes	11 (N)	13 (N)	77 (N)	0.4 (N)	0.84 (N)
69	Yes	13 (N)	13 (N)	68 (N)	0.2 (N)	0.83 (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	No	120 (N)	62 (N)	104 (H)	6.16 (N)
1	Yes	128.4 (H)	60 (N)	91 (N)	2.3 (N)
13	No	114.6 (N)	67 (N)	120 (H)	3.08 (N)
27	No	121.2 (N)	102 (N)	112 (H)	2.73 (N)
42	Yes	121.2 (N)	52 (N)	87 (N)	0.8 (N)
69	Yes	124.8 (N)	164 (N)	94 (N)	1.16 (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)	41 (N)	129 (N)	89 (N)
69	Yes	160 (N)	41 (N)	126 (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 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 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。

嘔吐（Day 71～74）（試験治療下の重篤な有害事象）（寛解導入試験）：
Day 71、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 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**
chronic gastritis	Ongoing
colitis ulcerative	Ongoing
hypercholesterolaemia	Ongoing
hypertension	Ongoing
myocardial infarction	Ongoing

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
atorvastatin calcium	HYPERCHOLESTEROLEMIA	ORAL	-1450 days	Ongoing
clopidogrel bisulfate	THROMBOSIS PREVENTION	ORAL	-1450 days	Ongoing
telmisartan	HYPERTENSION	ORAL	-1450 days	Ongoing
clostridium butyricum	INTESTINAL REGULATION	ORAL	-196 days	Ongoing
probiotics nos	INTESTINAL REGULATION	ORAL	-196 days	Ongoing
rabeprazole sodium	CHRONIC GASTRITIS	ORAL	-196 days	Ongoing
mesalazine	ULCERATIVE COLITIS	ORAL	-195 days	Ongoing
prednisolone	ULCERATIVE COLITIS	ORAL	-131 days	-125 days
azathioprine	ULCERATIVE COLITIS	ORAL	-50 days	-45 days
calcium chloride dihydrate;potassium chloride;sodium acetate trihydrate;sodium chloride	NAUSEA PREVENTION	INTRAVENOUS	-44 days	-43 days
metoclopramide hydrochloride	NAUSEA PREVENTION	ORAL	-44 days	-43 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
sodium picosulfate	PREMEDICATION FOR COLONOSCOPY	ORAL	-7 days	-7 days
ascorbic acid;macrogol 3350;potassium chloride;sodium ascorbate;sodium chloride;sodium sulfate	PREMEDICATION FOR COLONOSCOPY	ORAL	-6 days	-6 days
glucagon	PREMEDICATION FOR COLONOSCOPY	INTRAVENOUS	-6 days	-6 days
lidocaine	PREMEDICATION FOR COLONOSCOPY	RECTAL	-6 days	-6 days
midazolam	PREMEDICATION FOR COLONOSCOPY	INTRAVENOUS	-6 days	-6 days
sodium chloride	PREMEDICATION FOR COLONOSCOPY	INTRAVENOUS	-6 days	-6 days
domperidone	NAUSEA PREVENTION	ORAL	-44 days	60 days
glycerol	PREMEDICATION FOR SIGMOIDOSCOPY	RECTAL	69 days	69 days
indigo carmine	PREMEDICATION FOR SIGMOIDOSCOPY	RECTAL	69 days	69 days
lidocaine	PREMEDICATION FOR SIGMOIDOSCOPY	RECTAL	69 days	69 days
metoclopramide	VOMITING	ORAL	70 days	70 days
lansoprazole	VOMITING	INTRAVENOUS	71 days	71 days
sodium chloride	VOMITING	INTRAVENOUS	71 days	71 days
metoclopramide hydrochloride	VOMITING	INTRAVENOUS	70 days	72 days
paracetamol	VOMITING	INTRAVENOUS	72 days	72 days
glucose;sodium chloride	VOMITING	INTRAVENOUS	70 days	73 days
glucose;magnesium chloride hexahydrate;potassium chloride;potassium phosphate monobasic;sodium acetate trihydrate;sodium chloride	VOMITING	INTRAVENOUS	71 days	73 days
hydroxocobalamin acetate;pyridoxine hydrochloride;thiamine disulfide	VOMITING	INTRAVENOUS	71 days	73 days
panthenol	VOMITING	INTRAVENOUS	71 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
Vomiting	70	71	2	not related	dose not changed	not applicable	medication required
Vomiting	71	74	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)
-21	10.4 (L)	32 (L)	3.6 (L)	550 (H)	0.056 (N)	88 (N)
1	11.2 (L)	34 (L)	3.9 (L)	618 (H)	0.064 (N)	87 (N)
15	10.8 (L)	34 (L)	3.8 (L)	533 (H)	0.074 (N)	90 (N)
29	11.6 (L)	36 (L)	4 (N)	522 (H)	0.074 (N)	90 (N)
41	11.4 (L)	35 (L)	3.9 (L)	477 (H)	0.048 (N)	88 (N)
69	13.2 (N)	40 (N)	4.6 (N)	647 (H)	0.08 (N)	88 (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	7.27 (N)	5.51 (N)	1.3 (N)	0.39 (N)	0.05 (N)	0.03 (N)
1	7.39 (N)	5.49 (N)	1.42 (N)	0.43 (N)	0.04 (N)	0.02 (N)
15	6.45 (N)	4.19 (N)	1.79 (N)	0.39 (N)	0.05 (N)	0.03 (N)
29	6.76 (N)	4.86 (N)	1.48 (N)	0.34 (N)	0.05 (N)	0.03 (N)
41	5.73 (N)	3.69 (N)	1.65 (N)	0.33 (N)	0.03 (N)	0.02 (N)
69	9.9 (N)	8.17 (H)	1.29 (N)	0.33 (N)	0.07 (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)
-21	No	7 (N)	11 (N)	76 (N)	0.2 (N)	0.67 (N)
1	Yes	7 (N)	11 (N)	79 (N)	0.3 (N)	0.75 (N)
15	Yes	8 (N)	18 (N)	78 (N)	<0.2 (L)	0.71 (N)
29	Yes	6 (N)	12 (N)	83 (N)	<0.2 (L)	0.76 (N)
41	No	7 (N)	11 (N)	76 (N)	<0.2 (L)	0.74 (N)
69	Yes	9 (N)	13 (N)	82 (N)	0.4 (N)	0.9 (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	97.8 (N)	100 (N)	97 (N)	14.1 (H)
1	Yes	82.8 (L)	69 (N)	99 (N)	19.9 (H)
15	Yes	88.8 (N)	491 (H)	103 (H)	8.31 (N)
29	Yes	84 (L)	134 (N)	97 (N)	5.3 (N)
41	No	87 (N)	142 (N)	101 (H)	2.83 (N)
69	Yes	69 (L)	111 (N)	91 (N)	5.7 (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	Yes	119 (L)	40 (N)	77 (N)	65 (N)
69	Yes	126 (L)	47 (N)	75 (N)	60 (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－有害事象により投与中止（Day 221*）

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、米国からの参加であった。

帯状疱疹（Day 35～98）（試験治療下の注目すべき有害事象［TE-AEI］）（寛解導入試験）：
Day 35、Grade 1 の非重篤な帯状疱疹が発現した。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 98、Grade 1 の本事象は回復した。

麦粒腫（Day 204*～211*）（TE-AEI）（寛解維持試験）：
Day 204*、Grade 2 の非重篤な麦粒腫が発現した。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 2 の本事象は回復した。

虫垂炎（Day 214*～215*）（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 214*、Grade 3 の重篤な虫垂炎が発現した。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 215*、Grade 3 の本事象は回復した。

その他の関連情報：左側 T10 皮膚分節に 2 つの一連の病変が認められ、被験者は帯状疱疹感染と診断された。全身性の症状は認められなかった。治療薬として、Valtrex（バラシクロビル）が 2 週間投与された。
*寛解維持試験における study day

Medical History	
Medical History	**Resolution**
arthralgia	Ongoing
arthralgia	Ongoing
arthralgia	Ongoing
arthralgia	Ongoing
asthma exercise induced	Ongoing
asthma exercise induced	Ongoing
back pain	Ongoing
back pain	Ongoing
colitis ulcerative	Ongoing
colitis ulcerative	Ongoing
migraine	Ongoing
migraine	Ongoing
pain in extremity	Ongoing
pain in extremity	Ongoing
pain in extremity	Ongoing
pain in extremity	Ongoing
malignant melanoma	About -2753 days
gynaecomastia	About -2447 days
gynaecomastia	About -2447 days
malignant melanoma	About -2447 days
ulna fracture	About -2266 days

Medical History	
Medical History	**Resolution**
ulna fracture	About -2266 days
haemangioma	About -2235 days
haemangioma	About -2235 days
eye injury	About -1716 days
eye injury	About -1716 days
acne	About -1351 days
acne	About -1351 days
aphthous ulcer	About -743 days
aphthous ulcer	About -743 days
molluscum contagiosum	About -713 days
molluscum contagiosum	About -713 days
viral upper respiratory tract infection	About -316 days
dermatitis contact	-67 days
dermatitis contact	-67 days
salmonellosis	-56 days
leukocytosis	304 days

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
salbutamol	EXERCISE INDUCED ASTHMA	RESPIRATORY (INHALATION)	About -2081 days	Ongoing
ascorbic acid	DIETARY SUPPLEMENT	ORAL	About -1350 days	Ongoing
paracetamol	HEADACHE (MIGRAINE), STYE LEFT EYE, ABDOMINAL PAIN	ORAL	About -1350 days	Ongoing
mesalazine	ULCERATIVE COLITIS	ORAL	About -164 days	Ongoing
ciprofloxacin	SALMONELLOSIS	ORAL	-68 days	Ongoing
prednisone	ULCERATIVE COLITIS	ORAL	About -2081 days	About -1716 days
azathioprine	ULCERATIVE COLITIS	ORAL	About -2021 days	About -1716 days
budesonide	ULCERATIVE COLITIS	ORAL	-1537 days	About -1382 days
mesalazine	ULCERATIVE COLITIS	RECTAL	About -1411 days	About -1382 days
mesalazine	ULCERATIVE COLITIS	ORAL	About -2021 days	About -1351 days
infliximab	ULCERATIVE COLITIS	INTRAVENOUS	About -1534 days	About -1200 days
budesonide	ULCERATIVE COLITIS	ORAL	About -1230 days	About -1170 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
azathioprine	ULCERATIVE COLITIS	ORAL	About -1230 days	About -1139 days
adalimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	-1168 days	About -986 days
mesalazine	ULCERATIVE COLITIS	RECTAL	About -834 days	About -774 days
adalimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	-831 days	About -255 days
mercaptopurine	ULCERATIVE COLITIS	ORAL	-706 days	About -255 days
ciprofloxacin	SALMONELLOSIS	INTRAVENOUS	-70 days	-70 days
melatonin	INSOMNIA PROPHYLAXIS	ORAL	-70 days	-70 days
metronidazole	SALMONELLOSIS	INTRAVENOUS	-70 days	-70 days
morphine	SALMONELLOSIS	INTRAVENOUS	-70 days	-70 days
prochlorperazine	NAUSEA PROPHYLAXIS	INTRAVENOUS	-70 days	-70 days
metronidazole	SALMONELLOSIS	ORAL	-70 days	-69 days
ondansetron hydrochloride	NAUSEA PROPHYLAXIS	INTRAVENOUS	-70 days	-69 days
paracetamol	SALMONELLOSIS	ORAL	-70 days	-69 days
diphenhydramine hydrochloride	INSOMNIA PROPHYLAXIS	ORAL	-69 days	-69 days
heparin	PROPHYLAXIS DEEP VEIN THROMBOSIS	SUBCUTANEOUS	-69 days	-69 days
oxycodone	SALMONELLOSIS	ORAL	-69 days	-68 days
macrogol 3350	COLONOSCOPY PREP	ORAL	-15 days	-15 days
propofol	COLONOSCOPY SEDATION	INTRAVENOUS	-14 days	-14 days
valaciclovir hydrochloride	HERPES ZOSTER	ORAL	43 days	54 days
macrogol	COLONOSCOPY PREP	ORAL	70 days	70 days
propofol	COLONOSCOPY SEDATION	INTRAVENOUS	71 days	71 days
iohexol	CT SCAN CONTRAST DYE	INTRAVENOUS	137 days	137 days
bismuth subsalicylate	ABDOMINAL PAIN	ORAL	291 days	291 days
iohexol	CT IMAGING	INTRAVENOUS	291 days	291 days
calcium chloride;potassium chloride;sodium lactate	HYDRATION	INTRAVENOUS	291 days	292 days
ondansetron	ACUTE APPENDICITIS	INTRAVENOUS	291 days	292 days
paracetamol	ACUTE APPENDICITIS	ORAL	291 days	292 days
cefazolin	APPENDICITIS	INTRAVENOUS	292 days	292 days
famotidine	PROPHYLAXIS NAUSEA, PROPHYLAXIS VOMITING	INTRAVENOUS	292 days	292 days
fentanyl	APPENDECTOMY ANESTHESIA	INTRAVENOUS	292 days	292 days
heparin	PROPHYLAXIS BLOOD CLOT	SUBCUTANEOUS	292 days	292 days
lidocaine	APPENDECTOMY ANESTHESIA	INTRAVENOUS	292 days	292 days
metronidazole	APPENDICITIS	INTRAVENOUS	292 days	292 days
midazolam hydrochloride	APPENDECTOMY ANESTHESIA	INTRAVENOUS	292 days	292 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
propofol	APPENDECTOMY ANESTHESIA	INTRAVENOUS	292 days	292 days
rocuronium bromide	APPENDECTOMY ANESTHESIA	INTRAVENOUS	292 days	292 days
suxamethonium	APPENDECTOMY ANESTHESIA	INTRAVENOUS	292 days	292 days
oxycodone	ACUTE APPENDICITIS	ORAL	292 days	295 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	-71	-56	2	not related	not applicable	not applicable	none
Salmonellosis	-69	-56	2	not related	not applicable	not applicable	medication required
Herpes zoster	35	98	1	not related	dose not changed	not applicable	medication required
Large intestine polyp	71	71	1	not related	dose not changed	not applicable	none
Abdominal pain	7*	8*	2	not related	not applicable	dose not changed	none
Abdominal pain	58*	60*	2	not related	not applicable	dose not changed	other treatment required
Alanine aminotransferase increased	63*	105*	3	not related	not applicable	dose not changed	none
Hordeolum	204*	211*	2	not related	not applicable	dose not changed	medication required
Appendicitis	214*	215*	3	not related	not applicable	drug withdrawn	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)
-84	14.8 (N)	44 (N)	5.2 (N)	271 (N)	0.087 (N)	85 (N)
-29	14.2 (N)	42 (N)	5 (N)	257 (N)	0.084 (N)	85 (N)
1	14.7 (N)	42 (N)	5 (N)	269 (N)	0.113 (N)	84 (N)
15	13.7 (N)	43 (N)	5.1 (N)	318 (N)	0.08 (N)	85 (N)
29	15 (N)	43 (N)	5.3 (N)	319 (N)	0.095 (N)	81 (N)
43	14.6 (N)	45 (N)	5.2 (N)	261 (N)	0.061 (N)	87 (N)
70	14.7 (N)	44 (N)	5.2 (N)	288 (N)	0.084 (N)	84 (N)
-8*	14.7 (N)	44 (N)	5.2 (N)	288 (N)	0.084 (N)	84 (N)
21*	14.7 (N)	42 (N)	5 (N)	311 (N)	0.097 (N)	84 (N)
63*	13.7 (N)	40 (N)	4.7 (N)	288 (N)	0.092 (N)	86 (N)
66*	15 (N)	42 (N)	5 (N)	275 (N)		84 (N)
105*	15.5 (N)	47 (N)	5.5 (N)	329 (N)	0.079 (N)	86 (N)
162*	14.5 (N)	44 (N)	5.1 (N)	229 (N)	0.099 (N)	86 (N)
224*	14.4 (N)	45 (N)	5 (N)	254 (N)	0.07 (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)
-84	5.83 (N)	3.83 (N)	1.38 (N)	0.45 (N)	0.06 (N)	0.1 (N)
-29	4.62 (N)	2.59 (N)	1.52 (N)	0.4 (N)	0.06 (N)	0.06 (N)
1	5.94 (N)	3.75 (N)	1.53 (N)	0.41 (N)	0.05 (N)	0.19 (N)
15	4.42 (N)	2.54 (N)	1.47 (N)	0.3 (N)	0.04 (N)	0.07 (N)
29	5.36 (N)	2.77 (N)	1.97 (N)	0.39 (N)	0.08 (N)	0.14 (N)
43	4.48 (N)	2.54 (N)	1.5 (N)	0.34 (N)	0.04 (N)	0.06 (N)
70	4.79 (N)	2.74 (N)	1.55 (N)	0.37 (N)	0.05 (N)	0.07 (N)
-8*	4.79 (N)	2.74 (N)	1.55 (N)	0.37 (N)	0.05 (N)	0.07 (N)
21*	5.87 (N)	3.88 (N)	1.53 (N)	0.36 (N)	0.02 (N)	0.08 (N)
63*	3.84 (N)	1.94 (L)	1.43 (N)	0.33 (N)	0.02 (N)	0.12 (N)
66*	4.7 (N)	2.19 (N)	1.99 (N)	0.36 (N)	0.06 (N)	0.11 (N)
105*	4.62 (N)	2.56 (N)	1.58 (N)	0.32 (N)	0.06 (N)	0.11 (N)
162*	4.31 (N)	2.54 (N)	1.26 (N)	0.36 (N)	0.05 (N)	0.1 (N)
224*	6.72 (N)	4.21 (N)	1.65 (N)	0.69 (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)
-84	Yes	49 (H)	31 (N)	98 (N)	0.7 (N)	0.92 (N)
-29	No	67 (H)	41 (H)	100 (N)	0.4 (N)	0.86 (N)
1	Yes	61 (H)	32 (N)	137 (H)	0.5 (N)	0.87 (N)
15	Yes	62 (H)	36 (N)	106 (N)	0.8 (N)	0.93 (N)
29	No	35 (N)	22 (N)	93 (N)	0.6 (N)	0.93 (N)
43	No	59 (H)	30 (N)	84 (N)	0.7 (N)	0.84 (N)
70	No	57 (H)	32 (N)	85 (N)	0.7 (N)	0.88 (N)
-8*	No	57 (H)	32 (N)	85 (N)	0.7 (N)	0.88 (N)
21*	No	65 (H)	37 (H)	80 (N)	0.8 (N)	0.91 (N)
63*	Yes	381 (H)	130 (H)	163 (H)	0.6 (N)	0.84 (N)
66*	No	197 (H)	58 (H)	131 (H)	0.7 (N)	1.03 (N)
105*	Yes	36 (N)	25 (N)	87 (N)	1 (N)	0.92 (N)
162*	Yes	44 (H)	33 (N)	82 (N)	0.9 (N)	0.95 (N)
224*	No	59 (H)	32 (N)	80 (N)	0.5 (N)	0.83 (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)
-84	Yes	125 (N)	93 (N)	86 (N)	2.94 (N)
-29	No	131.3 (H)	108 (N)	86 (N)	5.86 (N)
1	Yes	130.7 (H)	63 (N)	78 (N)	13.3 (H)
15	Yes	122.8 (N)	89 (N)	94 (N)	2.32 (N)
29	No	123 (N)	87 (N)	70 (N)	1.03 (N)
43	No	137.7 (H)	73 (N)	70 (N)	0.87 (N)
70	No	133.1 (H)	202 (N)	78 (N)	0.98 (N)
-8*	No	133.1 (H)	202 (N)	78 (N)	0.98 (N)
21*	No	131 (H)	160 (N)	83 (N)	1.81 (N)
63*	Yes	144.8 (H)	100 (N)	77 (N)	12.7 (H)
66*	No	118.1 (N)	126 (N)	84 (N)	
105*	Yes	131 (H)	136 (N)	86 (N)	0.86 (N)
162*	Yes	126 (H)	152 (N)	90 (N)	1.07 (N)
224*	No	143.8 (H)	69 (N)	81 (N)	2.61 (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)
-84	Yes	176 (N)	50 (N)	106 (N)	107 (N)
-29	No	162 (N)	47 (N)	97 (N)	74 (N)
1	Yes	168 (N)	47 (N)	94 (N)	142 (N)
15	Yes	169 (N)	57 (N)	96 (N)	91 (N)
29	No	173 (N)	52 (N)	97 (N)	166 (N)
43	No	170 (N)	55 (N)	93 (N)	117 (N)
70	No	168 (N)	60 (N)	86 (N)	127 (N)
-8*	No	168 (N)	60 (N)	86 (N)	127 (N)
21*	No	174 (N)	60 (N)	100 (N)	98 (N)
63*	Yes	162 (N)	57 (N)	81 (N)	123 (N)
66*	No	168 (N)	52 (N)	105 (N)	80 (N)
105*	Yes	182 (N)	64 (H)	98 (N)	111 (N)
162*	Yes	173 (N)	58 (N)	100 (N)	113 (N)
224*	No	191 (N)	43 (N)	94 (N)	351 (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）；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 119*）

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、オーストリアからの参加であった。

上咽頭炎（Day 77～86）（試験治療下の注目すべき有害事象）（寛解導入試験）：
Day 77、Grade 1 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 86、Grade 1 の本事象は回復した。

発熱（Day 101*～106*）（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 101*、Grade 2 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 106*、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
hypertension	Ongoing

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
mesalazine	ULCERATIVE COLITIS	ORAL	-386 days	Ongoing
metamizole	HIP PAIN	ORAL	93 days	Ongoing
pantoprazole	HIP PAIN	ORAL	93 days	Ongoing
budesonide	ULCERATIVE COLITIS	RECTAL	About -705 days	About -371 days
budesonide	ULCERATIVE COLITIS	ORAL	About -584 days	About -371 days
azathioprine	ULCERATIVE COLITIS	ORAL	-386 days	About -309 days
ciprofloxacin	CHOLANGITIS	ORAL	About -308 days	About -281 days
vancomycin	CLOSTRIDIUM DIFFICILE	ORAL	-302 days	About -250 days
golimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	-246 days	-98 days
golimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	About -249 days	About -67 days
ascorbic acid;macrogol 3350;potassium chloride;sodium ascorbate;sodium chloride;sodium sulfate	BOWEL PREPARATION	ORAL	-8 days	-8 days
midazolam	ENDOSCOPY SEDATION	INTRAVENOUS	-7 days	-7 days
propofol	ENDOSCOPY SEDATION	INTRAVENOUS	-7 days	-7 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
lisinopril	ART. HYPERTENSION	ORAL	About -1070 days	About 57 days
paracetamol	COMMON COLD	ORAL	77 days	86 days
ascorbic acid;macrogol 3350;potassium chloride;sodium ascorbate;sodium chloride;sodium sulfate	BOWEL PREPARATION	ORAL	89 days	89 days
midazolam	ENDOSCOPY SEDATION	INTRAVENOUS	90 days	90 days
propofol	ENDOSCOPY SEDATION	INTRAVENOUS	90 days	90 days
methylprednisolone	ULCERATIVE COLITIS	ORAL	-62 days	98 days
methylprednisolone	ULCERATIVE COLITIS	ORAL	99 days	119 days
cefalexin	BURSITIS ON ELBOW	ORAL	156 days	160 days
sodium chloride	HYROVOLEMIA	INTRAVENOUS	199 days	201 days
enoxaparin	THROMBOSIS PROPHYLAXE	SUBCUTANEOUS	199 days	204 days
piperacillin sodium;tazobactam sodium	FEVER	INTRAVENOUS	199 days	211 days
levofloxacin	INFECTION WITH HIGH FEVER	ORAL	203 days	211 days
metronidazole	FEVER	ORAL	200 days	213 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
Nervous system disorder	30	58	1	not related	dose not changed	not applicable	none
Nasopharyngitis	77	86	1	not related	dose not changed	not applicable	medication required
Arthralgia	93	Ongoing	1	not related	dose not changed	dose not changed	medication required
Bursitis	About 49*	62*	1	not related	not applicable	dose not changed	medication required
Pyrexia	101*	106*	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)
-28	14 (N)	41 (N)	4.5 (N)	226 (N)	0.115 (N)	91 (N)
1	14.1 (N)	41 (N)	4.7 (N)	164 (N)	0.113 (N)	88 (N)
14	14.4 (N)	45 (N)	5 (N)	207 (N)	0.122 (N)	90 (N)
28	15 (N)	44 (N)	5 (N)	176 (N)	0.081 (N)	89 (N)
44	14.6 (N)	42 (N)	4.7 (N)	178 (N)	0.101 (N)	89 (N)
90	13.8 (N)	42 (N)	4.5 (N)	177 (N)	0.081 (N)	92 (N)
-9*	13.8 (N)	42 (N)	4.5 (N)	177 (N)	0.081 (N)	92 (N)
21*	14 (N)	43 (N)	4.6 (N)	219 (N)	0.079 (N)	94 (N)
62*	13.9 (N)	42 (N)	4.4 (N)	251 (N)	0.061 (N)	97 (N)
119*	13.6 (N)	41 (N)	4.5 (N)	285 (N)	0.05 (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)
-28	8.84 (N)	7.07 (N)	0.93 (N)	0.66 (N)	0.09 (N)	0.09 (N)
1	7.76 (N)	5.79 (N)	1.14 (N)	0.55 (N)	0.14 (N)	0.14 (N)
14	10.49 (N)	9.05 (H)	0.98 (N)	0.41 (N)	0.01 (N)	0.04 (N)
28	9.82 (N)	8.32 (H)	0.88 (N)	0.57 (N)	0.01 (N)	0.03 (N)
44	8.03 (N)	6.66 (N)	0.69 (L)	0.46 (N)	0.11 (N)	0.11 (N)
90	7.01 (N)	5.76 (N)	0.47 (L)	0.59 (N)	0.12 (N)	0.08 (N)
-9*	7.01 (N)	5.76 (N)	0.47 (L)	0.59 (N)	0.12 (N)	0.08 (N)
21*	6.42 (N)	5.31 (N)	0.7 (L)	0.37 (N)	0.02 (N)	0.03 (N)
62*	6.9 (N)	4.63 (N)	1.41 (N)	0.72 (N)	0.04 (N)	0.11 (N)
119*	5.56 (N)	3.22 (N)	1.59 (N)	0.65 (N)	0.04 (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)
-28	No	14 (N)	10 (L)	55 (N)	0.8 (N)	0.74 (N)
1	Yes	17 (N)	11 (N)	56 (N)	0.7 (N)	0.69 (N)
14	No	19 (N)	13 (N)	52 (N)	1.4 (H)	0.86 (N)
28	No	18 (N)	12 (N)	49 (N)	1.2 (N)	0.75 (N)
44	No	21 (N)	14 (N)	44 (N)	1.5 (H)	0.7 (N)
90	Yes	17 (N)	11 (N)	49 (N)	1.2 (N)	0.72 (N)
-9*	Yes	17 (N)	11 (N)	49 (N)	1.2 (N)	0.72 (N)
21*	No	13 (N)	10 (L)	55 (N)	0.7 (N)	0.76 (N)
62*	No	8 (N)	11 (N)	81 (N)	1.1 (N)	1.05 (N)
119*	No	7 (N)	11 (N)	57 (N)	0.8 (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)
-28	No	152.4 (H)	37 (L)	95 (N)	4.79 (N)
1	Yes	159 (H)	35 (L)	83 (N)	4.68 (N)
14	No	130.2 (H)	61 (N)	95 (N)	1.03 (N)
28	No	150 (H)	38 (L)	83 (N)	1.04 (N)
44	No	162.6 (H)	95 (N)	96 (N)	7.65 (N)
90	Yes	156 (H)	36 (L)	77 (N)	1.68 (N)
-9*	Yes	156 (H)	36 (L)	77 (N)	1.68 (N)
21*	No	149.4 (H)	63 (N)	95 (N)	5.42 (N)
62*	No	105.6 (N)	75 (N)	89 (N)	43.4 (H)
119*	No	129.6 (H)	59 (N)	85 (N)	2.94 (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)
-28	No	185 (N)	75 (H)	86 (N)	112 (N)
1	Yes	169 (L)	70 (N)	85 (N)	90 (N)
14	No	190 (N)	87 (H)	103 (N)	62 (N)
28	No	189 (N)	92 (H)	92 (N)	91 (N)

Lipid Panel					
Study Day	Fasting	Total Cholesterol (mg/dL)	HDL Cholesterol (mg/dL)	LDL Cholesterol (mg/dL)	Triglycerides (mg/dL)
44	No	172 (L)	79 (H)	92 (N)	62 (N)
90	Yes	178 (N)	56 (N)	103 (N)	136 (N)
-9*	Yes	178 (N)	56 (N)	103 (N)	136 (N)
119*	No	128 (L)	43 (N)	76 (N)	78 (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 10）；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、カナダからの参加であった。

ウイルス性胃腸炎（Day 2～21）（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、試験治療下の注目すべき有害事象）（寛解導入試験）：
Day 2、Grade 3 の重篤なウイルス性胃腸炎が発現した。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 21、Grade 3 の本事象は回復した。

潰瘍性大腸炎（Day 32～43）（TE-SAE）（寛解導入試験）：
Day 32、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。Day 43、Grade 3 の本事象は回復した。

その他の関連情報：被験者は、悪心による脱水のため入院した。血液培養検査の結果は陰性であった。被験者はウイルス性胃腸炎と診断され、治療として静脈内輸液が行われた。被験者は症状が回復した後に退院した。

Medical History	
Medical History	**Resolution**
arthritis	Ongoing
colitis ulcerative	Ongoing
headache	Ongoing
nausea	Ongoing
sinusitis	Ongoing
female sterilisation	-3805 days
weight decreased	-1 day

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
paracetamol	OCCASIONAL HEADACHES	ORAL	About -1763 days	Ongoing
iron	SUPPLEMENT	ORAL	-18 days	Ongoing
metoclopramide	NAUSEA	ORAL	-6 days	Ongoing
omeprazole	PROPHYLAXIS AGAINST GI BLEED	ORAL	12 days	Ongoing
vitamin b12 nos	SUPPLEMENT	ORAL	12 days	Ongoing
zopiclone	SLEEP AIDE	ORAL	15 days	Ongoing
potassium chloride	HYPOKALEMIA SECONDARY TO VIRAL GASTROENTERITIS	ORAL	16 days	Ongoing
tofacitinib	ULCERATIVE COLITIS	ORAL	17 days	Ongoing
cinchocaine hydrochloride;esculoside;framycetin sulfate;hydrocortisone	PAIN WITH STOOLS	RECTAL	18 days	Ongoing

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
lidocaine	PAIN WITH STOOLS	TOPICAL	19 days	Ongoing
paracetamol	ARTHRITIS	ORAL	32 days	Ongoing
hydrocortisone sodium succinate	ULCERATIVE COLITIS	INTRAVENOUS	36 days	Ongoing
mesalazine	ULCERATIVE COLITIS	ORAL	About -1582 days	About -1399 days
adalimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	-1285 days	About -1218 days
mesalazine	ULCERATIVE COLITIS	ORAL	About -1429 days	-1106 days
adalimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	About -1247 days	-1069 days
adalimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	-1069 days	About -943 days
vedolizumab	ULCERATIVE COLITIS	INTRAVENOUS	About -973 days	About -760 days
prednisone	ULCERATIVE COLITIS	ORAL	About -1582 days	About -272 days
mesalazine	ULCERATIVE COLITIS	RECTAL	-300 days	-198 days
prednisone	ULCERATIVE COLITIS	ORAL	About -302 days	-147 days
vedolizumab	ULCERATIVE COLITIS	INTRAVENOUS	About -789 days	-117 days
azathioprine	ULCERATIVE COLITIS	ORAL	About -1429 days	-97 days
sodium chloride	DEHYDRATION	INTRAVENOUS DRIP	-12 days	-11 days
vitamins nos	SUPPLEMENT	ORAL	-18 days	2 days
fluticasone propionate	SINUSITIS	RESPIRATORY (INHALATION)	-4 days	2 days
hydrocortisone sodium succinate	ULCERATIVE COLITIS	INTRAVENOUS	15 days	16 days
potassium chloride	HYPOKALEMIA SECONDARY TO VIRAL GASTROENTERITIS	INTRAVENOUS	2 days	20 days
sodium chloride	VIRAL GASTROENTERITIS	INTRAVENOUS DRIP	2 days	20 days
dimenhydrinate	NAUSEA	INTRAVENOUS	2 days	21 days
hydrocortisone sodium succinate	ULCERATIVE COLITIS	INTRAVENOUS	17 days	27 days
hydrocortisone sodium succinate	ULCERATIVE COLITIS	INTRAVENOUS	28 days	33 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
hydrocortisone sodium succinate	ULCERATIVE COLITIS	INTRAVENOUS	33 days	35 days
sodium chloride	UC FLARE	INTRAVENOUS BOLUS	33 days	36 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
Dehydration	-12	-11	3	not related	not applicable	not applicable	other treatment required
Gastroenteritis viral	2	21	3	not related	drug withdrawn	not applicable	medication required + other treatment required + permanent study discontinuation
Hypokalaemia	2	Ongoing	2	not related	not applicable	not applicable	medication required
Colitis ulcerative	32	43	3	not related	not applicable	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)
-21	12.8 (N)	38 (N)	4.5 (N)	441 (H)	0.078 (N)	84 (N)
1	11.7 (N)	35 (N)	4.4 (N)	809 (H)	0.056 (N)	80 (N)
31	10.4 (L)	34 (N)	3.8 (L)	502 (H)	0.13 (H)	89 (N)
38	11.7 (N)	37 (N)	4.1 (N)	426 (H)	0.106 (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	11.86 (H)	9.27 (H)	1.39 (N)	0.47 (N)	0.07 (N)	0.66 (H)
1	14.89 (H)	12.78 (H)	1.25 (N)	0.74 (N)	0.02 (N)	0.1 (N)
31	18.76 (H)	17.44 (H)	0.83 (L)	0.36 (N)	0.02 (N)	0.12 (N)
38	13.19 (H)	11.98 (H)	0.92 (N)	0.25 (N)	0.02 (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)
-21	No	9 (N)	13 (N)	93 (N)	0.3 (N)	1.2 (H)
-8	Yes	30 (N)	23 (N)	78 (N)	0.2 (N)	1.03 (N)
1	Yes	20 (N)	12 (N)	104 (N)	0.3 (N)	1.83 (H)
31	Yes	15 (N)	10 (N)	63 (N)	0.2 (N)	0.7 (N)
38	No	19 (N)	14 (N)	69 (N)	0.2 (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)
-21	No	84.6 (N)	46 (N)	92 (N)	67.2 (H)
-8	Yes	98.6 (N)	31 (N)	90 (N)	
1	Yes	50.4 (L)	25 (L)	104 (H)	239 (H)
31	Yes	139.7 (H)	30 (N)	88 (N)	4.63 (N)
38	No	117.8 (H)	29 (N)	112 (H)	8.07 (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)
-8	Yes	115 (L)	39 (N)	47 (N)	130 (N)
1	Yes	147 (N)	51 (N)	62 (N)	170 (N)
31	Yes	234 (N)	90 (H)	138 (H)	116 (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）；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 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、アイルランドからの参加であった。

喀血（Day 40～69）（試験治療下の重篤な有害事象）（寛解導入試験）：
Day 40、Grade 3 の重篤な喀血が発現した。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 69、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
emphysema	Ongoing
menopause	Ongoing
stasis dermatitis	Ongoing
vaginal haemorrhage	Ongoing
vitamin d decreased	Ongoing

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
sulfasalazine	ULCERATIVE COLITIS	ORAL	-1345 days	Ongoing
vitamin d nos	VITAMIN D DEFIENCY	ORAL	About -473 days	Ongoing
estradiol	HORMONE REPLACMENT TREATMNET	VAGINAL	54 days	Ongoing
tramadol	RIGHT ARM PAIN	ORAL	182 days	Ongoing
dydrogesterone;estradiol	MENOPAUSE	ORAL	245 days	Ongoing
diflucortolone valerate;isoconazole nitrate	RED SPOTS FACE	TOPICAL	260 days	Ongoing
quinine sulfate	LEG CRAMPS	ORAL	303 days	Ongoing
fluorouracil	ACTINIC KERATOSIS	TOPICAL	365 days	Ongoing
hydrocortisone;miconazole nitrate	INFLAMMATION UDER R BREAST	TOPICAL	365 days	Ongoing
salicylic acid	WARTS HANDS	TOPICAL	365 days	Ongoing
budesonide;formoterol fumarate	ASTHMA	RESPIRATORY (INHALATION)	384 days	Ongoing
azathioprine	ULCERATIVE COLITIS	ORAL	-7099 days	-491 days
adalimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	-1471 days	About -109 days
budesonide	ULCERATIVE COLITIS	ORAL	-227 days	About -109 days
prednisone	ULCERATIVE COLITIS	ORAL	-148 days	About -78 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
calcipotriol	STASIS DERMATITIS	TOPICAL	-21 days	-13 days
midazolam	SEDATION FOR ENDOSCOPY	INTRAVENOUS	-2 days	-2 days
enoxaparin sodium	POSSIBLE PE	SUBCUTANEOUS	43 days	44 days
dydrogesterone;estradiol	MENAPAUSE	ORAL	About -1204 days	54 days
midazolam	SEDATION FOR ENDOSCOPY PROCEDURE	INTRAVENOUS	69 days	69 days
tiotropium bromide	EMPHYSEAMA	RESPIRATORY (INHALATION)	44 days	97 days
nitrogen, liquid	ACTINIC KERATOSIS RIGHT HAND	TOPICAL	134 days	134 days
hydrocortisone	DRY EYELIDS	TOPICAL	134 days	148 days
caffeine;codeine phosphate hemihydrate;paracetamol	RIGHT ARM PAIN	ORAL	170 days	180 days
diclofenac	RIGHT ARM PAIN	ORAL	179 days	182 days
midazolam	SEDATION FOR ENDOSCOPY	INTRAVENOUS	188 days	188 days
mometasone furoate	?PSORIATIC PROCESS LEGS	TOPICAL	260 days	275 days
ferrous fumarate	LOW FERRITIN	ORAL	247 days	289 days
olodaterol hydrochloride;tiotropium bromide monohydrate	EMPHYSEMA	RESPIRATORY (INHALATION)	97 days	384 days
midazolam	SEDATION ENDOSCOPY	INTRAVENOUS	405 days	405 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
Dyspnoea	9	Ongoing	2	not related	dose not changed	dose not changed	none
Arthralgia	24	Ongoing	2	not related	dose not changed	not applicable	none
Haemoptysis	40	69	3	not related	dose not changed	not applicable	other treatment required
Eyelid skin dryness	63	147	1	not related	not applicable	dose not changed	medication required
Actinic keratosis	59*	Ongoing	2	not related	not applicable	dose not changed	other treatment required
Pain in extremity	94*	330*	2	not related	not applicable	dose not changed	medication required + other treatment required
Chronic obstructive pulmonary disease	107*	Ongoing	2	not related	not applicable	dose not changed	none
Serum ferritin decreased	171*	214*	1	not related	not applicable	dose not changed	medication required
Psoriasis	185*	Ongoing	1	not 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
Rash macular	185*	Ongoing	1	not related	not applicable	dose not changed	medication required
Muscle spasms	228*	Ongoing	1	not related	not applicable	dose not changed	medication required
Osteoarthritis	228*	Ongoing	1	not related	not applicable	dose not changed	none
Hyperkeratosis	290*	Ongoing	1	related	not applicable	dose not changed	none
Inflammation	290*	Ongoing	1	not related	not applicable	dose not changed	medication required
Skin papilloma	290*	Ongoing	1	not related	not applicable	dose not changed	medication required
Skin papilloma	290*	Ongoing	1	not related	not applicable	dose not changed	medication required
Asthma	309*	Ongoing	1	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)
-16	13.6 (N)	41 (N)	4.3 (N)	284 (N)	0.089 (N)	94 (N)
1	13.9 (N)	42 (N)	4.4 (N)	298 (N)	0.094 (N)	94 (N)
29	13.6 (N)	41 (N)	4.3 (N)	303 (N)	0.103 (N)	96 (N)
43	12.9 (N)	40 (N)	4.2 (N)	291 (N)	0.115 (N)	96 (N)
-33*	12.9 (N)	40 (N)	4.2 (N)	291 (N)	0.115 (N)	96 (N)
22*	12.2 (N)	39 (N)	4.3 (N)	312 (N)	0.091 (N)	90 (N)
59*	12.8 (N)	42 (N)	4.7 (N)	338 (N)	0.075 (N)	89 (N)
107*	12.2 (N)	38 (N)	4.5 (N)	263 (N)	0.064 (N)	85 (N)
163*	12.5 (N)	39 (N)	4.6 (N)	306 (N)	0.072 (N)	85 (N)
281*	14.2 (N)	41 (N)	4.5 (N)	255 (N)	0.05 (N)	92 (N)
330*	14.6 (N)	44 (N)	4.6 (N)	280 (N)	0.067 (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)
-16	6.92 (N)	4.26 (N)	1.64 (N)	0.57 (N)	0.04 (N)	0.41 (N)
1	6.29 (N)	3.67 (N)	1.59 (N)	0.5 (N)	0.05 (N)	0.49 (N)
29	7.32 (N)	4.61 (N)	1.37 (N)	0.56 (N)	0.05 (N)	0.73 (H)
43	7.2 (N)	3.38 (N)	1.66 (N)	1.01 (H)	0 (N)	1.15 (H)
-33*	7.2 (N)	3.38 (N)	1.66 (N)	1.01 (H)	0 (N)	1.15 (H)
22*	6.34 (N)	3.68 (N)	1.41 (N)	0.51 (N)	0.03 (N)	0.7 (H)
59*	6.04 (N)	3.48 (N)	1.55 (N)	0.42 (N)	0.03 (N)	0.57 (N)
107*	5.51 (N)	3.4 (N)	1.21 (N)	0.42 (N)	0.04 (N)	0.43 (N)
163*	5.07 (N)	3.17 (N)	1.06 (N)	0.36 (N)	0.03 (N)	0.45 (N)
281*	6.05 (N)	3.54 (N)	1.38 (N)	0.38 (N)	0.02 (N)	0.72 (H)
330*	4.63 (N)	2.79 (N)	1.05 (N)	0.39 (N)	0.05 (N)	0.36 (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	No	9 (N)	13 (N)	79 (N)	0.2 (N)	0.64 (N)
1	No	11 (N)	14 (N)	79 (N)	0.3 (N)	0.74 (N)
15	Yes	16 (N)	19 (N)	88 (N)	<0.2 (L)	0.69 (N)
29	Yes	17 (N)	19 (N)	88 (N)	0.4 (N)	0.68 (N)
43	No	17 (N)	22 (N)	91 (N)	0.3 (N)	0.66 (N)
69	Yes	12 (N)	15 (N)	94 (N)	0.2 (N)	0.75 (N)
-7*	Yes	12 (N)	15 (N)	94 (N)	0.2 (N)	0.75 (N)
22*	No	15 (N)	16 (N)	85 (N)	0.3 (N)	0.64 (N)
59*	Yes	13 (N)	15 (N)	89 (N)	0.2 (N)	0.66 (N)
107*	Yes	11 (N)	16 (N)	86 (N)	0.2 (N)	0.66 (N)
163*	Yes	12 (N)	16 (N)	92 (N)	0.2 (N)	0.62 (N)
219*	Yes	8 (N)	13 (N)	78 (N)	0.3 (N)	0.64 (N)
281*	Yes	13 (N)	15 (N)	87 (N)	0.5 (N)	0.64 (N)
330*	Yes	12 (N)	16 (N)	91 (N)	0.4 (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)
-16	No	133.8 (H)	35 (N)	83 (N)	31.8 (H)
1	No	118.8 (H)	46 (N)	92 (N)	9.73 (N)
15	Yes	126.6 (H)	44 (N)	61 (L)	50.5 (H)
29	Yes	127.2 (H)	45 (N)	86 (N)	9.3 (N)
43	No	130.2 (H)	71 (N)	77 (N)	15.8 (H)
69	Yes	114 (N)	38 (N)	92 (N)	33.2 (H)
-7*	Yes	114 (N)	38 (N)	92 (N)	33.2 (H)
22*	No	129 (H)	53 (N)	91 (N)	7.58 (N)
59*	Yes	122.4 (H)	53 (N)	92 (N)	8.51 (N)
107*	Yes	125.4 (H)	53 (N)	77 (N)	9.12 (N)
163*	Yes	132.6 (H)	56 (N)	89 (N)	5.15 (N)
219*	Yes	120 (H)	48 (N)	83 (N)	6.38 (N)
281*	Yes	121.8 (H)	62 (N)	86 (N)	13.9 (H)
330*	Yes	106.8 (N)	70 (N)	86 (N)	9.4 (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	224 (N)	61 (N)	138 (H)	139 (N)
69	Yes	211 (N)	49 (N)	140 (H)	135 (N)
-7*	Yes	211 (N)	49 (N)	140 (H)	135 (N)
107*	Yes	185 (N)	44 (N)	127 (N)	113 (N)
330*	Yes	191 (N)	57 (N)	128 (N)	68 (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 10）；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。

潰瘍性大腸炎（Day 7～16）（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 7、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 16、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

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
mesalazine	ULCERATIVE COLITIS	ORAL	-301 days	Ongoing
azathioprine	ULCERATIVE COLITIS	ORAL	-133 days	Ongoing
hydrocortisone	ULCERATIVE COLITIS	INTRAVENOUS	7 days	16 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	16	4	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)
-28	11.2 (L)	35 (N)	4 (L)	336 (N)	0.052 (N)	86 (N)
1	10.1 (L)	31 (L)	3.5 (L)	447 (H)	0.074 (N)	90 (N)
24	9.6 (L)	31 (L)	3.2 (L)	178 (N)	0.081 (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)
-28	5.29 (N)	2.83 (N)	1.46 (N)	0.45 (N)	0.06 (N)	0.5 (N)
1	5.96 (N)	4.47 (N)	0.83 (L)	0.44 (N)	0.04 (N)	0.18 (N)
24	2.64 (L)	1.4 (L)	1.12 (N)	0.08 (L)	0.01 (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)
-28	Yes	11 (N)	17 (N)	57 (N)	0.2 (N)	0.84 (N)
1	Yes	12 (N)	15 (N)	46 (N)	0.4 (N)	0.67 (N)
24	Yes	85 (H)	36 (H)	58 (N)	0.4 (N)	0.7 (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	100.2 (N)	85 (N)	101 (H)	10.7 (H)
1	Yes	112.2 (N)	46 (N)	105 (H)	141 (H)
24	Yes	102 (N)	24 (L)	84 (N)	9.16 (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)
-28	Yes	181 (N)	59 (N)	91 (N)	156 (H)
1	Yes	125 (L)	35 (L)	58 (N)	137 (N)
24	Yes	184 (N)	70 (N)	85 (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－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－有害事象により投与中止（Day 25*）

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、ウクライナからの参加であった。

急性 B 型肝炎（Day 34*～62*）（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 34*、Grade 4 の重篤な急性 B 型肝炎が発現した。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 62*、Grade 4 の本事象は回復した。

その他の関連情報：被験者は急性 B 型肝炎のため入院した。本試験のスクリーニング時において、被験者は B 型肝炎コア抗体陰性、B 型肝炎表面抗体陰性及び B 型肝炎表面抗原陰性であった。被験者は入院時に、B 型肝炎コア抗体陽性、B 型肝炎表面抗体陰性及び B 型肝炎表面抗原陽性であると診断された。過去の避妊手段を取らない性行為、注射針を共用した静注薬物乱用又はヒト血液への接触を伴う針刺し事故は報告されていなかった。
*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**
lactulose	ACUTE VIRAL HEPATITIS B	ORAL	112 days	Ongoing
bicyclol	ACUTE VIRAL HEPATITIS B	ORAL	127 days	Ongoing
macrogol 4000;potassium chloride;sodium bicarbonate;sodium chloride;sodium sulfate anhydrous	PREPARATION FOR ENDOSCOPY	ORAL	-6 days	-6 days
macrogol 4000;potassium chloride;sodium bicarbonate;sodium chloride;sodium sulfate anhydrous	PREPARATION FOR ENDOSCOPY	ORAL	71 days	71 days
methylprednisolone	ULCERATIVE COLITIS	ORAL	About 1 day	99 days
mesalazine	ULCERATIVE COLITIS	ORAL	About -662 days	103 days
methylprednisolone	ULCERATIVE COLITIS	ORAL	100 days	103 days
calcium chloride;magnesium chloride;potassium chloride;sodium chloride;sodium lactate;sorbitol	ACUTE VIRAL HEPATITIS B	INTRAVENOUS	112 days	119 days
ademetionine	ACUTE VIRAL HEPATITIS B	INTRAVENOUS	112 days	126 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
Alanine aminotransferase increased	22*	Ongoing	2	not related	not applicable	drug interrupted	none
Aspartate aminotransferase increased	22*	Ongoing	2	not related	not applicable	drug interrupted	none
Erectile dysfunction	22*	Ongoing	1	not related	not applicable	dose not changed	none
Acute hepatitis B	34*	62*	4	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)
-28	8 (L)	32 (L)	4.3 (N)	392 (N)	0.087 (N)	75 (L)
1	10.8 (L)	37 (N)	5 (N)	402 (H)	0.115 (N)	75 (L)
17	10.3 (L)	35 (L)	4.6 (N)	320 (N)	0.11 (N)	76 (L)
29	10.3 (L)	34 (L)	4.6 (N)	279 (N)	0.145 (H)	75 (L)
43	10 (L)	35 (L)	4.5 (N)	364 (N)	0.086 (N)	78 (L)
72	9.8 (L)	33 (L)	4.4 (N)	272 (N)	0.112 (N)	73 (L)
-7*	9.8 (L)	33 (L)	4.4 (N)	272 (N)	0.112 (N)	73 (L)
22*	9.2 (L)	33 (L)	4.4 (N)	319 (N)	0.082 (N)	75 (L)
29*	9.3 (L)	30 (L)	4.3 (N)	227 (N)		69 (L)
34*	8.8 (L)	31 (L)	4.2 (N)	327 (N)	0.098 (N)	74 (L)
65*	9.4 (L)	33 (L)	4.7 (N)	125 (L)	0.082 (N)	70 (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	10.73 (H)	6.8 (N)	3.25 (H)	0.44 (N)	0.03 (N)	0.21 (N)
1	8.29 (N)	6.11 (N)	1.61 (N)	0.31 (N)	0.04 (N)	0.23 (N)
17	10.94 (H)	8.8 (H)	1.66 (N)	0.27 (N)	0.03 (N)	0.19 (N)
29	8.61 (N)	7.35 (H)	0.89 (N)	0.22 (N)	0.04 (N)	0.1 (N)
43	6.49 (N)	4.04 (N)	1.97 (N)	0.32 (N)	0.04 (N)	0.12 (N)
72	5.87 (N)	3.02 (N)	2.16 (N)	0.37 (N)	0.03 (N)	0.28 (N)
-7*	5.87 (N)	3.02 (N)	2.16 (N)	0.37 (N)	0.03 (N)	0.28 (N)
22*	9.39 (N)	6.14 (N)	2.41 (N)	0.47 (N)	0.04 (N)	0.32 (N)
29*	9.15 (N)	7.41 (H)	1.09 (N)	0.32 (N)	0.11 (N)	0.22 (N)
34*	8.76 (N)	5.17 (N)	2.6 (N)	0.5 (N)	0.04 (N)	0.45 (N)
65*	5.9 (N)	2.59 (N)	2.78 (N)	0.35 (N)	0.06 (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)
-28	Yes	11 (N)	10 (L)	63 (N)	0.5 (N)	0.81 (N)
1	Yes	9 (N)	13 (N)	64 (N)	0.6 (N)	1.04 (N)
17	Yes	15 (N)	15 (N)	73 (N)	1.1 (N)	0.92 (N)
29	Yes	10 (N)	20 (N)	77 (N)	0.9 (N)	0.98 (N)
43	Yes	10 (N)	13 (N)	77 (N)	0.6 (N)	0.97 (N)
72	Yes	16 (N)	23 (N)	75 (N)	1.2 (N)	1.01 (N)
-7*	Yes	16 (N)	23 (N)	75 (N)	1.2 (N)	1.01 (N)
22*	Yes	213 (H)	158 (H)	86 (N)	0.7 (N)	0.92 (N)
29*	Yes	537 (H)	332 (H)	149 (H)	1.1 (N)	0.89 (N)
34*	Yes	291 (H)	158 (H)	135 (H)	0.7 (N)	0.87 (N)
65*	Yes	285 (H)	762 (H)	233 (H)	1.7 (H)	1.11 (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	117.6 (N)	29 (L)	80 (N)	2.11 (N)
1	Yes	89.4 (N)	29 (L)	71 (N)	10.4 (H)
17	Yes	104.4 (N)	51 (N)	82 (N)	6.04 (N)
29	Yes	97.2 (N)	258 (N)	87 (N)	9 (N)
43	Yes	99.6 (N)	53 (N)	82 (N)	4.56 (N)
72	Yes	99.6 (N)	75 (N)	66 (L)	4.96 (N)
-7*	Yes	99.6 (N)	75 (N)	66 (L)	4.96 (N)
22*	Yes	108 (N)	45 (N)	75 (N)	4.47 (N)
29*	Yes	108 (N)	191 (N)	88 (N)	
34*	Yes	109.8 (N)	51 (N)	75 (N)	8.02 (N)
65*	Yes	87 (N)	29 (L)	76 (N)	3.97 (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)
-28	Yes	199 (N)	60 (N)	121 (N)	108 (N)
1	Yes	194 (N)	36 (N)	127 (N)	188 (N)
17	Yes	195 (N)	61 (N)	116 (N)	124 (N)
29	Yes	207 (N)	50 (N)	125 (N)	131 (N)
43	Yes	226 (N)	42 (N)	154 (H)	121 (N)
72	Yes	183 (N)	38 (N)	129 (N)	79 (N)
-7*	Yes	183 (N)	38 (N)	129 (N)	79 (N)
22*	Yes	162 (L)	34 (N)	104 (N)	131 (N)
29*	Yes	135 (L)	29 (L)	84 (N)	95 (N)
34*	Yes	142 (L)	32 (N)	82 (N)	121 (N)
65*	Yes	128 (L)	23 (L)	68 (N)	119 (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 29）；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、日本からの参加であった。

潰瘍性大腸炎（Day 29～36）（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 29、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 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**
acne	Ongoing
colitis ulcerative	Ongoing
haemorrhoids	Ongoing
sapho syndrome	-477 days

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
mesalazine	ULCERATIVE COLITIS	ORAL	-536 days	Ongoing
esomeprazole magnesium	PREVENTION OF GASTRIC ULCER	ORAL	-473 days	Ongoing
pancrelipase	PREVENTION OF PANCREATITIS	ORAL	-470 days	Ongoing
escherichia coli;hydrocortisone	EXTERNAL HEMORRHOIDS	TOPICAL	-210 days	Ongoing
adapalene	ACNE	TOPICAL	-80 days	Ongoing
clindamycin phosphate	ACNE	TOPICAL	-25 days	Ongoing
tofacitinib citrate	ULCERATIVE COLITIS	ORAL	32 days	Ongoing
prednisolone	ULCERATIVE COLITIS	ORAL	43 days	Ongoing
infliximab	ULCERATIVE COLITIS	INTRAVENOUS	-467 days	-455 days
adalimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	-207 days	-207 days
adalimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	-193 days	-193 days
adalimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	-179 days	-94 days
budesonide	ULCERATIVE COLITIS	RECTAL	-118 days	-80 days
red blood cells, concentrated	ULCERATIVE COLITIS	INTRAVENOUS	-42 days	-41 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
prednisolone	ULCERATIVE COLITIS	ORAL	-57 days	-39 days
azathioprine	ULCERATIVE COLITIS	ORAL	-204 days	-29 days
prednisolone	ULCERATIVE COLITIS	ORAL	-38 days	-23 days
saccharated iron oxide	ULCERATIVE COLITIS	INTRAVENOUS	-21 days	-18 days
red blood cells, concentrated	ULCERATIVE COLITIS	INTRAVENOUS	-17 days	-16 days
clobetasol propionate	ACNE	TOPICAL	-6 days	-6 days
sodium picosulfate	ENDOSCOPY	ORAL	-6 days	-6 days
diazepam	ENDOSCOPY	INTRAVENOUS	-5 days	-5 days
domperidone	ENDOSCOPY	ORAL	-5 days	-5 days
hyoscine butylbromide	ENDOSCOPY	INTRAVENOUS	-5 days	-5 days
magnesium citrate	ENDOSCOPY	ORAL	-5 days	-5 days
metoclopramide	ENDOSCOPY	ORAL	-5 days	-5 days
red blood cells, concentrated	ULCERATIVE COLITIS	INTRAVENOUS	30 days	31 days
metronidazole	PROPHYLACTIC ADMINISTRATION FOR COLONIC WALL INFECTION	ORAL	-50 days	42 days
prednisolone	ULCERATIVE COLITIS	ORAL	-22 days	42 days
camostat mesilate	PREVENTION OF PANCREATITIS	ORAL	-470 days	55 days
flopropione	PREVENTION OF PANCREATITIS	ORAL	-470 days	55 days
ecabet monosodium	PREVENTION OF GASTRIC ULCER	ORAL	-108 days	55 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	36	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)
-36	10.5 (L)	32 (L)	3.4 (L)	345 (N)	0.078 (N)	94 (N)
-14	10.4 (L)	32 (L)	3.4 (L)	367 (N)	0.163 (H)	95 (N)
1	10 (L)	31 (L)	3.2 (L)	278 (N)	0.062 (N)	97 (H)
15	9.5 (L)	30 (L)	3.3 (L)	315 (N)	0.092 (N)	93 (N)
29	8.3 (L)	27 (L)	3 (L)	352 (N)	0.071 (N)	89 (N)
56	9.6 (L)	31 (L)	3.7 (L)	298 (N)	0.072 (N)	85 (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)
-36	4.47 (N)	3.59 (N)	0.6 (L)	0.22 (N)	0.02 (N)	0.03 (N)
-14	4.99 (N)	3.5 (N)	1.05 (N)	0.33 (N)	0.04 (N)	0.07 (N)
1	5.65 (N)	3.44 (N)	1.71 (N)	0.38 (N)	0.04 (N)	0.08 (N)
15	5.42 (N)	2.98 (N)	2.04 (N)	0.3 (N)	0.03 (N)	0.08 (N)
29	4.54 (N)	2.45 (N)	1.78 (N)	0.24 (N)	0.02 (N)	0.06 (N)
56	5.51 (N)	3.92 (N)	1.21 (N)	0.27 (N)	0.03 (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)
-36	No	12 (N)	12 (N)	97 (N)	0.5 (N)	1 (N)
-14	No	20 (N)	19 (N)	93 (N)	0.4 (N)	1.05 (N)
1	Yes	18 (N)	16 (N)	85 (N)	0.3 (N)	0.95 (N)
15	Yes	23 (N)	22 (N)	95 (N)	0.3 (N)	1.01 (N)
29	Yes	28 (N)	24 (N)	107 (N)	0.2 (N)	1.01 (N)
56	No	24 (N)	22 (N)	119 (N)	0.2 (N)	1.05 (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)
-36	No	91.8 (N)	48 (N)	113 (H)	4 (N)
-14	No	85.8 (N)	48 (N)	123 (H)	9.05 (N)
1	Yes	93.6 (N)	36 (L)	92 (N)	10 (H)
15	Yes	88.8 (N)	52 (N)	108 (H)	8.71 (N)
29	Yes	88.2 (N)	44 (N)	104 (H)	6.56 (N)
56	No	86.4 (N)	70 (N)	131 (H)	6.63 (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	115 (L)	47 (N)	67 (N)	64 (N)
29	Yes	145 (L)	57 (N)	82 (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－プラセボ群（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－被験者の判断により投与中止（Day 342*）

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、米国からの参加であった。

蜂巣炎（Day 84*～97*）（試験治療下の注目すべき有害事象［TE-AEI］）（寛解維持試験）：
Day 84*、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 97*、Grade 2 の本事象は回復した。

深部静脈血栓症（Day 94*～97*）（試験治療下の重篤な有害事象、TE-AEI）（寛解維持試験）：
Day 94*、Grade 3 の重篤な深部静脈血栓症が発現した。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 97*、Grade 3 の本事象は回復した。

その他の関連情報：左ふくらはぎに疼痛が 1 週間にわたり認められた。被験者はかかりつけ医により処方された Keflex（セファレキシン）を服用したが、疼痛が持続したため病院を受診した。被験者は超音波検査により左ふくらはぎの深部静脈血栓症と診断され、その後入院した。被験者は 3 日後に退院し、Eliquis（アピキサバン）を処方された。
*寛解維持試験における study day

Medical History	
Medical History	**Resolution**
abdominal pain	Ongoing
acne cystic	Ongoing
anaemia	Ongoing
anxiety	Ongoing
colitis ulcerative	Ongoing
depression	Ongoing
diarrhoea	Ongoing
drug dependence	Ongoing
drug hypersensitivity	Ongoing
migraine	Ongoing
rectal haemorrhage	Ongoing
urticaria	Ongoing
clostridium difficile infection	-143 days

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
mercaptopurine	ULCERATIVE COLITIS	ORAL	About -4985 days	Ongoing
paracetamol	MIGRAINE	ORAL	About -4985 days	Ongoing
alprazolam	ANXIETY	ORAL	About 1 day	Ongoing
fentanyl	CHRONIC ABDOMINAL PAIN	TRANSDERMAL	About 1 day	Ongoing
hydromorphone hydrochloride	CHRONIC ABDOMINAL PAIN	ORAL	About 1 day	Ongoing

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
citalopram	EXACERBATION OF ANXIETY/DEPRESSION	ORAL	82 days	Ongoing
escitalopram oxalate	DEPRESSION	ORAL	82 days	Ongoing
vitamin d nos	SUPPLEMENTS	ORAL	82 days	Ongoing
clonazepam	EXACERBATION OF ANXIETY	ORAL	135 days	Ongoing
hydromorphone	LEFT LOWER EXTREMITY CELLULITE PAIN	ORAL	172 days	Ongoing
quetiapine fumarate	DEPRESSION	ORAL	172 days	Ongoing
cyclobenzaprine	GENERAL ABDOMINAL PAIN	ORAL	198 days	Ongoing
infliximab	ULCERATIVE COLITIS	INTRAVENOUS	About -2793 days	About -2064 days
adalimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	About -2063 days	About -1333 days
adalimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	About -967 days	About -603 days
prednisone	ULCERATIVE COLITIS	ORAL	About -4985 days	About -543 days
adalimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	-815 days	About -329 days
prednisolone	ULCERATIVE COLITIS	ORAL	About -571 days	About -298 days
budesonide	ULCERATIVE COLITIS	ORAL	-311 days	About -237 days
mesalazine	ULCERATIVE COLITIS	ORAL	-308 days	About -206 days
vedolizumab	ULCERATIVE COLITIS	INTRAVENOUS	-757 days	-60 days
propofol	COLONOSCOPY ANESTHESIA	INTRAVENOUS	-2 days	-2 days
antipropulsives	ULCERATIVE COLITIS	ORAL	About -967 days	46 days
dicycloverine	ULCERATIVE COLITIS	ORAL	3 days	71 days
propofol	COLONSCOPY ANESTHESIA	INTRAVENOUS	71 days	71 days
prednisolone	ULCERATIVE COLITIS	ORAL	52 days	72 days
metronidazole	ULCERATIVE COLITIS	ORAL	About 1 day	About 129 days
cefalexin	LEFT LOWER EXTREMITY CELLULITIS	ORAL	161 days	170 days
clindamycin	LEFT LOWER EXTREMITY CELLULITE	ORAL	171 days	171 days
heparin	LT LOWER LEG DEEP VEIN THROMBOSIS.	INTRAVENOUS	171 days	171 days
vancomycin	LEFT LOWER EXTREMITY CELLULITIS	ORAL	171 days	174 days
prednisone	ULCERATIVE COLITIS	ORAL	About 99 days	211 days
prednisone	ULCERATIVE COLITIS	ORAL	212 days	222 days
prednisone	ULCERATIVE COLITIS	ORAL	223 days	242 days
apixaban	DVT LEFT LOWER EXTREMITY	ORAL	172 days	About 280 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
Rash	50	385	2	not related	dose not changed	dose not changed	none
Blood bilirubin increased	71	85	2	not related	dose not changed	drug interrupted	none
Liver function test increased	71	85	2	not related	dose not changed	drug interrupted	none
Anxiety	1*	Ongoing	1	not related	not applicable	dose not changed	medication required
Limb injury	22*	22*	1	not related	not applicable	dose not changed	none
Cellulitis	84*	97*	2	not related	not applicable	dose not changed	medication required
Deep vein thrombosis	94*	97*	3	not related	not applicable	dose not changed	medication required
Rash erythematous	258*	270*	2	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)
-15	12 (L)	36 (L)	3.7 (L)	234 (N)	0.107 (N)	96 (N)
1	12.5 (L)	38 (L)	3.8 (L)	318 (N)	0.127 (N)	99 (H)
14	12.6 (L)	42 (N)	3.9 (L)	228 (N)	0.168 (H)	108 (H)
28	13.6 (N)	44 (N)	4.1 (L)	287 (N)	0.1 (N)	108 (H)
41	12.6 (L)	40 (N)	3.9 (L)	260 (N)	0.113 (N)	102 (H)
71	12.9 (N)	38 (L)	3.8 (L)	263 (N)	0.112 (N)	99 (H)
-7*	12.9 (N)	38 (L)	3.8 (L)	263 (N)	0.112 (N)	99 (H)
18*	13.4 (N)	39 (N)	3.9 (L)	315 (N)	0.104 (N)	100 (H)
99*	13.1 (N)	38 (L)	3.8 (L)	228 (N)	0.084 (N)	98 (H)
155*	13.5 (N)	41 (N)	4.1 (L)	354 (N)	0.141 (H)	100 (H)
224*	12.6 (L)	42 (N)	4.2 (L)	239 (N)	0.109 (N)	99 (H)
270*	10.9 (L)	35 (L)	3.7 (L)	222 (N)	0.073 (N)	94 (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	6.65 (N)	5.36 (N)	0.86 (L)	0.35 (N)	0.02 (N)	0.07 (N)
1	7.67 (N)	4.92 (N)	2.29 (N)	0.4 (N)	0.02 (N)	0.04 (N)
14	6.33 (N)	4.91 (N)	1.05 (N)	0.28 (N)	0.01 (N)	0.08 (N)
28	5.37 (N)	4.63 (N)	0.41 (L)	0.27 (N)	0.02 (N)	0.04 (N)
41	5.58 (N)	4.13 (N)	1.04 (N)	0.34 (N)	0.02 (N)	0.05 (N)
71	5.06 (N)	3.04 (N)	1.81 (N)	0.14 (N)	0.02 (N)	0.06 (N)
-7*	5.06 (N)	3.04 (N)	1.81 (N)	0.14 (N)	0.02 (N)	0.06 (N)
18*	6.36 (N)	5.57 (N)	0.59 (L)	0.15 (N)	0.01 (N)	0.05 (N)
99*	8.62 (N)	7.58 (H)	0.65 (L)	0.3 (N)	0.03 (N)	0.07 (N)
155*	6.27 (N)	4.74 (N)	1.12 (N)	0.29 (N)	0.03 (N)	0.09 (N)
224*	5.22 (N)	3.64 (N)	1.12 (N)	0.29 (N)	0.02 (N)	0.15 (N)
270*	4.26 (N)	2.7 (N)	0.97 (N)	0.36 (N)	0.01 (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)
-15	Yes	32 (N)	20 (N)	41 (N)	1 (N)	0.74 (N)
1	Yes	55 (H)	28 (N)	56 (N)	1.8 (H)	1.01 (N)
14	No	55 (H)	19 (N)	47 (N)	1 (N)	0.86 (N)
28	Yes	43 (N)	21 (N)	45 (N)	0.8 (N)	0.85 (N)
41	No	35 (N)	16 (N)	41 (N)	0.9 (N)	0.93 (N)
71	Yes	329 (H)	135 (H)	49 (N)	2.1 (H)	0.98 (N)
78	Yes			44 (N)		0.85 (N)
-7*	Yes	329 (H)	135 (H)		2.1 (H)	
1*	Yes			44 (N)		0.85 (N)
8*	Yes	114 (H)	31 (N)	44 (N)	1.6 (H)	0.95 (N)
18*	No	79 (H)	27 (N)	41 (N)	1.7 (H)	0.96 (N)
64*	No			37 (N)		1.05 (N)
99*	No	43 (N)	21 (N)	40 (N)	1.7 (H)	0.93 (N)
155*	Yes	30 (N)	21 (N)	48 (N)	0.7 (N)	0.99 (N)
224*	No	22 (N)	23 (N)	62 (N)	0.9 (N)	0.88 (N)
270*	Yes	11 (N)	11 (N)	69 (N)	1 (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)
-15	Yes	213.4 (H)	94 (N)	108 (H)	4 (N)
1	Yes	156.5 (H)	63 (N)	96 (N)	4.3 (N)
14	No	184 (H)	33 (L)	118 (H)	1.8 (N)
28	Yes	189.7 (H)	26 (L)	122 (H)	14.5 (H)
41	No	173.4 (H)	29 (L)	109 (H)	0.82 (N)
71	Yes	161.3 (H)	42 (N)	94 (N)	0.59 (N)
78	Yes				
-7*	Yes	161.3 (H)	42 (N)	94 (N)	0.59 (N)
1*	Yes				
8*	Yes		72 (N)	128 (H)	
18*	No	169.8 (H)	112 (N)	121 (H)	0.35 (N)
64*	No	153 (H)			5.59 (N)
99*	No	171.8 (H)	167 (N)	116 (H)	1.87 (N)
155*	Yes	174.5 (H)	67 (N)	127 (H)	2.94 (N)
224*	No	189.9 (H)	55 (N)	100 (N)	8.9 (N)
270*	Yes	148.9 (H)	78 (N)	82 (N)	21.6 (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)
-15	Yes	204 (N)	68 (H)	117 (N)	154 (N)
1	Yes	240 (N)	69 (H)	150 (H)	135 (N)
14	No	230 (N)	82 (H)	126 (N)	152 (N)
28	Yes	214 (N)	48 (N)	124 (N)	208 (N)
41	No	216 (N)	58 (N)	131 (H)	167 (N)
71	Yes	237 (N)	58 (N)	152 (H)	187 (N)
-7*	Yes	237 (N)	58 (N)	152 (H)	187 (N)
18*	No	244 (N)	68 (H)	160 (H)	126 (N)
64*	No	227 (N)	83 (H)	120 (N)	160 (N)
99*	No	216 (N)	64 (H)	125 (N)	146 (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－有害事象により投与中止（Day 232*）

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、オーストラリアからの参加であった。

口腔ヘルペス（Day 74～82）（試験治療下の注目すべき有害事象［TE-AEI］）（寛解導入試験）：
Day 74、Grade 1 の非重篤な口腔ヘルペスが発現した。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 82、Grade 1 の本事象は回復した。

上咽頭炎（Day 53*～64*）（TE-AEI）（寛解維持試験）：
Day 53*、Grade 1 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 1 の本事象は回復した。

鼻ヘルペス（Day 89*～108*）（TE-AEI）（寛解維持試験）：
Day 89*、Grade 2 の非重篤な鼻ヘルペスが発現した。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 108*、Grade 2 の本事象は回復した。

ウイルス性上気道感染（Day 117*～132*）（TE-AEI）（寛解維持試験）：
Day 117*、Grade 1 の非重篤なウイルス性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 132*、Grade 1 の本事象は回復した。

口腔ヘルペス（Day 130*～137*）（TE-AEI）（寛解維持試験）：
Day 130*、Grade 1 の非重篤な口腔ヘルペスが発現した。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 137*、Grade 1 の本事象は回復した。

眼部単純ヘルペス（Day 153*～162*）（TE-AEI）（寛解維持試験）：
Day 153*、Grade 2 の非重篤な眼部単純ヘルペスが発現した。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 162*、Grade 2 の本事象は回復した。

単純ヘルペス（Day 167*～188*）（TE-AEI）（寛解維持試験）：
Day 167*、Grade 2 の非重篤な単純ヘルペスが発現した。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 188*、Grade 2 の本事象は回復した。

上咽頭炎（Day 181*～188*）（TE-AEI）（寛解維持試験）：
Day 181*、Grade 1 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 188*、Grade 1 の本事象は回復した。

悪性黒色腫（Day 221*～231*）（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 221*、Grade 3 の重篤な悪性黒色腫が発現した。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 231*、Grade 3 の本事象は回復した。

口腔ヘルペス（Day 241*～継続）（TE-AEI）（寛解維持試験）：
Day 241*、Grade 2 の非重篤な口腔ヘルペスが発現した。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：腰背部の皮膚病変の外科的切除術が実施された。最終の病理報告書によると、切除された皮膚病変の大きさは 14×7×10 mm であり、色素斑は 8×5 mm であった。被験者は表在拡大型浸潤性黒色腫と診断された。Breslow の腫瘍深達度は 1.3 mm であり、Clark レベルは 3 であった。追加で 1 cm の皮膚が切除され、当該切除検体中に黒色腫細胞は認められなかった。
*寛解維持試験における study day

Medical History	
Medical History	**Resolution**
cholangitis sclerosing	Ongoing
colitis ulcerative	Ongoing
intra-uterine contraceptive device insertion	Ongoing
ophthalmic herpes simplex	-833 days

Prior and Concomitant Medications				
Concomitant Med	**Indication**	**Route**	**Start Day**	**Stop Day**
lysine	IMMUNITY	ORAL	About -1383 days	Ongoing
probiotics nos	IMMUNITY	ORAL	About -1383 days	Ongoing
vitamin d nos	BONE STRENGTH	ORAL	About -1383 days	Ongoing
levonorgestrel	CONTRACEPTION	INTRAUTERINE	-621 days	Ongoing
calcium	BONE STRENGTH	ORAL	About -471 days	Ongoing
zinc	IMMUNITY	ORAL	About -409 days	Ongoing
mesalazine	ULCERATIVE COLITIS	ORAL	About -1049 days	-985 days
mesalazine	ULCERATIVE COLITIS	ORAL	-984 days	-910 days
mercaptopurine	ULCERATIVE COLITIS	ORAL	About -836 days	About -806 days
balsalazide	ULCERATIVE COLITIS	ORAL	About -836 days	About -684 days
balsalazide	ULCERATIVE COLITIS	ORAL	About -713 days	-590 days
tioguanine	ULCERATIVE COLITIS	ORAL	-609 days	About -502 days
tioguanine	ULCERATIVE COLITIS	ORAL	About -532 days	-391 days
infliximab	ULCERATIVE COLITIS	INTRAVENOUS	-520 days	About -349 days
adalimumab	ULCERATIVE COLITIS	SUBCUTANEOUS	-286 days	-160 days

Prior and Concomitant Medications				
Concomitant Med	Indication	Route	Start Day	Stop Day
prednisone	ULCERATIVE COLITIS	ORAL	About -287 days	-30 days
prednisone	ULCERATIVE COLITIS	ORAL	-29 days	-24 days
prednisone	ULCERATIVE COLITIS	ORAL	-23 days	-21 days
sodium picosulfate	BOWEL PREP	ORAL	65 days	65 days
famciclovir	HERPES ORAL	ORAL	74 days	74 days
aciclovir	HERPES ORAL	ORAL	74 days	82 days
codeine phosphate;paracetamol;pseudoephedrine hydrochloride	COLD	ORAL	134 days	137 days
prednisone	ULCERATIVE COLITIS	ORAL	-20 days	145 days
prednisone	ULCERATIVE COLITIS	ORAL	146 days	160 days
famciclovir	HERPES LESION RIGHT NOSTRIL	ORAL	171 days	171 days
cough and cold preparations	UPPER RESPIRATORY TRACT INFECTION	ORAL	198 days	213 days
oxymetazoline hydrochloride	UPPER RESPIRATORY TRACT INFECTION	NASAL	198 days	213 days
aciclovir	ORAL HERPES SIMPLEX	TOPICAL	211 days	218 days
ketotifen fumarate	HERPES KERATITIS	INTRAOCULAR	231 days	232 days
cetirizine hydrochloride	HERPES KERATITIS	ORAL	232 days	232 days
famciclovir	HERPES KERATITIS L EYE	ORAL	233 days	238 days
aciclovir	HERPES SIMPLEX VIRUS LEFT EYE	INTRAOCULAR	234 days	246 days
tioguanine	ULCERATIVE COLITIS	ORAL	-390 days	264 days
cetirizine	COLD	ORAL	262 days	265 days
promethazine	COLD	ORAL	264 days	265 days
oxymetazoline hydrochloride	COLD	NASAL	260 days	268 days
benzalkonium chloride;idoxuridine;lidocaine hydrochloride	NASAL HERPES SIMPLEX	TOPICAL	265 days	268 days
aciclovir	NASAL HERPES SIMPLEX	NASAL	248 days	269 days
valaciclovir	NASAL HERPES	ORAL	260 days	287 days
benzalkonium chloride;idoxuridine;lidocaine hydrochloride	ORAL HERPES SIMPLEX	TOPICAL	322 days	331 days
valaciclovir hydrochloride	ORAL HERPES SIMPLEX	ORAL	322 days	331 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
Oropharyngeal pain	6	13	1	not related	dose not changed	not applicable	none
Alopecia	17	About 78	1	related	dose not changed	not applicable	none
Oral herpes	74	82	1	not related	dose not changed	not applicable	medication required
Lethargy	11*	103*	1	not related	not applicable	dose not changed	none
Muscular weakness	11*	103*	1	not related	not applicable	dose not changed	none
Defaecation urgency	17*	103*	1	not related	not applicable	dose not changed	none
Frequent bowel movements	17*	103*	1	not related	not applicable	dose not changed	none
Abdominal discomfort	18*	103*	1	not related	not applicable	dose not changed	none
Nasopharyngitis	53*	64*	1	not related	not applicable	dose not changed	medication required
Arthralgia	64*	103*	1	not related	not applicable	dose not changed	none
Nasal herpes	89*	108*	2	not related	not applicable	dose not changed	medication required
Viral upper respiratory tract infection	117*	132*	1	not related	not applicable	dose not changed	medication required
Oral herpes	130*	137*	1	not related	not applicable	dose not changed	medication required
Ophthalmic herpes simplex	153*	162*	2	not related	not applicable	drug interrupted	medication required
Herpes simplex	167*	188*	2	not related	not applicable	drug interrupted	medication required
Nasopharyngitis	181*	188*	1	not related	not applicable	dose not changed	medication required
Malignant melanoma	221*	231*	3	not related	not applicable	drug withdrawn	permanent study discontinuation
Oral herpes	241*	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)
-33	13.8 (N)	41 (N)	4.4 (N)	302 (N)	0.087 (N)	93 (N)
1	14.7 (N)	45 (N)	4.8 (N)	348 (N)	0.027 (L)	93 (N)
17	13.7 (N)	41 (N)	4.4 (N)	309 (N)	0.03 (N)	93 (N)
31	13.8 (N)	42 (N)	4.6 (N)	279 (N)	0.045 (N)	93 (N)
45	13.4 (N)	41 (N)	4.3 (N)	267 (N)	0.045 (N)	94 (N)
68	13.4 (N)	41 (N)	4.3 (N)	288 (N)	0.021 (L)	94 (N)
-14*	13.4 (N)	41 (N)	4.3 (N)	288 (N)	0.021 (L)	94 (N)
18*	13.8 (N)	40 (N)	4.3 (N)	259 (N)	0.039 (N)	93 (N)
64*	14.3 (N)	42 (N)	4.5 (N)	275 (N)	0.029 (L)	94 (N)
103*	12.9 (N)	40 (N)	4.3 (N)	251 (N)	0.05 (N)	93 (N)
174*	13.8 (N)	42 (N)	4.5 (N)	339 (N)	0.015 (L)	93 (N)
214*	13.5 (N)	40 (N)	4.4 (N)	268 (N)	0.029 (L)	91 (N)
244*	13.6 (N)	42 (N)	4.5 (N)	286 (N)	0.032 (N)	94 (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	12.48 (H)	8.71 (H)	2.79 (N)	0.83 (N)	0.06 (N)	0.09 (N)
1	11.5 (H)	9.2 (H)	1.52 (N)	0.46 (N)	0.08 (N)	0.23 (N)
17	7.15 (N)	5.28 (N)	1.5 (N)	0.28 (N)	0.04 (N)	0.06 (N)
31	8.1 (N)	6.13 (N)	1.6 (N)	0.3 (N)	0.03 (N)	0.05 (N)
45	6.39 (N)	4.39 (N)	1.68 (N)	0.28 (N)	0.02 (N)	0.02 (N)
68	7.14 (N)	4.85 (N)	1.76 (N)	0.39 (N)	0.04 (N)	0.1 (N)
-14*	7.14 (N)	4.85 (N)	1.76 (N)	0.39 (N)	0.04 (N)	0.1 (N)
18*	9.61 (N)	7.38 (H)	1.73 (N)	0.41 (N)	0.04 (N)	0.05 (N)
64*	8.89 (N)	5.91 (N)	2.3 (N)	0.54 (N)	0.05 (N)	0.09 (N)
103*	7.1 (N)	4.41 (N)	1.94 (N)	0.5 (N)	0.05 (N)	0.2 (N)
174*	9.72 (N)	6.45 (N)	2.25 (N)	0.6 (N)	0.07 (N)	0.34 (N)
214*	8.27 (N)	6.2 (N)	1.57 (N)	0.5 (N)	0 (N)	0 (N)
244*	7.35 (N)	4.77 (N)	1.72 (N)	0.62 (N)	0.06 (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)
-33	No	9 (N)	13 (N)	52 (N)	0.3 (N)	1.04 (N)
1	No	9 (N)	13 (N)	67 (N)	0.2 (N)	1.01 (N)
17	No	10 (N)	16 (N)	63 (N)	0.3 (N)	1.02 (N)
31	No	10 (N)	15 (N)	60 (N)	0.4 (N)	0.93 (N)
45	No	9 (N)	16 (N)	58 (N)	0.4 (N)	1.01 (N)
68	Yes	10 (N)	17 (N)	51 (N)	0.4 (N)	0.93 (N)
-14*	Yes	10 (N)	17 (N)	51 (N)	0.4 (N)	0.93 (N)
18*	No	10 (N)	17 (N)	46 (N)	0.5 (N)	0.97 (N)
64*	No	9 (N)	17 (N)	49 (N)	0.5 (N)	1 (N)
103*	Yes	9 (N)	18 (N)	41 (N)	0.7 (N)	0.97 (N)
174*	No	16 (N)	24 (N)	48 (N)	0.5 (N)	0.88 (N)
214*	No	11 (N)	18 (N)	44 (N)	0.6 (N)	0.96 (N)
244*	No	10 (N)	17 (N)	47 (N)	0.5 (N)	0.97 (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	No	64.8 (L)	38 (N)	63 (L)	1.21 (N)
1	No	66 (L)	49 (N)	128 (H)	8.5 (N)
17	No	64.8 (L)	75 (N)	87 (N)	2.27 (N)
31	No	71.4 (L)	67 (N)	129 (H)	1.99 (N)
45	No	66 (L)	108 (N)	115 (H)	1.22 (N)
68	Yes	72 (L)	78 (N)	87 (N)	20.7 (H)
-14*	Yes	72 (L)	78 (N)	87 (N)	20.7 (H)
18*	No	69.6 (L)	69 (N)	120 (H)	1.39 (N)
64*	No	67.8 (L)	76 (N)	87 (N)	1.34 (N)
103*	Yes	70.2 (L)	100 (N)	82 (N)	1.05 (N)
174*	No	79.2 (N)	157 (N)	87 (N)	1.31 (N)
214*	No	73.8 (L)	105 (N)	94 (N)	2.63 (N)
244*	No	70.8 (L)	84 (N)	89 (N)	2.13 (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	190 (N)	40 (N)	137 (H)	81 (N)
68	Yes	196 (N)	64 (N)	129 (N)	50 (N)
-14*	Yes	196 (N)	64 (N)	129 (N)	50 (N)
103*	Yes	216 (N)	60 (N)	166 (H)	56 (N)
244*	No	210 (N)	51 (N)	150 (H)	88 (N)
* denotes the Maintenance study day. H = High; L = Low; N = Normal.					