



Clinical trial results:

A Phase 2B, Multicenter, Randomized, Double-blind, Placebo-controlled Dose-ranging Study to Evaluate the Efficacy, Safety, and Pharmacokinetics of PF-06480605 in Adult Participants With Moderate to Severe Ulcerative Colitis

Summary

EudraCT number	2019-002698-74
Trial protocol	ES FR BG SK PL DE GB BE HU AT IT RO
Global end of trial date	25 October 2022

Results information

Result version number	v3 (current)
This version publication date	04 July 2026
First version publication date	07 November 2025
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	XA45397
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04090411
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	F. Hoffmann-La Roche AG
Sponsor organisation address	Grenzacherstrasse 124, Basel, Switzerland, CH-4058
Public contact	F. Hoffmann-La Roche AG, F. Hoffmann-La Roche AG, +41 616878333, global.trial_information@roche.com
Scientific contact	F. Hoffmann-La Roche AG, F. Hoffmann-La Roche AG, +41 616878333, global.trial_information@roche.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	25 October 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	25 October 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary purpose of this study was to evaluate the safety and efficacy of PF-06480605 in participants with moderate to severe active ulcerative colitis (UC).

Protection of trial subjects:

All study subjects were required to read and sign an Informed Consent Form (ICF).

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	19 December 2019
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 5
Country: Number of subjects enrolled	Belgium: 3
Country: Number of subjects enrolled	Bulgaria: 1
Country: Number of subjects enrolled	Germany: 5
Country: Number of subjects enrolled	Spain: 1
Country: Number of subjects enrolled	France: 6
Country: Number of subjects enrolled	United Kingdom: 3
Country: Number of subjects enrolled	Hungary: 10
Country: Number of subjects enrolled	India: 35
Country: Number of subjects enrolled	Italy: 23
Country: Number of subjects enrolled	Japan: 10
Country: Number of subjects enrolled	Mexico: 7
Country: Number of subjects enrolled	Poland: 32
Country: Number of subjects enrolled	Romania: 2
Country: Number of subjects enrolled	Russian Federation: 26
Country: Number of subjects enrolled	Serbia: 4
Country: Number of subjects enrolled	Slovakia: 7
Country: Number of subjects enrolled	Thailand: 3
Country: Number of subjects enrolled	Türkiye: 8
Country: Number of subjects enrolled	Ukraine: 26
Country: Number of subjects enrolled	United States: 24
Country: Number of subjects enrolled	South Africa: 4

Worldwide total number of subjects	245
EEA total number of subjects	90

Notes:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	232
From 65 to 84 years	13
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

A total of 246 participants with moderate to severe UC took part in the study at 114 investigative sites across 23 countries from 19 December 2019 to 25 October 2022. The study consisted of a 12-week induction period and a 40-week chronic therapy period.

Pre-assignment

Screening details:

Participants were randomized in 2:2:2:2:3:1:1:1 to 1 of 9 treatment sequences to receive PF-06480605 50 milligrams (mg), 150 mg, 450 mg or a matched placebo during the induction & chronic therapy periods. 1 participant in PF-06480605 450 mg arm was enrolled but did not receive any treatment & hence was not presented in the subject disposition.

Period 1

Period 1 title	Induction Period
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Induction Period: Placebo

Arm description:

Participants received PF-06480605 matching placebo, as a subcutaneous (SC) injection, every 4 weeks (Q4W) up to Week 12.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

PF-06480605 matching placebo, as a SC injection, Q4W up to Week 12.

Arm title	Induction Period: PF-06480605 50 mg
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Arm description:

Participants received PF-06480605, 50 mg, as a SC injection, Q4W up to Week 12.

Arm type	Experimental
Investigational medicinal product name	PF-06480605
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

PF-06480605, 50 mg, as a SC injection, Q4W up to Week 12.

Arm title	Induction Period: PF-06480605 150 mg
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Arm description:

Participants received PF-06480605, 150 mg, as a SC injection, Q4W up to Week 12.

Arm type	Experimental
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Investigational medicinal product name	PF-06480605
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use
Dosage and administration details: PF-06480605, 150 mg, as a SC injection, Q4W up to Week 12.	
Arm title	Induction Period: PF-06480605 450 mg

Arm description:

Participants received PF-06480605, 450 mg, as a SC injection, Q4W up to Week 12.

Arm type	Experimental
Investigational medicinal product name	PF-06480605
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

PF-06480605, 450 mg, as a SC injection, Q4W up to Week 12.

Number of subjects in period 1	Induction Period: Placebo	Induction Period: PF-06480605 50 mg	Induction Period: PF-06480605 150 mg
Started	45	47	62
Completed	40	46	58
Not completed	5	1	4
Consent withdrawn by subject	2	-	1
Physician decision	-	-	1
Adverse Event	3	1	1
Lack of efficacy	-	-	1
Protocol deviation	-	-	-

Number of subjects in period 1	Induction Period: PF-06480605 450 mg
Started	91
Completed	84
Not completed	7
Consent withdrawn by subject	4
Physician decision	-
Adverse Event	1
Lack of efficacy	1
Protocol deviation	1

Period 2	
Period 2 title	Chronic Period
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator
Arms	
Are arms mutually exclusive?	Yes
Arm title	Placebo (Induction) to PF-06480605 (Chronic) 50 mg
Arm description:	
Participants who received placebo and completed the 12-week induction period received PF-06480605, 50 mg, as a SC injection, Q4W from Week 16 to Week 52 in the chronic period.	
Arm type	Experimental
Investigational medicinal product name	PF-06480605
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
PF-06480605, 50 mg, as a SC injection, Q4W from Week 16 to Week 52.	
Arm title	Placebo (Induction) to PF-06480605 (Chronic) 150 mg
Arm description:	
Participants who received placebo and completed the 12-week induction period received PF-06480605, 150 mg, as a SC injection, Q4W from Week 16 to Week 52 in the chronic period.	
Arm type	Experimental
Investigational medicinal product name	PF-06480605
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
PF-06480605, 150 mg, as a SC injection, Q4W from Week 16 to Week 52.	
Arm title	Placebo (Induction) to PF-06480605 (Chronic) 450 mg
Arm description:	
Participants who received placebo and completed the 12-week induction period received PF-06480605, 450 mg, as a SC injection, Q4W from Week 16 to Week 52 in the chronic period.	
Arm type	Experimental
Investigational medicinal product name	PF-06480605
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
PF-06480605, 450 mg, as a SC injection, Q4W from Week 16 to Week 52.	
Arm title	PF-06480605 50 mg (Induction) to PF-06480605 (Chronic) 50 mg

Arm description:

Participants who received PF-06480605, 50 mg, and completed the 12-week induction period received PF-06480605, 50 mg, as a SC injection, Q4W from Week 16 to Week 52 in the chronic period.

Arm type	Experimental
Investigational medicinal product name	PF-06480605
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

PF-06480605, 50 mg, as a SC injection, Q4W from Week 16 to Week 52.

Arm title	PF-06480605 150 mg (Induction) to PF-06480605 (Chronic) 50 mg
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Arm description:

Participants who received PF-06480605, 150 mg, and completed the 12-week induction period received PF-06480605, 50 mg, as a SC injection, Q4W from Week 16 to Week 52 in the chronic period.

Arm type	Experimental
Investigational medicinal product name	PF-06480605
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

PF-06480605, 50 mg, as a SC injection, Q4W from Week 16 to Week 52.

Arm title	PF-06480605 150 mg (Induction) to PF-06480605 (Chronic) 150 mg
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Arm description:

Participants who received PF-06480605, 150 mg, and completed the 12-week induction period received PF-06480605, 150 mg, as a SC injection, Q4W from Week 16 to Week 52 in the chronic period.

Arm type	Experimental
Investigational medicinal product name	PF-06480605
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

PF-06480605, 150 mg, as a SC injection, Q4W from Week 16 to Week 52.

Arm title	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 50 mg
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Arm description:

Participants who received PF-06480605, 450 mg, and completed the 12-week induction period received PF-06480605, 50 mg, as a SC injection, Q4W from Week 16 to Week 52 in the chronic period.

Arm type	Experimental
Investigational medicinal product name	PF-06480605
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

PF-06480605, 50 mg, as a SC injection, Q4W from Week 16 to Week 52.

Arm title	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 150 mg
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Arm description:

Participants who received PF-06480605, 450 mg, and completed the 12-week induction period received PF-06480605, 150 mg, as a SC injection, Q4W from Week 16 to Week 52 in the chronic period.

Arm type	Experimental
Investigational medicinal product name	PF-06480605
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

PF-06480605, 150 mg, as a SC injection, Q4W from Week 16 to Week 52.

Arm title	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 450 mg
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Arm description:

Participants who received PF-06480605, 450 mg, and completed the 12-week induction period received PF-06480605, 450 mg, as a SC injection, Q4W from Week 16 to Week 52 in the chronic period.

Arm type	Experimental
Investigational medicinal product name	PF-06480605
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

PF-06480605, 450 mg, as a SC injection, Q4W from Week 16 to Week 52.

Number of subjects in period 2^[1]	Placebo (Induction) to PF-06480605 (Chronic) 50 mg	Placebo (Induction) to PF-06480605 (Chronic) 150 mg	Placebo (Induction) to PF-06480605 (Chronic) 450 mg
Started	12	14	14
Completed	11	12	12
Not completed	1	2	2
Relocation	-	-	-
Physician decision	1	-	-
Consent withdrawn by subject	-	1	1
Adverse Event	-	1	-
Lack of efficacy	-	-	1
Protocol deviation	-	-	-

Number of subjects in period 2^[1]	PF-06480605 50 mg (Induction) to PF-06480605 (Chronic) 50 mg	PF-06480605 150 mg (Induction) to PF-06480605 (Chronic) 50 mg	PF-06480605 150 mg (Induction) to PF-06480605 (Chronic) 150 mg
Started	46	27	30
Completed	34	22	25
Not completed	12	5	5
Relocation	1	-	-
Physician decision	1	-	-
Consent withdrawn by subject	3	3	3
Adverse Event	3	-	-
Lack of efficacy	4	2	2

Protocol deviation	-	-	-
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Number of subjects in period 2^[1]	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 50 mg	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 150 mg	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 450 mg
Started	26	26	29
Completed	18	20	24
Not completed	8	6	5
Relocation	-	-	-
Physician decision	-	1	1
Consent withdrawn by subject	1	3	-
Adverse Event	5	1	1
Lack of efficacy	2	1	2
Protocol deviation	-	-	1

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: All participants who completed the induction period did not enter CTP.

Baseline characteristics

Reporting groups

Reporting group title	Induction Period: Placebo
Reporting group description: Participants received PF-06480605 matching placebo, as a subcutaneous (SC) injection, every 4 weeks (Q4W) up to Week 12.	
Reporting group title	Induction Period: PF-06480605 50 mg
Reporting group description: Participants received PF-06480605, 50 mg, as a SC injection, Q4W up to Week 12.	
Reporting group title	Induction Period: PF-06480605 150 mg
Reporting group description: Participants received PF-06480605, 150 mg, as a SC injection, Q4W up to Week 12.	
Reporting group title	Induction Period: PF-06480605 450 mg
Reporting group description: Participants received PF-06480605, 450 mg, as a SC injection, Q4W up to Week 12.	

Reporting group values	Induction Period: Placebo	Induction Period: PF- 06480605 50 mg	Induction Period: PF-06480605 150 mg
Number of subjects	45	47	62
Age categorical Units: Subjects			

Age Continuous Units: years arithmetic mean standard deviation	39.9 ± 12.90	37.8 ± 13.91	42.2 ± 13.02
Sex: Female, Male Units: participants			
Female	21	19	23
Male	24	28	39
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	1	2	0
Asian	13	9	9
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	1	0	0
White	30	35	49
More than one race	0	0	0
Unknown or Not Reported	0	1	4
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	2	3	2
Not Hispanic or Latino	42	43	55
Unknown or Not Reported	1	1	5

Reporting group values	Induction Period: PF-06480605 450 mg	Total	
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Number of subjects	91	245	
Age categorical			
Units: Subjects			

Age Continuous			
Units: years			
arithmetic mean	41.6		
standard deviation	± 13.79	-	
Sex: Female, Male			
Units: participants			
Female	36	99	
Male	55	146	
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	2	5	
Asian	18	49	
Native Hawaiian or Other Pacific Islander	0	0	
Black or African American	0	1	
White	70	184	
More than one race	0	0	
Unknown or Not Reported	1	6	
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	3	10	
Not Hispanic or Latino	86	226	
Unknown or Not Reported	2	9	

End points

End points reporting groups

Reporting group title	Induction Period: Placebo
Reporting group description: Participants received PF-06480605 matching placebo, as a subcutaneous (SC) injection, every 4 weeks (Q4W) up to Week 12.	
Reporting group title	Induction Period: PF-06480605 50 mg
Reporting group description: Participants received PF-06480605, 50 mg, as a SC injection, Q4W up to Week 12.	
Reporting group title	Induction Period: PF-06480605 150 mg
Reporting group description: Participants received PF-06480605, 150 mg, as a SC injection, Q4W up to Week 12.	
Reporting group title	Induction Period: PF-06480605 450 mg
Reporting group description: Participants received PF-06480605, 450 mg, as a SC injection, Q4W up to Week 12.	
Reporting group title	Placebo (Induction) to PF-06480605 (Chronic) 50 mg
Reporting group description: Participants who received placebo and completed the 12-week induction period received PF-06480605, 50 mg, as a SC injection, Q4W from Week 16 to Week 52 in the chronic period.	
Reporting group title	Placebo (Induction) to PF-06480605 (Chronic) 150 mg
Reporting group description: Participants who received placebo and completed the 12-week induction period received PF-06480605, 150 mg, as a SC injection, Q4W from Week 16 to Week 52 in the chronic period.	
Reporting group title	Placebo (Induction) to PF-06480605 (Chronic) 450 mg
Reporting group description: Participants who received placebo and completed the 12-week induction period received PF-06480605, 450 mg, as a SC injection, Q4W from Week 16 to Week 52 in the chronic period.	
Reporting group title	PF-06480605 50 mg (Induction) to PF-06480605 (Chronic) 50 mg
Reporting group description: Participants who received PF-06480605, 50 mg, and completed the 12-week induction period received PF-06480605, 50 mg, as a SC injection, Q4W from Week 16 to Week 52 in the chronic period.	
Reporting group title	PF-06480605 150 mg (Induction) to PF-06480605 (Chronic) 50 mg
Reporting group description: Participants who received PF-06480605, 150 mg, and completed the 12-week induction period received PF-06480605, 50 mg, as a SC injection, Q4W from Week 16 to Week 52 in the chronic period.	
Reporting group title	PF-06480605 150 mg (Induction) to PF-06480605 (Chronic) 150 mg
Reporting group description: Participants who received PF-06480605, 150 mg, and completed the 12-week induction period received PF-06480605, 150 mg, as a SC injection, Q4W from Week 16 to Week 52 in the chronic period.	
Reporting group title	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 50 mg
Reporting group description: Participants who received PF-06480605, 450 mg, and completed the 12-week induction period received PF-06480605, 50 mg, as a SC injection, Q4W from Week 16 to Week 52 in the chronic period.	
Reporting group title	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 150 mg
Reporting group description: Participants who received PF-06480605, 450 mg, and completed the 12-week induction period received PF-06480605, 150 mg, as a SC injection, Q4W from Week 16 to Week 52 in the chronic period.	
Reporting group title	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 450 mg

Reporting group description:

Participants who received PF-06480605, 450 mg, and completed the 12-week induction period received PF-06480605, 450 mg, as a SC injection, Q4W from Week 16 to Week 52 in the chronic period.

Primary: Induction Period: Percentage of Participants Who Achieved Clinical Remission at Week 14

End point title	Induction Period: Percentage of Participants Who Achieved Clinical Remission at Week 14
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End point description:

Clinical remission was defined as total Mayo Score ≤ 2 , with no individual subscore > 1 . Mayo Score was a tool designed to measure disease activity for UC. The score ranges from 0 – 12 and was a composite of the four following assessments of disease activity: stool frequency subscore, rectal bleeding subscore, endoscopy subscore, and physician's global assessment (PGA) subscore. Each of the four assessments was rated with a score from 0 to 3, with higher scores indicating more severe disease activity.

Percentages have been rounded off to the nearest whole number. Evaluable population ITT included all participants randomly assigned to investigational product (IP) and who took at least one dose of IP in induction period. Participants were analyzed according to the product they received. Number analyzed is the number of participants with data available for analysis.

End point type	Primary
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End point timeframe:

At Week 14

End point values	Induction Period: Placebo	Induction Period: PF-06480605 50 mg	Induction Period: PF-06480605 150 mg	Induction Period: PF-06480605 450 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	43	47	60	88
Units: percentage of participants				
number (confidence interval 90%)	11.6 (5.77 to 22.88)	25.5 (15.44 to 37.19)	23.3 (14.98 to 33.98)	23.9 (16.58 to 32.06)

Statistical analyses

Statistical analysis title	Placebo vs PF-06480605 50 mg
Comparison groups	Induction Period: Placebo v Induction Period: PF-06480605 50 mg
Number of subjects included in analysis	90
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0545 ^[1]
Method	Chan and Zhang Method
Parameter estimate	Risk difference (RD)
Point estimate	13.9
Confidence interval	
level	90 %
sides	2-sided
lower limit	-0.2
upper limit	27.65

Notes:

[1] - One-sided P-value

Statistical analysis title	Placebo vs PF-06480605 450 mg
Comparison groups	Induction Period: Placebo v Induction Period: PF-06480605 450 mg
Number of subjects included in analysis	131
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0642 ^[2]
Method	Chan and Zhang Method
Parameter estimate	Risk difference (RD)
Point estimate	12.24
Confidence interval	
level	90 %
sides	2-sided
lower limit	-0.64
upper limit	22.91

Notes:

[2] - One-sided P-value

Statistical analysis title	Placebo vs PF-06480605 150 mg
Comparison groups	Induction Period: Placebo v Induction Period: PF-06480605 150 mg
Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0823 ^[3]
Method	Chan and Zhang Method
Parameter estimate	Risk difference (RD)
Point estimate	11.71
Confidence interval	
level	90 %
sides	2-sided
lower limit	-1.7
upper limit	24.09

Notes:

[3] - One-sided P-value

Primary: Induction Period: Number of Participants With Treatment-Emergent Adverse Events (TEAEs)

End point title	Induction Period: Number of Participants With Treatment-Emergent Adverse Events (TEAEs) ^[4]
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End point description:

TEAEs was defined as all events that started on or after the first dosing day and time, but before the last dose plus the lag time. An adverse event (AE) was any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of study intervention. Safety analysis population included all participants who received at least one dose of IP during the induction period. Participants were analyzed according to the product they received. Results may differ from publications that used Week 14 as the end of the AE reporting timeframe.

End point type	Primary
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End point timeframe:

From initiation of study treatment to either first dose in the chronic period or end of safety follow-up, whichever occurs first. (Approximately 16 weeks plus 12-week safety follow-up, if applicable.)

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No formal statistical analysis was planned for this study.

End point values	Induction Period: Placebo	Induction Period: PF-06480605 50 mg	Induction Period: PF-06480605 150 mg	Induction Period: PF-06480605 450 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	45	47	62	91
Units: participants	25	16	29	49

Statistical analyses

No statistical analyses for this end point

Primary: Induction Period: Number of Participants With Serious Adverse Events (SAEs)

End point title	Induction Period: Number of Participants With Serious Adverse Events (SAEs) ^[5]
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End point description:

An AE was any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of study intervention. SAE was defined as any untoward medical occurrence that, at any dose: results in death; is life-threatening; requires inpatient hospitalization or prolongation of existing hospitalization; results in persistent disability/incapacity; or is a congenital anomaly/birth defect. Safety analysis population included all participants who received at least one dose of IP during the induction period. Participants were analyzed according to the product they received. Results may differ from publications that used Week 14 as the end of the AE reporting timeframe.

End point type	Primary
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End point timeframe:

From initiation of study treatment to either first dose in the chronic period or end of safety follow-up, whichever occurs first. (Approximately 16 weeks plus 12-week safety follow-up, if applicable.)

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No formal statistical analysis was planned for this study.

End point values	Induction Period: Placebo	Induction Period: PF-06480605 50 mg	Induction Period: PF-06480605 150 mg	Induction Period: PF-06480605 450 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	45	47	62	91
Units: participants	4	3	1	4

Statistical analyses

No statistical analyses for this end point

Primary: Induction Period: Number of Participants With AEs or SAEs Leading to Discontinuation

End point title	Induction Period: Number of Participants With AEs or SAEs Leading to Discontinuation ^[6]
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End point description:

An AE was any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. An AE can therefore be any unfavorable and unintended sign (including an abnormal lab finding), symptom, or disease (new or exacerbated) temporally associated with the use of study intervention. SAE was defined as any untoward medical occurrence that, at any dose: results in death; is life-threatening; requires inpatient hospitalization or prolongation of existing hospitalization; results in persistent disability/incapacity; or is a congenital anomaly/birth defect. Participants who had an AE/SAE that led to study discontinuation have been reported here. Safety Population: All participants who took ≥ 1 dose of IP during induction. Participants were analyzed according to the product they received. Results may differ from publications that used Week 14 as the end of the AE reporting timeframe.

End point type	Primary
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End point timeframe:

From initiation of study treatment to either first dose in the chronic period or end of safety follow-up, whichever occurs first. (Approximately 16 weeks plus 12-week safety follow-up, if applicable.)

Notes:

[6] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No formal statistical analysis was planned for this study.

End point values	Induction Period: Placebo	Induction Period: PF-06480605 50 mg	Induction Period: PF-06480605 150 mg	Induction Period: PF-06480605 450 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	45	47	62	91
Units: participants	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Chronic Period: Number of Participants With TEAEs

End point title	Chronic Period: Number of Participants With TEAEs ^[7]
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End point description:

TEAEs was defined as all events that started on or after the first dosing day and time, but before the last dose plus the lag time. An AE was any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of study intervention. Evaluable population modified intent-to-treat (mITT) included all participants randomly assigned to IP who took at least one dose of IP in CPT. Participants were analyzed according to the treatment sequence they were randomized. Results may differ from publications that used Week 56 as the end of the AE reporting timeframe.

End point type	Primary
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End point timeframe:

From first dose of study treatment in the chronic period to end of safety follow-up. (Approximately 40 weeks plus 12-week safety follow-up.)

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No formal statistical analysis was planned for this study.

End point values	Placebo (Induction) to PF-06480605 (Chronic) 50 mg	Placebo (Induction) to PF-06480605 (Chronic) 150 mg	Placebo (Induction) to PF-06480605 (Chronic) 450 mg	PF-06480605 50 mg (Induction) to PF-06480605 (Chronic) 50 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	14	14	46
Units: participants	5	9	9	30

End point values	PF-06480605 150 mg (Induction) to PF-06480605 (Chronic) 50 mg	PF-06480605 150 mg (Induction) to PF-06480605 (Chronic) 150 mg	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 50 mg	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 150 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	27	30	26	26
Units: participants	16	15	18	18

End point values	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 450 mg			
Subject group type	Reporting group			
Number of subjects analysed	29			
Units: participants	20			

Statistical analyses

No statistical analyses for this end point

Primary: Chronic Period: Number of Participants With SAEs

End point title	Chronic Period: Number of Participants With SAEs ^[8]
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End point description:

An AE was any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of study intervention. SAE was defined as any untoward medical occurrence that, at any dose: results in death; is life-threatening; requires inpatient hospitalization or prolongation of existing hospitalization; results in persistent disability/incapacity; or is a congenital anomaly/birth defect. Evaluable population mITT included all participants randomly assigned to IP who took at least one dose of IP in CPT. Participants were analyzed according to the treatment sequence they were randomized. Results may differ from publications that

used Week 56 as the end of the AE reporting timeframe.

End point type	Primary
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End point timeframe:

From first dose of study treatment in the chronic period to end of safety follow-up. (Approximately 40 weeks plus 12-week safety follow-up.)

Notes:

[8] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No formal statistical analysis was planned for this study.

End point values	Placebo (Induction) to PF-06480605 (Chronic) 50 mg	Placebo (Induction) to PF-06480605 (Chronic) 150 mg	Placebo (Induction) to PF-06480605 (Chronic) 450 mg	PF-06480605 50 mg (Induction) to PF-06480605 (Chronic) 50 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	14	14	46
Units: participants	0	0	0	5

End point values	PF-06480605 150 mg (Induction) to PF-06480605 (Chronic) 50 mg	PF-06480605 150 mg (Induction) to PF-06480605 (Chronic) 150 mg	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 50 mg	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 150 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	27	30	26	26
Units: participants	1	0	2	1

End point values	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 450 mg			
Subject group type	Reporting group			
Number of subjects analysed	29			
Units: participants	4			

Statistical analyses

No statistical analyses for this end point

Primary: Chronic Period: Number of Participants With AEs or SAEs Leading to Discontinuation

End point title	Chronic Period: Number of Participants With AEs or SAEs Leading to Discontinuation ^[9]
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End point description:

An AE is any untoward medical occurrence in a study participant, temporally associated with study intervention use, regardless of causality. It is any unfavorable/unintended sign (e.g., abnormal lab finding), symptom, or disease (new/exacerbated) temporally associated with study intervention. An SAE is any untoward medical occurrence that, at any dose, results in: death; is life-threatening; requires inpatient hospitalization/prolongation; results in persistent disability/incapacity; or is a congenital anomaly/birth defect. Evaluable mITT Population: All randomized participants who took ≥ 1 dose of IP in the chronic period, analyzed per randomized treatment sequence. AE/SAE-related study discontinuations are reported here. Results may differ from publications that used Week 56 as the end of the AE reporting timeframe.

End point type	Primary
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End point timeframe:

From first dose of study treatment in the chronic period to end of safety follow-up. (Approximately 40 weeks plus 12-week safety follow-up.)

Notes:

[9] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No formal statistical analysis was planned for this study.

End point values	Placebo (Induction) to PF-06480605 (Chronic) 50 mg	Placebo (Induction) to PF-06480605 (Chronic) 150 mg	Placebo (Induction) to PF-06480605 (Chronic) 450 mg	PF-06480605 50 mg (Induction) to PF-06480605 (Chronic) 50 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	14	14	46
Units: participants	0	0	0	0

End point values	PF-06480605 150 mg (Induction) to PF-06480605 (Chronic) 50 mg	PF-06480605 150 mg (Induction) to PF-06480605 (Chronic) 150 mg	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 50 mg	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 150 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	27	30	26	26
Units: participants	0	0	0	0

End point values	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 450 mg			
Subject group type	Reporting group			
Number of subjects analysed	29			
Units: participants	0			

Statistical analyses

Secondary: Induction and Chronic Periods: Percentage of Participants Who Achieved Remission as per Food and Drug Administration (FDA) Definition 1 (Modified Remission 1)

End point title	Induction and Chronic Periods: Percentage of Participants Who Achieved Remission as per Food and Drug Administration (FDA) Definition 1 (Modified Remission 1)
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End point description:

Modified remission 1 was defined as an endoscopic subscore = 0 (normal or inactive disease) or 1 (mild disease), stool frequency subscore = 0 (normal number of stools per day), and rectal bleeding subscore = 0 (no blood seen) at Week 14/Week 56. Mayo Score was a tool designed to measure disease activity for UC. The score ranges from 0 – 12 and was a composite of the four following assessments of disease activity: stool frequency subscore, rectal bleeding subscore, endoscopy subscore, and PGA subscore. Each of the four assessments was rated with a score from 0 to 3, with higher scores indicating more severe disease activity. Percentages have been rounded off to the nearest whole number. Evaluable ITT and mITT populations included all participants randomly assigned to IP and who took at least one dose of IP in induction and chronic, respectively. Number analyzed is the number of participants with data available for analysis.

End point type	Secondary
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End point timeframe:

Induction Period: At Week 14; Chronic Period: At Week 56

End point values	Induction Period: Placebo	Placebo (Induction) to PF-06480605 (Chronic) 50 mg	Induction Period: PF-06480605 50 mg	Placebo (Induction) to PF-06480605 (Chronic) 150 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	43	12	47	13
Units: percentage of participants				
number (confidence interval 90%)	7.0 (2.59 to 16.96)	16.7 (4.52 to 39.84)	14.9 (8.05 to 25.12)	23.1 (8.80 to 46.97)

End point values	Induction Period: PF-06480605 150 mg	Placebo (Induction) to PF-06480605 (Chronic) 450 mg	Induction Period: PF-06480605 450 mg	PF-06480605 50 mg (Induction) to PF-06480605 (Chronic) 50 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60	14	88	42
Units: percentage of participants				
number (confidence interval 90%)	13.3 (6.81 to 21.83)	21.4 (8.15 to 46.00)	14.8 (9.50 to 21.77)	16.7 (9.06 to 27.68)

End point values	PF-06480605 150 mg (Induction) to PF-06480605 (Chronic) 50	PF-06480605 150 mg (Induction) to PF-06480605 (Chronic) 150	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 50	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 150
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	mg	mg	mg	mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	27	26	25	24
Units: percentage of participants				
number (confidence interval 90%)	22.2 (10.15 to 38.16)	23.1 (10.56 to 39.84)	16.0 (7.17 to 30.73)	20.8 (10.50 to 36.99)

End point values	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 450 mg			
Subject group type	Reporting group			
Number of subjects analysed	28			
Units: percentage of participants				
number (confidence interval 90%)	17.9 (8.95 to 33.31)			

Statistical analyses

Statistical analysis title	Placebo vs PF-06480605 50 mg
Comparison groups	Induction Period: Placebo v Induction Period: PF-06480605 50 mg
Number of subjects included in analysis	90
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1398 ^[10]
Method	Chan and Zhang Method
Parameter estimate	Risk difference (RD)
Point estimate	7.92
Confidence interval	
level	90 %
sides	2-sided
lower limit	-3.62
upper limit	20.04

Notes:

[10] - One-sided P-value

Statistical analysis title	Placebo vs PF-06480605 450 mg
Comparison groups	Induction Period: Placebo v Induction Period: PF-06480605 450 mg

Number of subjects included in analysis	131
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1498 ^[11]
Method	Chan and Zhang Method
Parameter estimate	Risk difference (RD)
Point estimate	7.8
Confidence interval	
level	90 %
sides	2-sided
lower limit	-3.7
upper limit	17.06

Notes:

[11] - One-sided P-value

Statistical analysis title	Placebo vs PF-06480605 150 mg
Comparison groups	Induction Period: Placebo v Induction Period: PF-06480605 150 mg
Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2038 ^[12]
Method	Chan and Zhang Method
Parameter estimate	Risk difference (RD)
Point estimate	6.36
Confidence interval	
level	90 %
sides	2-sided
lower limit	-4.88
upper limit	17.06

Notes:

[12] - One-sided P-value

Secondary: Induction and Chronic Periods: Percentage of Participants Who Achieved Remission as per FDA Definition 2 (Modified Remission 2)

End point title	Induction and Chronic Periods: Percentage of Participants Who Achieved Remission as per FDA Definition 2 (Modified Remission 2)
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End point description:

Modified remission 2 was defined as an endoscopic subscore = 0 (normal/inactive disease) or 1 (mild disease), ≥ 1 point decrease from baseline to achieve a stool frequency subscore = 0 (normal number of stools per day) or 1 (1 or 2 more stools than normal), and rectal bleeding subscore = 0 (no blood seen) at Week 14/Week 56. Mayo Score was a tool designed to measure disease activity for UC. The score ranges from 0 – 12 and was a composite of the four following assessments of disease activity: stool frequency subscore, rectal bleeding subscore, endoscopy subscore, and PGA subscore. The four assessments were rated with a score from 0 to 3, with higher scores indicating more severe disease activity. Percentages have been rounded off to the nearest whole number. Evaluable ITT and mITT populations=all participants randomly assigned to IP and who took at least one dose of IP in induction and chronic, respectively. Number analyzed=number of participants with data available for analysis.

End point type	Secondary
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End point timeframe:

Induction Period: At Week 14; Chronic Period: At Week 56

End point values	Induction Period: Placebo	Placebo (Induction) to PF-06480605 (Chronic) 50 mg	Induction Period: PF- 06480605 50 mg	Placebo (Induction) to PF-06480605 (Chronic) 150 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	43	12	47	13
Units: percentage of participants				
number (confidence interval 90%)	11.6 (5.77 to 22.88)	50.0 (27.13 to 72.87)	29.8 (19.94 to 42.34)	30.8 (14.16 to 54.45)

End point values	Induction Period: PF- 06480605 150 mg	Placebo (Induction) to PF-06480605 (Chronic) 450 mg	Induction Period: PF- 06480605 450 mg	PF-06480605 50 mg (Induction) to PF-06480605 (Chronic) 50 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60	14	88	42
Units: percentage of participants				
number (confidence interval 90%)	35.0 (25.14 to 45.24)	35.7 (16.30 to 59.44)	31.8 (23.65 to 40.77)	31.0 (19.38 to 43.33)

End point values	PF-06480605 150 mg (Induction) to PF-06480605 (Chronic) 50 mg	PF-06480605 150 mg (Induction) to PF-06480605 (Chronic) 150 mg	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 50 mg	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 150 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	27	26	25	24
Units: percentage of participants				
number (confidence interval 90%)	33.3 (20.38 to 50.00)	38.5 (23.32 to 56.43)	28.0 (15.76 to 45.61)	33.3 (17.80 to 52.14)

End point values	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 450 mg			
Subject group type	Reporting group			
Number of subjects analysed	28			
Units: percentage of participants				
number (confidence interval 90%)	35.7 (20.85 to 52.70)			

Statistical analyses

Statistical analysis title	Placebo vs PF-06480605 50 mg
Comparison groups	Induction Period: Placebo v Induction Period: PF-06480605 50 mg
Number of subjects included in analysis	90
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0189 ^[13]
Method	Chan and Zhang Method
Parameter estimate	Risk difference (RD)
Point estimate	18.16
Confidence interval	
level	90 %
sides	2-sided
lower limit	3.25
upper limit	32.23

Notes:

[13] - One-sided P-value

Statistical analysis title	Placebo vs PF-06480605 450 mg
Comparison groups	Induction Period: Placebo v Induction Period: PF-06480605 450 mg
Number of subjects included in analysis	131
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0117 ^[14]
Method	Chan and Zhang Method
Parameter estimate	Risk difference (RD)
Point estimate	20.19
Confidence interval	
level	90 %
sides	2-sided
lower limit	3.22
upper limit	31.31

Notes:

[14] - One-sided P-value

Statistical analysis title	Placebo vs PF-06480605 150 mg
Comparison groups	Induction Period: Placebo v Induction Period: PF-06480605 150 mg

Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0045 ^[15]
Method	Chan and Zhang Method
Parameter estimate	Risk difference (RD)
Point estimate	23.37
Confidence interval	
level	90 %
sides	2-sided
lower limit	6.24
upper limit	36.28

Notes:

[15] - One-sided P-value

Secondary: Induction and Chronic Periods: Percentage of Participants Who Achieved Endoscopic Improvement

End point title	Induction and Chronic Periods: Percentage of Participants Who Achieved Endoscopic Improvement
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End point description:

Endoscopic improvement was defined as an endoscopic subscore of 0 (Normal or inactive disease) or 1 (Mild disease [erythema, decreased vascular pattern, mild friability]) at Week 14/Week 56. Mayo Score was a tool designed to measure disease activity for UC. The score ranges from 0 – 12 and was a composite of the four following assessments of disease activity: stool frequency subscore, rectal bleeding subscore, endoscopy subscore, and PGA subscore. Each of the four assessments was rated with a score from 0 to 3. Higher scores indicate more severe disease activity. Percentages have been rounded off to the nearest whole number. Evaluable ITT and mITT populations included all participants randomly assigned to IP and who took at least one dose of IP in induction and chronic, respectively. Number analyzed is the number of participants with data available for analysis.

End point type	Secondary
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End point timeframe:

Induction Period: At Week 14; Chronic Period: At Week 56

End point values	Induction Period: Placebo	Placebo (Induction) to PF-06480605 (Chronic) 50 mg	Induction Period: PF-06480605 50 mg	Placebo (Induction) to PF-06480605 (Chronic) 150 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	43	12	47	13
Units: percentage of participants				
number (confidence interval 90%)	18.6 (9.61 to 30.24)	66.7 (39.84 to 84.58)	40.4 (28.33 to 53.46)	38.5 (17.28 to 62.14)

End point values	Induction Period: PF-06480605 150 mg	Placebo (Induction) to PF-06480605 (Chronic) 450 mg	Induction Period: PF-06480605 450 mg	PF-06480605 50 mg (Induction) to PF-06480605 (Chronic) 50 mg
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Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60	14	88	42
Units: percentage of participants				
number (confidence interval 90%)	38.3 (27.81 to 48.61)	42.9 (22.38 to 64.51)	40.9 (32.06 to 50.00)	38.1 (25.56 to 51.95)

End point values	PF-06480605 150 mg (Induction) to PF-06480605 (Chronic) 50 mg	PF-06480605 150 mg (Induction) to PF-06480605 (Chronic) 150 mg	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 50 mg	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 150 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	27	28	25	24
Units: percentage of participants				
number (confidence interval 90%)	37.0 (22.12 to 54.66)	39.3 (23.83 to 56.49)	36.0 (21.43 to 54.39)	37.5 (22.08 to 55.27)

End point values	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 450 mg			
Subject group type	Reporting group			
Number of subjects analysed	28			
Units: percentage of participants				
number (confidence interval 90%)	50.0 (33.31 to 66.69)			

Statistical analyses

Statistical analysis title	Placebo vs PF-06480605 50 mg
Comparison groups	Induction Period: Placebo v Induction Period: PF-06480605 50 mg
Number of subjects included in analysis	90
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0146 ^[16]
Method	Chan and Zhang Method
Parameter estimate	Risk difference (RD)
Point estimate	21.82
Confidence interval	
level	90 %
sides	2-sided
lower limit	4.14
upper limit	37.3

Notes:

[16] - One-sided P-value

Statistical analysis title	Placebo vs PF-06480605 450 mg
Comparison groups	Induction Period: Placebo v Induction Period: PF-06480605 450 mg
Number of subjects included in analysis	131
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0094 ^[17]
Method	Chan and Zhang Method
Parameter estimate	Risk difference (RD)
Point estimate	22.3
Confidence interval	
level	90 %
sides	2-sided
lower limit	3.22
upper limit	34.95

Notes:

[17] - One-sided P-value

Statistical analysis title	Placebo vs PF-06480605 150 mg
Comparison groups	Induction Period: Placebo v Induction Period: PF-06480605 150 mg
Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0167 ^[18]
Method	Chan and Zhang Method
Parameter estimate	Risk difference (RD)
Point estimate	19.73
Confidence interval	
level	90 %
sides	2-sided
lower limit	2.76
upper limit	34.05

Notes:

[18] - One-sided P-value

Secondary: Induction and Chronic Periods: Percentage of Participants Who Achieved Endoscopic Remission

End point title	Induction and Chronic Periods: Percentage of Participants Who Achieved Endoscopic Remission
End point description:	Endoscopic remission was defined as an endoscopic subscore of 0 (Normal or inactive disease) at Week 14/Week 56. Mayo Score was a tool designed to measure disease activity for UC. The score ranges from 0 – 12 and was a composite of the four following assessments of disease activity: stool frequency subscore, rectal bleeding subscore, endoscopy subscore, and PGA subscore. Each of the four assessments was rated with a score from 0 to 3. Higher scores indicate more severe disease activity. Percentages have been rounded off to the nearest whole number. Evaluable ITT and mITT populations included all participants randomly assigned to IP and who took at least one dose of IP in induction and chronic, respectively. Number analyzed is the number of participants with data available for analysis.
End point type	Secondary

End point timeframe:

Induction Period: At Week 14; Chronic Period: At Week 56

End point values	Induction Period: Placebo	Placebo (Induction) to PF-06480605 (Chronic) 50 mg	Induction Period: PF-06480605 50 mg	Placebo (Induction) to PF-06480605 (Chronic) 150 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	43	12	47	13
Units: percentage of participants				
number (confidence interval 90%)	7.0 (2.59 to 16.96)	16.7 (4.52 to 39.84)	19.1 (11.18 to 30.27)	23.1 (8.80 to 46.97)

End point values	Induction Period: PF-06480605 150 mg	Placebo (Induction) to PF-06480605 (Chronic) 450 mg	Induction Period: PF-06480605 450 mg	PF-06480605 50 mg (Induction) to PF-06480605 (Chronic) 50 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60	14	88	42
Units: percentage of participants				
number (confidence interval 90%)	10.0 (4.45 to 18.01)	28.6 (13.09 to 54.00)	10.2 (5.72 to 16.58)	11.9 (5.91 to 22.74)

End point values	PF-06480605 150 mg (Induction) to PF-06480605 (Chronic) 50 mg	PF-06480605 150 mg (Induction) to PF-06480605 (Chronic) 150 mg	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 50 mg	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 150 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	27	28	25	24
Units: percentage of participants				
number (confidence interval 90%)	7.4 (1.99 to 20.38)	7.1 (1.92 to 20.10)	16.0 (7.17 to 30.73)	8.3 (2.24 to 22.08)

End point values	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 450 mg			
Subject group type	Reporting group			
Number of subjects analysed	28			
Units: percentage of participants				

number (confidence interval 90%)	21.4 (9.77 to 36.62)			
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Statistical analyses

Statistical analysis title	Placebo vs PF-06480605 50 mg
Comparison groups	Induction Period: Placebo v Induction Period: PF-06480605 50 mg
Number of subjects included in analysis	90
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0489 ^[19]
Method	Chan and Zhang Method
Parameter estimate	Risk difference (RD)
Point estimate	12.17
Confidence interval	
level	90 %
sides	2-sided
lower limit	0.05
upper limit	25.25

Notes:

[19] - One-sided P-value

Statistical analysis title	Placebo vs PF-06480605 450 mg
Comparison groups	Induction Period: Placebo v Induction Period: PF-06480605 450 mg
Number of subjects included in analysis	131
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3995 ^[20]
Method	Chan and Zhang Method
Parameter estimate	Risk difference (RD)
Point estimate	3.25
Confidence interval	
level	90 %
sides	2-sided
lower limit	-7.42
upper limit	11.58

Notes:

[20] - One-sided P-value

Statistical analysis title	Placebo vs PF-06480605 150 mg
Comparison groups	Induction Period: Placebo v Induction Period: PF-06480605 150 mg

Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3396 ^[21]
Method	Chan and Zhang Method
Parameter estimate	Risk difference (RD)
Point estimate	3.02
Confidence interval	
level	90 %
sides	2-sided
lower limit	-7.66
upper limit	12.88

Notes:

[21] - One-sided P-value

Secondary: Induction and Chronic Periods: Trough Concentration (Ctrough) of PF-06480605

End point title	Induction and Chronic Periods: Trough Concentration (Ctrough) of PF-06480605 ^[22]
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End point description:

Pharmacokinetic (PK) population included all participants randomly assigned to IP and received at least one dose of PF-06480605 for whom at least one concentration value was reported. Number analyzed is the number of participants with data available for analysis. n = number of participants with data available for analysis at the specified timepoint. 9999 = The mean and standard deviation (SD) was not estimable as samples were below the limit of quantification (BLQ). 99999 = No participants were analyzed at the specified timepoint.

End point type	Secondary
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End point timeframe:

Induction Period: 30 mins postdose (PD) on Day 1, Weeks (W) 4, 8, 12 and 14; Chronic Period: 30 mins PD on Weeks 16, 20, 24, 28, 32, 36, 40, 44, 48; End of Treatment (EOT) (W52) and Follow-up Visits (FUV) 1 (W56), 2 (W60) and 3 (W64)

Notes:

[22] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Participants who received at least one dose of PF-06480605 are included here.

End point values	Placebo (Induction) to PF-06480605 (Chronic) 50 mg	Induction Period: PF-06480605 50 mg	Placebo (Induction) to PF-06480605 (Chronic) 150 mg	Induction Period: PF-06480605 150 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	45	14	59
Units: nanograms per milliliter (ng/mL)				
arithmetic mean (standard deviation)				
PD-D1 (n=41,59,86,0,0,0,0,0,0,0,0)	99999 (± 99999)	9999 (± 9999)	99999 (± 99999)	1.227 (± 6.7722)
PD-W4 (n=45,58,85,0,0,0,0,0,0,0,0)	99999 (± 99999)	2251 (± 1122.5)	99999 (± 99999)	6568 (± 3043.4)
PD-W8 (n=45,59,84,0,0,0,0,0,0,0,0)	99999 (± 99999)	2232 (± 1858.5)	99999 (± 99999)	8381 (± 4769.8)
PD-W12 (n=45,55,82,0,0,0,0,0,0,0,0)	99999 (± 99999)	2181 (± 2080.3)	99999 (± 99999)	8914 (± 5425.9)
PD-W14 (n=33,40,55,0,0,0,0,0,0,0,0)	99999 (± 99999)	4198 (± 3252.9)	99999 (± 99999)	17110 (± 9380.6)

PD-W16 (n=0,0,0,11,13,13,42,24,28,24,25,29)	9999 (± 9999)	99999 (± 99999)	240.4 (± 862.23)	99999 (± 99999)
PD-W20 (n=0,0,0,12,13,13,43,26,28,21,26,29)	2924 (± 1706.7)	99999 (± 99999)	6680 (± 4188.0)	99999 (± 99999)
PD-W24 (n=0,0,0,12,13,12,39,22,27,24,25,26)	2897 (± 1494.1)	99999 (± 99999)	10990 (± 8884.5)	99999 (± 99999)
PD-W28 (n=0,0,0,11,14,12,39,24,28,20,24,25)	2915 (± 2739.1)	99999 (± 99999)	7587 (± 4748.7)	99999 (± 99999)
PD-W32 (n=0,0,0,11,14,12,38,23,25,21,24,23)	2672 (± 2275.6)	99999 (± 99999)	10520 (± 8027.4)	99999 (± 99999)
PD-W36 (n=0,0,0,11,14,12,36,21,23,20,22,22)	3478 (± 2422.7)	99999 (± 99999)	9279 (± 8345.1)	99999 (± 99999)
PD-W40 (n=0,0,0,11,12,12,36,21,24,18,22,24)	2793 (± 1893.0)	99999 (± 99999)	9246 (± 6289.2)	99999 (± 99999)
PD-W44 (n=0,0,0,10,12,12,33,21,23,17,21,21)	3314 (± 2152.2)	99999 (± 99999)	9346 (± 5199.5)	99999 (± 99999)
PD-W48 (n=0,0,0,9,10,11,33,20,23,15,20,22)	2921 (± 2084.1)	99999 (± 99999)	10750 (± 8216.0)	99999 (± 99999)
EOT (W52) (n=0,0,0,10,9,12,28,21,19,17,19,24)	3532 (± 2447.9)	99999 (± 99999)	10510 (± 10337)	99999 (± 99999)
FUV1 (W56) (n=0,0,0,9,8,9,27,15,14,14,18,21)	4152 (± 3804.3)	99999 (± 99999)	9755 (± 6903.0)	99999 (± 99999)
FUV2 (W60) (n=0,0,0,9,11,8,30,18,19,13,16,20)	1550 (± 1580.2)	99999 (± 99999)	3797 (± 4065.6)	99999 (± 99999)
FUV3 (W64) (n=0,0,0,8,11,8,29,17,19,17,17,17)	1099 (± 2081.3)	99999 (± 99999)	1332 (± 2390.4)	99999 (± 99999)

End point values	Placebo (Induction) to PF-06480605 (Chronic) 450 mg	Induction Period: PF- 06480605 450 mg	PF-06480605 50 mg (Induction) to PF-06480605 (Chronic) 50 mg	PF-06480605 150 mg (Induction) to PF-06480605 (Chronic) 50 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	86	43	26
Units: nanograms per milliliter (ng/mL)				
arithmetic mean (standard deviation)				
PD-D1 (n=41,59,86,0,0,0,0,0,0,0,0)	99999 (± 99999)	1.279 (± 10.209)	99999 (± 99999)	99999 (± 99999)
PD-W4 (n=45,58,85,0,0,0,0,0,0,0,0)	99999 (± 99999)	19660 (± 8637.7)	99999 (± 99999)	99999 (± 99999)
PD-W8 (n=45,59,84,0,0,0,0,0,0,0,0)	99999 (± 99999)	25160 (± 12194)	99999 (± 99999)	99999 (± 99999)
PD-W12 (n=45,55,82,0,0,0,0,0,0,0,0)	99999 (± 99999)	30900 (± 15724)	99999 (± 99999)	99999 (± 99999)
PD-W14 (n=33,40,55,0,0,0,0,0,0,0,0)	99999 (± 99999)	49480 (± 18086)	99999 (± 99999)	99999 (± 99999)
PD-W16 (n=0,0,0,11,13,13,42,24,28,24,25,29)	6.123 (± 22.077)	99999 (± 99999)	1969 (± 1932.7)	9613 (± 6568.8)
PD-W20 (n=0,0,0,12,13,13,43,26,28,21,26,29)	25030 (± 9240.1)	99999 (± 99999)	2516 (± 2279.8)	5476 (± 4062.3)
PD-W24 (n=0,0,0,12,13,12,39,22,27,24,25,26)	29820 (± 15940)	99999 (± 99999)	2956 (± 3018.7)	4811 (± 3089.1)
PD-W28 (n=0,0,0,11,14,12,39,24,28,20,24,25)	38270 (± 12846)	99999 (± 99999)	2613 (± 2763.5)	3391 (± 2267.9)
PD-W32 (n=0,0,0,11,14,12,38,23,25,21,24,23)	38950 (± 21386)	99999 (± 99999)	2330 (± 2253.4)	3608 (± 3088.1)

PD-W36 (n=0,0,0,11,14,12,36,21,23,20,22,22)	36520 (± 20234)	99999 (± 99999)	2802 (± 2573.3)	3417 (± 2301.7)
PD-W40 (n=0,0,0,11,12,12,36,21,24,18,22,24)	41770 (± 18436)	99999 (± 99999)	2820 (± 2590.1)	3374 (± 2922.0)
PD-W44 (n=0,0,0,10,12,12,33,21,23,17,21,21)	45770 (± 20693)	99999 (± 99999)	2867 (± 2655.4)	3385 (± 3540.7)
PD-W48 (n=0,0,0,9,10,11,33,20,23,15,20,22)	46150 (± 19825)	99999 (± 99999)	3159 (± 2810.1)	3876 (± 3276.1)
EOT (W52) (n=0,0,0,10,9,12,28,21,19,17,19,24)	49880 (± 21069)	99999 (± 99999)	2848 (± 3037.0)	3156 (± 2337.1)
FUV1 (W56) (n=0,0,0,9,8,9,27,15,14,14,18,21)	43710 (± 26683)	99999 (± 99999)	3246 (± 2965.2)	3124 (± 2443.2)
FUV2 (W60) (n=0,0,0,9,11,8,30,18,19,13,16,20)	19390 (± 13334)	99999 (± 99999)	1092 (± 1232.9)	1025 (± 858.32)
FUV3 (W64) (n=0,0,0,8,11,8,29,17,19,17,17,17)	7976 (± 5279.5)	99999 (± 99999)	766.1 (± 2372.9)	257.3 (± 318.70)

End point values	PF-06480605 150 mg (Induction) to PF-06480605 (Chronic) 150 mg	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 50 mg	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 150 mg	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 450 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	28	24	26	29
Units: nanograms per milliliter (ng/mL)				
arithmetic mean (standard deviation)				
PD-D1 (n=41,59,86,0,0,0,0,0,0,0,0)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
PD-W4 (n=45,58,85,0,0,0,0,0,0,0,0)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
PD-W8 (n=45,59,84,0,0,0,0,0,0,0,0)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
PD-W12 (n=45,55,82,0,0,0,0,0,0,0,0)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
PD-W14 (n=33,40,55,0,0,0,0,0,0,0,0)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
PD-W16 (n=0,0,0,11,13,13,42,24,28,24,25,29)	12450 (± 7605.4)	39180 (± 19045)	36320 (± 18215)	32450 (± 17064)
PD-W20 (n=0,0,0,12,13,13,43,26,28,21,26,29)	11500 (± 6289.0)	19540 (± 10180)	18200 (± 12244)	34980 (± 17895)
PD-W24 (n=0,0,0,12,13,12,39,22,27,24,25,26)	11090 (± 6765.1)	10040 (± 6001.7)	16890 (± 13735)	35110 (± 16669)
PD-W28 (n=0,0,0,11,14,12,39,24,28,20,24,25)	9840 (± 6630.1)	5894 (± 3973.7)	12920 (± 8418.9)	35080 (± 14331)
PD-W32 (n=0,0,0,11,14,12,38,23,25,21,24,23)	11790 (± 5931.7)	5465 (± 3299.1)	12060 (± 8871.1)	36720 (± 16880)
PD-W36 (n=0,0,0,11,14,12,36,21,23,20,22,22)	11680 (± 6728.9)	4610 (± 2651.5)	12360 (± 7217.1)	33660 (± 14185)
PD-W40 (n=0,0,0,11,12,12,36,21,24,18,22,24)	12050 (± 7678.1)	3900 (± 2874.5)	11830 (± 7571.4)	33660 (± 11189)
PD-W44 (n=0,0,0,10,12,12,33,21,23,17,21,21)	12190 (± 6504.8)	3708 (± 2471.4)	13060 (± 8745.9)	36450 (± 12884)
PD-W48 (n=0,0,0,9,10,11,33,20,23,15,20,22)	13230 (± 7740.3)	4494 (± 3860.2)	13700 (± 10253)	38310 (± 13146)
EOT (W52) (n=0,0,0,10,9,12,28,21,19,17,19,24)	14580 (± 7988.8)	4215 (± 3708.6)	13930 (± 8673.4)	40710 (± 15146)

FUV1 (W56) (n=0,0,0,9,8,9,27,15,14,14,18,21)	12870 (± 7884.4)	4036 (± 3398.6)	13410 (± 9499.7)	43290 (± 17036)
FUV2 (W60) (n=0,0,0,9,11,8,30,18,19,13,16,20)	4806 (± 2827.2)	1285 (± 1436.1)	5266 (± 5457.1)	13930 (± 9036.0)
FUV3 (W64) (n=0,0,0,8,11,8,29,17,19,17,17,17)	2011 (± 1752.1)	825.8 (± 1883.2)	1840 (± 2045.6)	7136 (± 5642.6)

Statistical analyses

No statistical analyses for this end point

Secondary: Induction Period: Change From Baseline in Fecal Calprotectin

End point title	Induction Period: Change From Baseline in Fecal Calprotectin
End point description: Biomarker analysis population included all participants randomly assigned to IP and who took at least one dose of PF-06480605 and in whom at least one measurement of biomarker of interest was reported. Number analyzed is the number of participants with data available for analysis. n = number of participants with data available for analysis at the specified timepoint.	
End point type	Secondary
End point timeframe: Baseline, Weeks 4, 8, and 12	

End point values	Induction Period: Placebo	Induction Period: PF-06480605 50 mg	Induction Period: PF-06480605 150 mg	Induction Period: PF-06480605 450 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	37	41	55	82
Units: micrograms per gram (µg/g)				
arithmetic mean (standard deviation)				
Baseline (n=37,41,55,82)	10.62 (± 2.145)	9.99 (± 2.105)	10.78 (± 2.120)	10.23 (± 1.618)
Change at Week 4 (n=35,36,49,79)	-0.32 (± 2.294)	-0.38 (± 1.973)	-1.24 (± 2.429)	-0.86 (± 2.618)
Change at Week 8 (n=34,40,43,75)	-0.77 (± 2.601)	-1.28 (± 2.620)	-1.84 (± 2.779)	-1.69 (± 2.991)
Change at Week 12 (n=34,35,44,74)	-0.62 (± 3.208)	-1.36 (± 2.837)	-2.43 (± 2.859)	-1.44 (± 3.003)

Statistical analyses

No statistical analyses for this end point

Secondary: Induction Period: Change From Baseline in High Sensitivity C-reactive Protein (hsCRP)

End point title	Induction Period: Change From Baseline in High Sensitivity C-reactive Protein (hsCRP)
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End point description:

Biomarker analysis population included all participants randomly assigned to IP and who took at least one dose of PF-06480605 and in whom at least one measurement of biomarker of interest was reported. n = number of participants with data available for analysis at the specified timepoint.

End point type	Secondary
End point timeframe:	
Baseline, Weeks 4, 8, and 12	

End point values	Induction Period: Placebo	Induction Period: PF-06480605 50 mg	Induction Period: PF-06480605 150 mg	Induction Period: PF-06480605 450 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	47	62	91
Units: log2-transformed milligrams/liter (mg/L)				
arithmetic mean (standard deviation)				
Baseline (n=40,47,62,91)	1.76 (± 2.135)	1.47 (± 1.990)	1.41 (± 1.799)	1.82 (± 1.924)
Change at Week 4 (n=40,46,61,89)	-0.49 (± 1.503)	-0.48 (± 1.669)	-0.75 (± 1.762)	-1.08 (± 1.577)
Change at Week 8 (n=39,47,58,86)	-0.49 (± 1.929)	-0.45 (± 1.896)	-0.94 (± 2.120)	-1.09 (± 1.697)
Change at Week 12 (n=38,43,54,82)	-0.96 (± 2.305)	-0.71 (± 1.764)	-1.25 (± 1.748)	-1.06 (± 1.834)

Statistical analyses

No statistical analyses for this end point

Secondary: Induction Period: Change From Baseline in Serum Soluble TL1A (sTL1A)

End point title	Induction Period: Change From Baseline in Serum Soluble TL1A (sTL1A)
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End point description:

Biomarker analysis population included all participants randomly assigned to IP and who took at least one dose of PF-06480605 and in whom at least one measurement of biomarker of interest was reported. Number analyzed is the number of participants with data available for analysis. n = number of participants with data available for analysis at the specified timepoint.

End point type	Secondary
End point timeframe:	
Baseline, Weeks 4, 8, and 12	

End point values	Induction Period: Placebo	Induction Period: PF-06480605 50 mg	Induction Period: PF-06480605 150 mg	Induction Period: PF-06480605 450 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	42	58	88
Units: picograms per milliliter (pg/mL)				

arithmetic mean (standard deviation)				
Baseline (n=39,42,58,88)	6.86 (± 0.441)	6.74 (± 0.499)	6.77 (± 0.534)	6.83 (± 0.558)
Change at Week 4 (n=39,40,56,86)	0.01 (± 0.347)	3.45 (± 1.097)	3.85 (± 1.294)	4.91 (± 0.834)
Change at Week 8 (n=39,42,55,83)	-0.05 (± 0.549)	3.14 (± 1.340)	3.80 (± 1.486)	4.88 (± 1.294)
Change at Week 12 (n=36,40,53,81)	-0.02 (± 0.371)	2.86 (± 1.666)	3.72 (± 1.530)	4.71 (± 1.908)

Statistical analyses

No statistical analyses for this end point

Secondary: Induction Period: Number of Participants With Anti-drug Antibodies (ADAs) and Neutralizing Antibodies (NAb) to PF-06480605

End point title	Induction Period: Number of Participants With Anti-drug Antibodies (ADAs) and Neutralizing Antibodies (NAb) to PF-06480605 ^[23]
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End point description:

Samples were considered to be positive for ADA against PF-06480605 if the titer was ≥ 60 , and an ADA sample was considered to be negative if the titer was < 60 . Samples were considered to be positive for NAb against PF-06480605 if the titer was ≥ 5 , and an NAb sample was considered to be negative if the titer was < 5 . Evaluation of NAb is generally relevant only in participants who are positive for ADA. Immunogenicity analysis population included all participants randomly assigned to IP and who took at least one dose of PF-06480605 and in whom at least one post-treatment ADA determination was reported. Number analyzed is the number of participants with data available for analysis. n = number of participants with data available for analysis at the specified timepoint. 9999 = No participants were analyzed at the specified timepoint.

End point type	Secondary
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End point timeframe:

Baseline, Weeks 4, 8, 12, 14

Notes:

[23] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Participants who received at least one dose of PF-06480605 in the induction period only are included here.

End point values	Induction Period: PF-06480605 50 mg	Induction Period: PF-06480605 150 mg	Induction Period: PF-06480605 450 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	45	59	88	
Units: participants				
ADA at Baseline (n=41,59,88)	0	1	2	
NAb at Baseline (n=0,2,2)	9999	0	0	
ADA at Week 4 (n=45,58,86)	29	16	24	
NAb at Week 4 (n=33,27,35)	1	0	0	
ADA at Week 8 (n=45,58,84)	39	34	34	
NAb at Week 8 (n=44,41,41)	10	4	1	
ADA at Week 12 (n=44,56,82)	41	36	36	
NAb at Week 12 (n=42,40,46)	12	7	3	
ADA at Week 14 (n=45,54,83)	41	35	33	
NAb at Week 14 (n=42,39,38)	14	7	3	

Statistical analyses

No statistical analyses for this end point

Secondary: Chronic Period: Percentage of Participants Who Achieved Clinical Remission

End point title	Chronic Period: Percentage of Participants Who Achieved Clinical Remission
End point description:	
Clinical remission was defined as total Mayo Score ≤ 2 , with no individual subscore > 1 . Mayo Score was a tool designed to measure disease activity for UC. The score ranges from 0 – 12 and was a composite of the four following assessments of disease activity: stool frequency subscore, rectal bleeding subscore, endoscopy subscore, and PGA subscore. Each of the four assessments was rated with a score from 0 to 3, with higher scores indicating more severe disease activity. Percentages have been rounded off to the nearest whole number. Evaluable mITT population included all participants randomly assigned to IP and who took at least one dose of IP in the chronic period. Number analyzed is the number of participants with data available for analysis.	
End point type	Secondary
End point timeframe:	
At Week 56	

End point values	Placebo (Induction) to PF-06480605 (Chronic) 50 mg	Placebo (Induction) to PF-06480605 (Chronic) 150 mg	Placebo (Induction) to PF-06480605 (Chronic) 450 mg	PF-06480605 50 mg (Induction) to PF-06480605 (Chronic) 50 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	13	14	42
Units: percentage of participants				
number (confidence interval 90%)	33.3 (15.42 to 60.16)	38.5 (17.28 to 62.14)	35.7 (16.30 to 59.44)	31.0 (19.38 to 43.33)

End point values	PF-06480605 150 mg (Induction) to PF-06480605 (Chronic) 50 mg	PF-06480605 150 mg (Induction) to PF-06480605 (Chronic) 150 mg	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 50 mg	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 150 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	27	26	25	24
Units: percentage of participants				
number (confidence interval 90%)	29.6 (15.68 to 45.34)	34.6 (20.86 to 52.62)	24.0 (11.01 to 41.68)	25.0 (11.49 to 42.28)

End point values	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 450 mg			
Subject group type	Reporting group			
Number of subjects analysed	28			
Units: percentage of participants				
number (confidence interval 90%)	39.3 (23.83 to 56.49)			

Statistical analyses

No statistical analyses for this end point

Secondary: Chronic Period: Percentage of Participants Who Achieved Sustained Clinical Remission

End point title	Chronic Period: Percentage of Participants Who Achieved Sustained Clinical Remission
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End point description:

Clinical remission was defined as total Mayo Score ≤ 2 , with no individual subscore > 1 . Mayo Score was a tool designed to measure disease activity for UC. The score ranges from 0 – 12 and was a composite of the four following assessments of disease activity: stool frequency subscore, rectal bleeding subscore, endoscopy subscore, and PGA subscore. Each of the four assessments was rated with a score from 0 to 3, with higher scores indicating more severe disease activity. Participants with sustained clinical remission were defined as those who achieved clinical remission at both Weeks 14 and 56. Percentages have been rounded off to the nearest whole number. Evaluable mITT population. Number analyzed is the number of participants with data available for analysis. Participants were assessed at Week 56 if they achieved remission at Week 14. No participants in the Placebo (Induction) to PF-06480605 50 mg (Chronic) met the remission criteria at Week 14. Hence, this arm has been excluded.

End point type	Secondary
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End point timeframe:

At Weeks 14 and 56

End point values	Placebo (Induction) to PF-06480605 (Chronic) 150 mg	Placebo (Induction) to PF-06480605 (Chronic) 450 mg	PF-06480605 50 mg (Induction) to PF-06480605 (Chronic) 50 mg	PF-06480605 150 mg (Induction) to PF-06480605 (Chronic) 50 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	4	12	6
Units: percentage of participants				
number (confidence interval 90%)	0 (0 to 0)	25.0 (2.60 to 67.95)	50.0 (27.13 to 72.87)	50.0 (20.09 to 79.91)

End point values	PF-06480605 150 mg (Induction) to PF-06480605 (Chronic) 150 mg	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 50 mg	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 150 mg	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 450 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	7	6	7
Units: percentage of participants				
number (confidence interval 90%)	62.5 (28.92 to 85.31)	28.6 (7.88 to 65.87)	50.0 (20.09 to 79.91)	85.7 (50.00 to 98.51)

Statistical analyses

No statistical analyses for this end point

Secondary: Chronic Period: Percentage of Participants Who Achieved Sustained Remission as per FDA Definition 1 (Modified Remission 1)

End point title	Chronic Period: Percentage of Participants Who Achieved Sustained Remission as per FDA Definition 1 (Modified Remission 1)
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End point description:

Modified remission 1 = endoscopic subscore = 0 (normal/inactive disease) / 1 (mild disease), stool frequency subscore = 0 (normal number of stools per day), & rectal bleeding subscore = 0 (no blood seen) at Week 14/Week 56. Mayo Score was used to measure disease activity for UC. Score range = 0-12 & was a composite of 4 following assessments of disease activity: stool frequency subscore, rectal bleeding subscore, endoscopy subscore, & PGA subscore. The 4 assessments were rated with a score from 0-3, with higher scores indicating more severe disease activity. Participants with sustained clinical remission = who achieved clinical remission at both Weeks 14 & 56. Percentages have been rounded off. Evaluable mITT population. Number analyzed = number of participants with data available for analysis. No participants in Placebo (Induction) to PF-06480605 50 mg (Chronic) & Placebo (Induction) to PF-06480605 150 mg (Chronic) met remission criteria at Week 14. Hence, these arms have been excluded.

End point type	Secondary
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End point timeframe:

At Weeks 14 and 56

End point values	Placebo (Induction) to PF-06480605 (Chronic) 450 mg	PF-06480605 50 mg (Induction) to PF-06480605 (Chronic) 50 mg	PF-06480605 150 mg (Induction) to PF-06480605 (Chronic) 50 mg	PF-06480605 150 mg (Induction) to PF-06480605 (Chronic) 150 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	7	5	3
Units: percentage of participants				
number (confidence interval 90%)	33.3 (3.45 to 80.42)	28.6 (7.88 to 65.87)	40.0 (11.22 to 75.34)	66.7 (19.58 to 96.55)

End point values	PF-06480605 450 mg	PF-06480605 450 mg	PF-06480605 450 mg	
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	(Induction) to PF-06480605 (Chronic) 50 mg	(Induction) to PF-06480605 (Chronic) 150 mg	(Induction) to PF-06480605 (Chronic) 450 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	4	3	5	
Units: percentage of participants				
number (confidence interval 90%)	25.0 (2.60 to 67.95)	0 (0 to 53.58)	80.0 (37.93 to 97.91)	

Statistical analyses

No statistical analyses for this end point

Secondary: Chronic Period: Percentage of Participants Who Achieved Sustained Remission as per FDA Definition 2 (Modified Remission 2)

End point title	Chronic Period: Percentage of Participants Who Achieved Sustained Remission as per FDA Definition 2 (Modified Remission 2)
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End point description:

Modified remission 2 = an endoscopic subscore = 0 (normal/inactive disease) or 1 (mild disease), ≥ 1 point decrease from baseline to achieve a stool frequency subscore = 0 (normal number of stools per day) or 1 (1 or 2 more stools than normal), & rectal bleeding subscore = 0 (no blood seen) at Week 14/Week 56. Mayo Score was a tool designed to measure disease activity for UC. Score ranges from 0–12 & was a mix of the four assessments of disease activity: stool frequency subscore, rectal bleeding subscore, endoscopy subscore, & PGA subscore. Each of these assessments was rated with a score from 0 to 3; higher scores indicated more severe disease activity. Participants with sustained CR were defined as those who achieved CR at Weeks 14 & 56. Percentages have been rounded off to the nearest whole number. Evaluable mITT population. Number analyzed is the number of participants with data available for analysis. Participants were assessed at Week 56 if they achieved remission at Week 14.

End point type	Secondary
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End point timeframe:

At Weeks 14 and 56

End point values	Placebo (Induction) to PF-06480605 (Chronic) 50 mg	Placebo (Induction) to PF-06480605 (Chronic) 150 mg	Placebo (Induction) to PF-06480605 (Chronic) 450 mg	PF-06480605 50 mg (Induction) to PF-06480605 (Chronic) 50 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	1	3	14
Units: percentage of participants				
number (confidence interval 90%)	0 (0.00 to 90.00)	0 (0.00 to 90.00)	33.3 (3.45 to 80.42)	42.9 (22.38 to 64.51)

End point values	PF-06480605 150 mg (Induction) to PF-06480605 (Chronic) 50	PF-06480605 150 mg (Induction) to PF-06480605 (Chronic) 150	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 50	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 150
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	mg	mg	mg	mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	11	9	10
Units: percentage of participants				
number (confidence interval 90%)	70.0 (39.34 to 88.42)	54.5 (30.24 to 80.04)	33.3 (12.95 to 61.04)	60.0 (34.08 to 81.24)

End point values	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 450 mg			
Subject group type	Reporting group			
Number of subjects analysed	8			
Units: percentage of participants				
number (confidence interval 90%)	75.0 (41.82 to 93.14)			

Statistical analyses

No statistical analyses for this end point

Secondary: Chronic Period: Percentage of Participants Who Achieved Sustained Endoscopic Improvement

End point title	Chronic Period: Percentage of Participants Who Achieved Sustained Endoscopic Improvement
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End point description:

Endoscopic improvement (EI) = an endoscopic subscore of 0 (Normal or inactive disease) or 1 (Mild disease [erythema, decreased vascular pattern, mild friability]) at Weeks 14 & Week 56. Mayo Score was a tool designed to measure disease activity for UC. The score ranges from 0–12 & was a mix of the four assessments of disease activity: stool frequency subscore, rectal bleeding subscore, endoscopy subscore, and PGA subscore. Each of these assessments was rated with a score from 0 to 3; higher scores indicated more severe disease activity. Participants with sustained EI were defined as those who achieved improvement at Weeks 14 & 56. Percentages have been rounded off to the nearest whole number. Evaluable mITT population included all participants randomly assigned to and who took at least one dose of IP in the chronic period. Number analyzed is the number of participants with data available for analysis. Participants were assessed at Week 56 if they achieved improvement at Week 14.

End point type	Secondary
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End point timeframe:

At Weeks 14 and 56

End point values	Placebo (Induction) to PF-06480605 (Chronic) 50 mg	Placebo (Induction) to PF-06480605 (Chronic) 150 mg	Placebo (Induction) to PF-06480605 (Chronic) 450 mg	PF-06480605 50 mg (Induction) to PF-06480605 (Chronic) 50 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	4	19

Units: percentage of participants				
number (confidence interval 90%)	50.0 (5.13 to 94.87)	0 (0.00 to 68.38)	25.0 (2.60 to 67.95)	47.4 (27.39 to 66.28)

End point values	PF-06480605 150 mg (Induction) to PF-06480605 (Chronic) 50 mg	PF-06480605 150 mg (Induction) to PF-06480605 (Chronic) 150 mg	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 50 mg	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 150 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	13	13	11
Units: percentage of participants				
number (confidence interval 90%)	80.0 (50.00 to 94.55)	61.5 (37.86 to 82.72)	46.2 (24.55 to 71.30)	63.6 (34.98 to 83.08)

End point values	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 450 mg			
Subject group type	Reporting group			
Number of subjects analysed	10			
Units: percentage of participants				
number (confidence interval 90%)	80.0 (50.00 to 94.55)			

Statistical analyses

No statistical analyses for this end point

Secondary: Chronic Period: Percentage of Participants Who Achieved Sustained Endoscopic Remission

End point title	Chronic Period: Percentage of Participants Who Achieved Sustained Endoscopic Remission
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End point description:

Endoscopic remission was defined as an endoscopic subscore of 0 (Normal or inactive disease) at both Week 14 & Week 56. Mayo Score was a tool designed to measure disease activity for UC. The score ranges from 0-12 & was a composite of the 4 following assessments of disease activity: stool frequency subscore, rectal bleeding subscore, endoscopy subscore, & PGA subscore. Each of the 4 assessments was rated with a score from 0-3. Higher scores indicate more severe disease activity. Participants with sustained endoscopic remission were defined as those who achieved endoscopic remission at both Weeks 14 & 56. Percentages have been rounded off to the nearest whole number. Evaluable mITT population. Number analyzed is the number of participants with data available for analysis. Participants were assessed at Week 56 if they achieved remission at Week 14. No participants in Placebo (Induction) to PF-06480605 50 mg (Chronic) met remission criteria at Week 14. Hence, this arm has been excluded.

End point type	Secondary
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End point timeframe:

At Weeks 14 and 56

End point values	Placebo (Induction) to PF-06480605 (Chronic) 150 mg	Placebo (Induction) to PF-06480605 (Chronic) 450 mg	PF-06480605 50 mg (Induction) to PF-06480605 (Chronic) 50 mg	PF-06480605 150 mg (Induction) to PF-06480605 (Chronic) 50 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	1	9	2
Units: percentage of participants				
number (confidence interval 90%)	0 (0 to 68.38)	0 (0 to 90.00)	22.2 (6.08 to 51.52)	50.0 (5.13 to 94.87)

End point values	PF-06480605 150 mg (Induction) to PF-06480605 (Chronic) 150 mg	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 50 mg	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 150 mg	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 450 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	2	3
Units: percentage of participants				
number (confidence interval 90%)	25.0 (2.60 to 67.95)	66.7 (19.58 to 96.55)	50.0 (5.13 to 94.87)	66.7 (19.58 to 96.55)

Statistical analyses

No statistical analyses for this end point

Secondary: Chronic Period: Change From Week 16 in Fecal Calprotectin

End point title	Chronic Period: Change From Week 16 in Fecal Calprotectin
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End point description:

Evaluable mITT population included all participants randomly assigned to IP and who took at least one dose of IP in the chronic period. Number analyzed is the number of participants with data available for analysis. n = number of participants with data available for analysis at the specified time point.

End point type	Secondary
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End point timeframe:

Week 16 (baseline), Weeks 20, 24, 28, 32, 36, 40, 44, 48, 52, 60, and 64

End point values	Placebo (Induction) to PF-06480605 (Chronic) 50 mg	Placebo (Induction) to PF-06480605 (Chronic) 150 mg	Placebo (Induction) to PF-06480605 (Chronic) 450 mg	PF-06480605 50 mg (Induction) to PF-06480605 (Chronic) 50 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	11	12	43
Units: µg/g				
arithmetic mean (standard deviation)				
Week 16 (n=12,11,12,43,23,27,22,24,29)	10.22 (± 1.414)	9.28 (± 2.578)	9.77 (± 2.347)	8.86 (± 2.728)
Change at Week 20 (n=12,10,12,39,23,27,21,23,29)	-0.40 (± 1.174)	-1.46 (± 2.251)	-1.32 (± 1.956)	-0.31 (± 2.114)
Change at Week 24 (n=12,10,12,41,21,26,19,24,28)	-0.71 (± 1.302)	-0.84 (± 1.718)	-1.47 (± 3.331)	0.24 (± 2.242)
Change at Week 28 (n=12,11,11,37,21,24,20,22,23)	-1.55 (± 1.984)	-1.17 (± 3.018)	-1.48 (± 1.817)	-0.16 (± 2.928)
Change at Week 32 (n=10,11,11,36,21,20,19,21,24)	-0.91 (± 2.497)	-1.36 (± 3.553)	-2.47 (± 3.044)	0.21 (± 2.321)
Change at Week 36 (n=11,10,11,32,19,21,17,22,21)	-0.68 (± 2.353)	-1.83 (± 2.542)	-2.36 (± 4.202)	-0.37 (± 2.465)
Change at Week 40 (n=11,10,11,34,17,21,15,19,24)	-1.62 (± 1.814)	0.22 (± 3.962)	-2.59 (± 2.493)	0.17 (± 2.604)
Change at Week 44 (n=11,9,11,32,19,20,14,18,22)	-0.68 (± 2.015)	-1.48 (± 2.693)	-1.81 (± 2.705)	-0.09 (± 2.023)
Change at Week 48 (n=11,10,11,31,19,20,14,19,24)	-0.85 (± 1.843)	-1.01 (± 3.642)	-2.56 (± 3.178)	0.60 (± 2.255)
Change at Week 52 (n=11,10,11,32,17,19,13,15,23)	-1.39 (± 1.922)	-0.39 (± 3.222)	-2.84 (± 2.668)	-0.02 (± 2.327)
Change at Week 60 (n=10,7,9,28,16,15,11,14,20)	-1.31 (± 2.119)	-0.09 (± 1.780)	-1.96 (± 3.041)	0.36 (± 3.169)
Change at Week 64 (n=10,8,9,27,16,16,12,15,20)	-0.54 (± 2.208)	-1.48 (± 2.426)	-0.86 (± 2.562)	0.58 (± 2.705)

End point values	PF-06480605 150 mg (Induction) to PF-06480605 (Chronic) 50 mg	PF-06480605 150 mg (Induction) to PF-06480605 (Chronic) 150 mg	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 50 mg	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 150 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	23	27	22	24
Units: µg/g				
arithmetic mean (standard deviation)				
Week 16 (n=12,11,12,43,23,27,22,24,29)	9.03 (± 2.765)	7.72 (± 2.642)	9.34 (± 2.500)	8.39 (± 2.368)
Change at Week 20 (n=12,10,12,39,23,27,21,23,29)	0.26 (± 2.247)	0.43 (± 1.403)	-0.32 (± 1.740)	0.18 (± 2.569)
Change at Week 24 (n=12,10,12,41,21,26,19,24,28)	-0.15 (± 2.433)	0.36 (± 2.638)	-0.16 (± 1.874)	-0.30 (± 1.619)
Change at Week 28 (n=12,11,11,37,21,24,20,22,23)	-0.15 (± 2.409)	0.03 (± 1.996)	-0.32 (± 2.440)	-0.16 (± 1.716)
Change at Week 32 (n=10,11,11,36,21,20,19,21,24)	-0.32 (± 2.516)	0.31 (± 2.453)	-0.13 (± 2.192)	0.17 (± 2.102)
Change at Week 36 (n=11,10,11,32,19,21,17,22,21)	-0.21 (± 2.584)	0.50 (± 2.152)	-0.67 (± 1.889)	-0.36 (± 2.362)

Change at Week 40 (n=11,10,11,34,17,21,15,19,24)	0.02 (± 1.779)	0.35 (± 2.179)	0.01 (± 2.696)	-0.42 (± 1.672)
Change at Week 44 (n=11,9,11,32,19,20,14,18,22)	-0.98 (± 2.089)	0.02 (± 2.568)	0.21 (± 2.377)	-0.97 (± 1.890)
Change at Week 48 (n=11,10,11,31,19,20,14,19,24)	-0.78 (± 2.542)	0.09 (± 3.320)	0.03 (± 3.027)	-0.54 (± 2.248)
Change at Week 52 (n=11,10,11,32,17,19,13,15,23)	-0.12 (± 1.386)	0.09 (± 2.558)	-0.20 (± 3.294)	-0.61 (± 2.259)
Change at Week 60 (n=10,7,9,28,16,15,11,14,20)	-0.60 (± 1.840)	0.17 (± 2.939)	1.61 (± 1.426)	-0.91 (± 2.915)
Change at Week 64 (n=10,8,9,27,16,16,12,15,20)	0.29 (± 1.834)	0.10 (± 3.982)	0.85 (± 3.321)	-1.18 (± 4.080)

End point values	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 450 mg			
Subject group type	Reporting group			
Number of subjects analysed	29			
Units: µg/g				
arithmetic mean (standard deviation)				
Week 16 (n=12,11,12,43,23,27,22,24,29)	9.21 (± 2.438)			
Change at Week 20 (n=12,10,12,39,23,27,21,23,29)	-0.46 (± 1.435)			
Change at Week 24 (n=12,10,12,41,21,26,19,24,28)	0.10 (± 1.892)			
Change at Week 28 (n=12,11,11,37,21,24,20,22,23)	-0.53 (± 2.136)			
Change at Week 32 (n=10,11,11,36,21,20,19,21,24)	-0.08 (± 1.491)			
Change at Week 36 (n=11,10,11,32,19,21,17,22,21)	-0.32 (± 1.724)			
Change at Week 40 (n=11,10,11,34,17,21,15,19,24)	-0.62 (± 2.434)			
Change at Week 44 (n=11,9,11,32,19,20,14,18,22)	-0.69 (± 1.737)			
Change at Week 48 (n=11,10,11,31,19,20,14,19,24)	-0.47 (± 2.150)			
Change at Week 52 (n=11,10,11,32,17,19,13,15,23)	-0.75 (± 2.355)			
Change at Week 60 (n=10,7,9,28,16,15,11,14,20)	-0.95 (± 2.131)			
Change at Week 64 (n=10,8,9,27,16,16,12,15,20)	-0.82 (± 2.007)			

Statistical analyses

No statistical analyses for this end point

Secondary: Chronic Period: Change From Week 14 in hsCRP

End point title	Chronic Period: Change From Week 14 in hsCRP
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End point description:

Evaluable mITT population included all participants randomly assigned to IP and who took at least one dose of IP in the chronic period. Number analyzed is the number of participants with data available for analysis. n = number of participants with data available for analysis at the specified time point.

End point type	Secondary
End point timeframe:	
Week 14 (baseline), Weeks 16, 20, 24, 28, 32, 36, 40, 44, 48, 52, 56, 60, and 64	

End point values	Placebo (Induction) to PF-06480605 (Chronic) 50 mg	Placebo (Induction) to PF-06480605 (Chronic) 150 mg	Placebo (Induction) to PF-06480605 (Chronic) 450 mg	PF-06480605 50 mg (Induction) to PF-06480605 (Chronic) 50 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	14	14	46
Units: log2-transformed mg/L				
arithmetic mean (standard deviation)				
Week 14 (n=12,14,14,46,26,30,26,26,29)	1.22 (± 1.667)	2.49 (± 2.149)	0.43 (± 2.484)	0.72 (± 2.322)
Change at Week 16 (n=12,12,13,45,25,30,25,25,29)	-0.17 (± 0.745)	-0.32 (± 1.057)	-0.05 (± 1.622)	0.12 (± 0.895)
Change at Week 20 (n=12,14,14,42,25,29,25,25,29)	-0.41 (± 1.420)	-1.06 (± 1.370)	-0.48 (± 2.403)	0.34 (± 1.390)
Change at Week 24 (n=12,14,14,42,23,28,24,26,27)	-0.76 (± 1.232)	-1.52 (± 1.440)	-1.01 (± 2.445)	0.28 (± 1.328)
Change at Week 28 (n=11,13,12,39,22,28,22,24,26)	-1.01 (± 1.398)	-1.12 (± 1.917)	-0.36 (± 1.665)	0.31 (± 1.362)
Change at Week 32 (n=11,14,13,40,24,25,23,24,24)	-0.32 (± 1.893)	-0.79 (± 1.535)	-0.85 (± 2.253)	0.30 (± 1.720)
Change at Week 36 (n=11,14,13,36,22,25,21,24,22)	-1.04 (± 2.335)	-1.29 (± 1.786)	-0.67 (± 2.760)	0.07 (± 1.430)
Change at Week 40 (n=11,13,12,33,20,25,19,23,23)	-0.50 (± 1.893)	-1.09 (± 1.827)	-1.56 (± 2.351)	0.17 (± 1.596)
Change at Week 44 (n=11,12,12,34,21,22,18,22,22)	-0.11 (± 1.709)	-1.31 (± 1.707)	-1.28 (± 2.448)	-0.06 (± 1.589)
Change at Week 48 (n=10,12,12,33,21,23,18,21,23)	-0.59 (± 1.596)	-1.29 (± 1.700)	-1.23 (± 2.619)	0.28 (± 1.749)
Change at Week 52 (n=11,12,12,33,21,23,19,20,22)	-0.01 (± 2.228)	-1.05 (± 1.726)	-1.59 (± 2.195)	0.10 (± 1.248)
Change at Week 56 (n=10,10,10,29,19,21,16,19,22)	-0.28 (± 1.346)	-0.92 (± 1.776)	-0.57 (± 1.766)	0.25 (± 1.525)
Change at Week 60 (n=9,11,10,30,20,20,16,17,21)	-0.50 (± 2.114)	-0.93 (± 1.857)	-0.63 (± 2.397)	0.40 (± 1.804)
Change at Week 64 (n=10,11,10,28,21,22,17,17,17)	0.35 (± 1.750)	-0.97 (± 2.090)	-1.12 (± 2.366)	0.28 (± 1.633)

End point values	PF-06480605 150 mg (Induction) to PF-06480605 (Chronic) 50 mg	PF-06480605 150 mg (Induction) to PF-06480605 (Chronic) 150 mg	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 50 mg	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 150 mg
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Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	30	26	26
Units: log2-transformed mg/L				
arithmetic mean (standard deviation)				
Week 14 (n=12,14,14,46,26,30,26,26,29)	0.26 (± 1.898)	0.11 (± 1.724)	0.49 (± 2.152)	0.56 (± 1.843)
Change at Week 16 (n=12,12,13,45,25,30,25,25,29)	0.28 (± 1.218)	0.04 (± 1.074)	-0.18 (± 1.247)	-0.21 (± 1.390)
Change at Week 20 (n=12,14,14,42,25,29,25,25,29)	0.32 (± 1.449)	0.48 (± 1.736)	-0.22 (± 1.141)	0.68 (± 2.359)
Change at Week 24 (n=12,14,14,42,23,28,24,26,27)	0.23 (± 1.063)	0.06 (± 0.882)	-0.20 (± 1.391)	-0.13 (± 1.372)
Change at Week 28 (n=11,13,12,39,22,28,22,24,26)	0.29 (± 1.156)	0.26 (± 1.050)	-0.28 (± 1.546)	-0.25 (± 1.347)
Change at Week 32 (n=11,14,13,40,24,25,23,24,24)	0.32 (± 1.565)	0.72 (± 1.347)	-0.56 (± 1.572)	0.28 (± 1.474)
Change at Week 36 (n=11,14,13,36,22,25,21,24,22)	0.29 (± 1.490)	0.28 (± 1.179)	-0.43 (± 1.507)	0.36 (± 2.013)
Change at Week 40 (n=11,13,12,33,20,25,19,23,23)	0.16 (± 1.432)	0.31 (± 1.206)	-0.35 (± 1.645)	0.19 (± 1.252)
Change at Week 44 (n=11,12,12,34,21,22,18,22,22)	-0.15 (± 1.612)	0.66 (± 1.083)	0.05 (± 1.513)	0.20 (± 1.457)
Change at Week 48 (n=10,12,12,33,21,23,18,21,23)	0.31 (± 1.314)	0.21 (± 1.213)	0.07 (± 0.985)	0.07 (± 1.674)
Change at Week 52 (n=11,12,12,33,21,23,19,20,22)	0.09 (± 1.299)	-0.13 (± 0.985)	0.43 (± 1.144)	-0.02 (± 1.760)
Change at Week 56 (n=10,10,10,29,19,21,16,19,22)	0.17 (± 1.998)	0.21 (± 1.129)	0.65 (± 0.994)	0.31 (± 1.801)
Change at Week 60 (n=9,11,10,30,20,20,16,17,21)	1.21 (± 1.844)	0.51 (± 0.992)	0.14 (± 1.395)	-0.55 (± 1.390)
Change at Week 64 (n=10,11,10,28,21,22,17,17,17)	0.33 (± 1.848)	0.22 (± 1.699)	0.52 (± 1.659)	-0.06 (± 2.231)

End point values	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 450 mg			
Subject group type	Reporting group			
Number of subjects analysed	29			
Units: log2-transformed mg/L				
arithmetic mean (standard deviation)				
Week 14 (n=12,14,14,46,26,30,26,26,29)	1.55 (± 1.376)			
Change at Week 16 (n=12,12,13,45,25,30,25,25,29)	-0.12 (± 1.283)			
Change at Week 20 (n=12,14,14,42,25,29,25,25,29)	-0.19 (± 1.362)			
Change at Week 24 (n=12,14,14,42,23,28,24,26,27)	-0.16 (± 1.387)			
Change at Week 28 (n=11,13,12,39,22,28,22,24,26)	-0.23 (± 1.044)			
Change at Week 32 (n=11,14,13,40,24,25,23,24,24)	-0.29 (± 1.347)			
Change at Week 36 (n=11,14,13,36,22,25,21,24,22)	-0.24 (± 1.614)			

Change at Week 40 (n=11,13,12,33,20,25,19,23,23)	-0.66 (± 1.154)			
Change at Week 44 (n=11,12,12,34,21,22,18,22,22)	-0.75 (± 1.272)			
Change at Week 48 (n=10,12,12,33,21,23,18,21,23)	-0.53 (± 1.254)			
Change at Week 52 (n=11,12,12,33,21,23,19,20,22)	-0.63 (± 1.221)			
Change at Week 56 (n=10,10,10,29,19,21,16,19,22)	-0.34 (± 1.463)			
Change at Week 60 (n=9,11,10,30,20,20,16,17,21)	-0.91 (± 1.643)			
Change at Week 64 (n=10,11,10,28,21,22,17,17,17)	-0.64 (± 1.802)			

Statistical analyses

No statistical analyses for this end point

Secondary: Chronic Period: Change From Week 14 in Serum sTL1A

End point title	Chronic Period: Change From Week 14 in Serum sTL1A
End point description: Evaluable mITT population included all participants randomly assigned to IP and who took at least one dose of IP in the chronic period. Number analyzed is the number of participants with data available for analysis. n=number of participants with data available for analysis at the specified time point.	
End point type	Secondary
End point timeframe: Week 14 (baseline), Weeks 16, 20, 24, 28, 32, 36, 40, 44, 48, 52, 56, 60, and 64	

End point values	Placebo (Induction) to PF-06480605 (Chronic) 50 mg	Placebo (Induction) to PF-06480605 (Chronic) 150 mg	Placebo (Induction) to PF-06480605 (Chronic) 450 mg	PF-06480605 50 mg (Induction) to PF-06480605 (Chronic) 50 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	13	14	46
Units: pg/mL				
arithmetic mean (standard deviation)				
Week 14 (n=12,13,14,46,25,29,25,26,29)	6.84 (± 0.443)	7.21 (± 1.254)	6.67 (± 0.463)	9.78 (± 1.421)
Change at Week 16 (n=11,12,13,44,23,27,25,25,29)	-0.13 (± 0.576)	0.29 (± 0.328)	0.12 (± 0.330)	-0.03 (± 0.431)
Change at Week 20 (n=12,13,13,44,25,27,23,26,29)	3.97 (± 0.722)	3.43 (± 1.840)	5.42 (± 0.954)	-0.03 (± 0.675)
Change at Week 24 (n=12,12,13,41,21,26,23,25,27)	2.85 (± 1.141)	3.84 (± 1.872)	5.65 (± 0.909)	-0.02 (± 0.999)
Change at Week 28 (n=12,13,12,39,23,27,22,24,26)	2.96 (± 1.033)	3.78 (± 1.759)	5.88 (± 0.731)	-0.16 (± 1.032)
Change at Week 32 (n=11,13,13,40,22,25,22,24,24)	3.18 (± 1.346)	3.65 (± 1.749)	5.87 (± 0.588)	-0.10 (± 1.158)
Change at Week 36 (n=10,13,13,36,22,24,20,22,23)	3.35 (± 1.185)	3.53 (± 1.811)	5.77 (± 0.745)	0.06 (± 1.285)

Change at Week 40(n=11,12,12,35,20,25,18,23,24)	3.45 (± 0.990)	3.17 (± 1.909)	5.66 (± 0.926)	0.04 (± 1.243)
Change at Week 44(n=11,11,12,36,21,24,18,22,24)	3.41 (± 1.068)	3.09 (± 1.640)	5.58 (± 1.106)	-0.01 (± 1.289)
Change at Week 48 (n=11,11,12,34,21,24,17,21,23)	3.36 (± 1.108)	2.83 (± 1.601)	5.73 (± 1.029)	0.03 (± 1.138)
Change at Week 52 (n=11,11,12,33,21,23,18,20,25)	3.59 (± 1.128)	2.83 (± 1.875)	5.74 (± 1.224)	0.06 (± 1.119)
Change at Week 56 (n=10,11,10,30,18,22,16,19,23)	3.72 (± 1.114)	2.71 (± 1.999)	5.69 (± 1.173)	0.31 (± 1.155)
Change at Week 60 (n=9,10,10,32,20,20,15,16,22)	2.95 (± 1.646)	2.87 (± 1.505)	5.37 (± 1.556)	-0.08 (± 1.557)
Change at Week 64 (n=10,10,9,29,21,21,15,18,21)	3.15 (± 1.775)	2.88 (± 1.730)	4.83 (± 1.860)	-0.28 (± 1.391)

End point values	PF-06480605 150 mg (Induction) to PF-06480605 (Chronic) 50 mg	PF-06480605 150 mg (Induction) to PF-06480605 (Chronic) 150 mg	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 50 mg	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 150 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	29	25	26
Units: pg/mL				
arithmetic mean (standard deviation)				
Week 14 (n=12,13,14,46,25,29,25,26,29)	10.71 (± 1.543)	10.61 (± 1.488)	11.30 (± 2.495)	11.34 (± 1.752)
Change at Week 16 (n=11,12,13,44,23,27,25,25,29)	-0.16 (± 0.302)	0.03 (± 0.494)	0.00 (± 0.987)	-0.26 (± 0.510)
Change at Week 20 (n=12,13,13,44,25,27,23,26,29)	-0.36 (± 0.645)	-0.01 (± 0.762)	-0.22 (± 1.086)	-0.74 (± 0.638)
Change at Week 24(n=12,12,13,41,21,26,23,25,27)	-0.59 (± 0.912)	-0.41 (± 1.518)	-0.60 (± 1.133)	-0.90 (± 0.831)
Change at Week 28 (n=12,13,12,39,23,27,22,24,26)	-0.69 (± 1.036)	-0.33 (± 1.531)	-0.78 (± 1.384)	-0.87 (± 1.017)
Change at Week 32 (n=11,13,13,40,22,25,22,24,24)	-0.73 (± 1.092)	-0.07 (± 0.857)	-1.08 (± 1.337)	-0.93 (± 0.935)
Change at Week 36(n=10,13,13,36,22,24,20,22,23)	-0.80 (± 1.036)	0.01 (± 0.743)	-1.28 (± 1.630)	-0.81 (± 0.992)
Change at Week 40(n=11,12,12,35,20,25,18,23,24)	-0.95 (± 1.188)	-0.01 (± 0.919)	-1.32 (± 1.739)	-0.75 (± 1.017)
Change at Week 44(n=11,11,12,36,21,24,18,22,24)	-0.83 (± 1.282)	-0.11 (± 0.634)	-1.35 (± 1.812)	-0.60 (± 0.958)
Change at Week 48 (n=11,11,12,34,21,24,17,21,23)	-0.79 (± 1.198)	0.14 (± 0.779)	-1.25 (± 1.554)	-0.54 (± 1.145)
Change at Week 52 (n=11,11,12,33,21,23,18,20,25)	-0.65 (± 1.090)	0.26 (± 0.675)	-1.49 (± 1.711)	-0.54 (± 1.031)
Change at Week 56 (n=10,11,10,30,18,22,16,19,23)	-0.57 (± 1.191)	0.26 (± 0.976)	-1.36 (± 1.870)	-0.29 (± 0.990)
Change at Week 60 (n=9,10,10,32,20,20,15,16,22)	-0.60 (± 1.303)	-0.13 (± 0.924)	-1.55 (± 1.985)	-0.70 (± 1.583)
Change at Week 64 (n=10,10,9,29,21,21,15,18,21)	-0.68 (± 1.200)	-0.19 (± 0.823)	-1.45 (± 2.361)	-0.97 (± 1.697)

End point values	PF-06480605			
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	450 mg (Induction) to PF-06480605 (Chronic) 450 mg			
Subject group type	Reporting group			
Number of subjects analysed	29			
Units: pg/mL				
arithmetic mean (standard deviation)				
Week 14 (n=12,13,14,46,25,29,25,26,29)	11.83 (± 0.726)			
Change at Week 16 (n=11,12,13,44,23,27,25,25,29)	-0.35 (± 0.435)			
Change at Week 20 (n=12,13,13,44,25,27,23,26,29)	-0.61 (± 0.780)			
Change at Week 24(n=12,12,13,41,21,26,23,25,27)	-0.70 (± 1.047)			
Change at Week 28 (n=12,13,12,39,23,27,22,24,26)	-0.65 (± 1.047)			
Change at Week 32 (n=11,13,13,40,22,25,22,24,24)	-0.67 (± 0.914)			
Change at Week 36(n=10,13,13,36,22,24,20,22,23)	-0.60 (± 0.812)			
Change at Week 40(n=11,12,12,35,20,25,18,23,24)	-0.67 (± 0.891)			
Change at Week 44(n=11,11,12,36,21,24,18,22,24)	-0.59 (± 0.873)			
Change at Week 48 (n=11,11,12,34,21,24,17,21,23)	-0.47 (± 0.853)			
Change at Week 52 (n=11,11,12,33,21,23,18,20,25)	-0.55 (± 1.134)			
Change at Week 56 (n=10,11,10,30,18,22,16,19,23)	-0.33 (± 0.919)			
Change at Week 60 (n=9,10,10,32,20,20,15,16,22)	-0.64 (± 0.929)			
Change at Week 64 (n=10,10,9,29,21,21,15,18,21)	-0.75 (± 1.062)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Fecal Calprotectin Through the End of Study

End point title	Change From Baseline in Fecal Calprotectin Through the End of Study
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End point description:

Evaluable mITT population included all participants randomly assigned to IP and who took at least one dose of IP in the chronic period. Number analyzed is the number of participants with data available for analysis. n= number of participants with data available for analysis at the specified time point. As pre-specified in the statistical analysis plan (SAP), data is presented using the treatment sequence in the chronic period.

End point type	Secondary
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End point timeframe:

Baseline, Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48, 52, 60, and 64

End point values	Placebo (Induction) to PF-06480605 (Chronic) 50 mg	Placebo (Induction) to PF-06480605 (Chronic) 150 mg	Placebo (Induction) to PF-06480605 (Chronic) 450 mg	PF-06480605 50 mg (Induction) to PF-06480605 (Chronic) 50 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	11	14	40
Units: µg/g				
arithmetic mean (standard deviation)				
Baseline(n=12,11,14,40,24,26,23,21,28)	10.43 (± 1.530)	11.06 (± 1.450)	10.44 (± 2.984)	9.91 (± 2.069)
Change at Week 4(n=12,11,12,36,22,23,22,20,28)	0.41 (± 2.745)	-0.21 (± 0.925)	-1.15 (± 2.572)	-0.38 (± 1.973)
Change at Week 8(n=10,10,14,39,20,21,22,20,28)	-0.36 (± 1.169)	-0.56 (± 1.601)	-1.21 (± 3.752)	-1.27 (± 2.652)
Change at Week 12(n=11,9,14,35,18,24,21,21,28)	0.46 (± 2.788)	-0.84 (± 2.026)	-1.32 (± 4.008)	-1.36 (± 2.837)
Change at Week 16(n=12,10,12,37,21,25,21,20,28)	-0.21 (± 1.742)	-1.73 (± 2.941)	-0.67 (± 3.908)	-1.48 (± 3.378)
Change at Week 20(n=12,10,14,39,23,25,22,19,28)	-0.61 (± 2.247)	-2.48 (± 2.935)	-2.35 (± 3.701)	-1.71 (± 3.104)
Change at Week 24(n=12,10,14,38,22,24,19,21,27)	-0.92 (± 2.115)	-1.68 (± 2.505)	-2.52 (± 3.263)	-1.00 (± 3.050)
Change at Week 28(n=12,11,12,32,21,22,21,18,22)	-1.76 (± 2.456)	-3.08 (± 3.021)	-2.70 (± 2.246)	-1.31 (± 3.225)
Change at Week 32(n=10,11,12,35,27,20,20,17,24)	-1.43 (± 2.920)	-2.45 (± 2.916)	-2.87 (± 2.951)	-1.19 (± 3.384)
Change at Week 36(n=11,10,12,30,21,21,17,18,20)	-1.05 (± 2.958)	-3.14 (± 2.233)	-3.11 (± 3.401)	-1.80 (± 3.019)
Change at Week 40(n=11,9,12,31,19,20,15,17,23)	-1.99 (± 2.555)	-1.30 (± 2.745)	-3.02 (± 2.912)	-1.35 (± 3.354)
Change at Week 44(n=11,8,12,31,21,20,14,15,21)	-1.05 (± 2.653)	-1.87 (± 2.871)	-2.35 (± 2.768)	-1.60 (± 3.435)
Change at Week 48(n=11,9,12,29,21,19,14,16,23)	-1.22 (± 2.640)	-1.95 (± 3.001)	-2.87 (± 4.006)	-0.78 (± 2.906)
Change at Week 52(n=11,9,12,30,20,17,13,12,22)	-1.76 (± 2.420)	-1.53 (± 2.796)	-3.27 (± 2.568)	-1.36 (± 3.019)
Change at Week 60(n=10,7,10,26,19,15,11,11,19)	-1.89 (± 2.781)	-1.00 (± 1.778)	-1.63 (± 3.097)	-1.20 (± 3.371)
Change at Week 64(n=10,7,10,26,19,16,12,13,19)	-1.19 (± 2.692)	-2.56 (± 2.525)	-0.43 (± 3.261)	-1.16 (± 2.744)

End point values	PF-06480605 150 mg (Induction) to PF-06480605 (Chronic) 50 mg	PF-06480605 150 mg (Induction) to PF-06480605 (Chronic) 150 mg	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 50 mg	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 150 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	27	26	23	21
Units: µg/g				
arithmetic mean (standard deviation)				

Baseline(n=12,11,14,40,24,26,23,21,28)	11.12 (± 1.472)	10.38 (± 2.683)	10.41 (± 1.218)	9.95 (± 2.225)
Change at Week 4(n=12,11,12,36,22,23,22,20,28)	-1.56 (± 1.722)	-1.03 (± 3.037)	-1.28 (± 3.038)	-0.80 (± 2.727)
Change at Week 8(n=10,10,14,39,20,21,22,20,28)	-2.03 (± 2.251)	-1.69 (± 3.357)	-2.29 (± 3.142)	-1.76 (± 3.108)
Change at Week 12(n=11,9,14,35,18,24,21,21,28)	-2.62 (± 2.563)	-2.42 (± 3.174)	-1.21 (± 3.159)	-1.75 (± 3.477)
Change at Week 16(n=12,10,12,37,21,25,21,20,28)	-2.30 (± 2.662)	-2.55 (± 2.883)	-0.87 (± 3.039)	-1.26 (± 3.043)
Change at Week 20(n=12,10,14,39,23,25,22,19,28)	-1.87 (± 2.328)	-2.10 (± 2.824)	-1.61 (± 3.685)	-1.70 (± 3.353)
Change at Week 24(n=12,10,14,38,22,24,19,21,27)	-2.31 (± 2.910)	-2.29 (± 3.768)	-1.25 (± 2.899)	-1.52 (± 3.478)
Change at Week 28(n=12,11,12,32,21,22,21,18,22)	-2.46 (± 2.750)	-2.85 (± 3.782)	-1.60 (± 3.431)	-1.58 (± 3.213)
Change at Week 32(n=10,11,12,35,27,20,20,17,24)	-2.62 (± 2.906)	-2.61 (± 3.609)	-1.56 (± 3.253)	-1.48 (± 3.014)
Change at Week 36(n=11,10,12,30,21,21,17,18,20)	-2.39 (± 2.680)	-2.31 (± 3.468)	-2.11 (± 3.406)	-2.08 (± 3.070)
Change at Week 40(n=11,9,12,31,19,20,15,17,23)	-2.17 (± 2.130)	-2.24 (± 3.311)	-1.58 (± 3.128)	-1.73 (± 3.158)
Change at Week 44(n=11,8,12,31,21,20,14,15,21)	-2.93 (± 2.999)	-2.96 (± 3.311)	-1.09 (± 3.077)	-2.41 (± 3.338)
Change at Week 48(n=11,9,12,29,21,19,14,16,23)	-2.81 (± 2.789)	-2.89 (± 3.346)	-1.74 (± 3.257)	-1.46 (± 3.800)
Change at Week 52(n=11,9,12,30,20,17,13,12,22)	-2.20 (± 2.564)	-2.50 (± 3.129)	-1.90 (± 3.306)	-2.20 (± 2.991)
Change at Week 60(n=10,7,10,26,19,15,11,11,19)	-2.59 (± 2.491)	-2.63 (± 3.885)	-1.17 (± 2.198)	-2.39 (± 3.217)
Change at Week 64(n=10,7,10,26,19,16,12,13,19)	-2.05 (± 2.327)	-2.40 (± 4.271)	-1.46 (± 2.729)	-2.03 (± 4.805)

End point values	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 450 mg			
Subject group type	Reporting group			
Number of subjects analysed	28			
Units: µg/g				
arithmetic mean (standard deviation)				
Baseline(n=12,11,14,40,24,26,23,21,28)	10.23 (± 1.446)			
Change at Week 4(n=12,11,12,36,22,23,22,20,28)	-0.69 (± 2.513)			
Change at Week 8(n=10,10,14,39,20,21,22,20,28)	-1.27 (± 2.874)			
Change at Week 12(n=11,9,14,35,18,24,21,21,28)	-1.31 (± 2.634)			
Change at Week 16(n=12,10,12,37,21,25,21,20,28)	-1.08 (± 2.368)			
Change at Week 20(n=12,10,14,39,23,25,22,19,28)	-1.55 (± 2.490)			
Change at Week 24(n=12,10,14,38,22,24,19,21,27)	-0.95 (± 2.877)			

Change at Week 28(n=12,11,12,32,21,22,21,18,22)	-1.61 (± 2.428)			
Change at Week 32(n=10,11,12,35,27,20,20,17,24)	-1.31 (± 2.032)			
Change at Week 36(n=11,10,12,30,21,21,17,18,20)	-2.05 (± 2.502)			
Change at Week40(n=11,9,12,31,19,20,15,17,23)	-1.87 (± 2.751)			
Change at Week 44(n=11,8,12,31,21,20,14,15,21)	-2.08 (± 2.932)			
Change at Week 48(n=11,9,12,29,21,19,14,16,23)	-1.75 (± 2.562)			
Change at Week 52(n=11,9,12,30,20,17,13,12,22)	-2.07 (± 2.400)			
Change at Week 60(n=10,7,10,26,19,15,11,11,19)	-2.07 (± 2.843)			
Change at Week 64(n=10,7,10,26,19,16,12,13,19)	-2.38 (± 2.247)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in hsCRP Through the End of Study

End point title	Change From Baseline in hsCRP Through the End of Study
End point description:	
Evaluable mITT population included all participants randomly assigned to IP and who took at least one dose of IP in the chronic period. Number analyzed is the number of participants with data available for analysis. n= number of participants with data available for analysis at the specified time point. As pre-specified in the SAP, data is presented using the treatment sequence in the chronic period	
End point type	Secondary
End point timeframe:	
Baseline, Weeks 4, 8, 12, 14, 16, 20, 24, 28, 32, 36, 40, 44, 48, 52, 56, 60, and 64	

End point values	Placebo (Induction) to PF-06480605 (Chronic) 50 mg	Placebo (Induction) to PF-06480605 (Chronic) 150 mg	Placebo (Induction) to PF-06480605 (Chronic) 450 mg	PF-06480605 50 mg (Induction) to PF-06480605 (Chronic) 50 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	14	14	46
Units: log2-transformed mg/L				
arithmetic mean (standard deviation)				
Baseline (n=12,14,14,46,27,30,26,26,29)	2.08 (± 2.625)	2.41 (± 1.630)	0.86 (± 1.942)	1.42 (± 1.989)
Change at Week 4 (n=12,14,14,45,27,29,26,25,29)	-1.02 (± 1.888)	0.18 (± 1.323)	-0.70 (± 1.108)	-0.43 (± 1.660)
Change at Week 8 (n=12,13,14,46,26,29,26,25,29)	-0.58 (± 2.105)	-0.22 (± 1.859)	-0.67 (± 1.957)	-0.47 (± 1.912)
Change at Week 12 (n=11,13,14,42,22,29,25,25,28)	-1.22 (± 2.248)	-0.60 (± 2.635)	-1.09 (± 2.151)	-0.66 (± 1.749)

Change at Week 14 (n=12,14,14,46,26,30,26,26,29)	-0.86 (± 2.162)	0.08 (± 2.194)	-0.43 (± 2.529)	-0.71 (± 2.026)
Change at Week 16 (n=12,12,13,45,26,30,25,25,29)	-1.03 (± 2.061)	-0.19 (± 2.184)	-0.72 (± 2.025)	-0.56 (± 2.112)
Change at Week 20 (n=12,14,14,42,26,29,25,25,29)	-1.27 (± 1.253)	-0.98 (± 2.164)	-0.91 (± 2.855)	-0.44 (± 2.106)
Change at Week 24 (n=12,14,14,42,24,28,24,26,27)	-1.62 (± 1.786)	-1.43 (± 1.914)	-1.44 (± 1.935)	-0.53 (± 2.056)
Change at Week 28 (n=11,13,12,39,23,28,22,24,26)	-1.39 (± 1.585)	-1.00 (± 2.277)	-0.84 (± 2.000)	-0.61 (± 2.078)
Change at Week 32 (n=11,14,13,40,25,25,23,24,24)	-1.23 (± 1.930)	-0.71 (± 1.585)	-1.36 (± 1.937)	-0.58 (± 1.887)
Change at Week 36 (n=11,14,13,36,23,25,21,24,22)	-1.94 (± 2.158)	-1.21 (± 1.951)	-1.18 (± 1.032)	-0.89 (± 2.009)
Change at Week 40 (n=11,13,12,33,21,25,19,23,23)	-1.40 (± 2.470)	-1.03 (± 2.294)	-1.92 (± 1.184)	-0.74 (± 2.371)
Change at Week 44 (n=11,12,12,34,22,22,18,22,22)	-1.01 (± 2.243)	-1.07 (± 2.041)	-1.64 (± 1.592)	-0.99 (± 2.154)
Change at Week 48 (n=10,12,12,33,22,23,18,21,23)	-0.97 (± 1.965)	-1.06 (± 2.213)	-1.59 (± 1.530)	-0.77 (± 2.377)
Change at Week 52 (n=11,12,12,33,21,23,19,20,22)	-0.92 (± 3.093)	-0.82 (± 1.873)	-1.94 (± 1.744)	-0.94 (± 1.993)
Change at Week 56 (n=10,10,10,29,20,21,16,19,22)	-1.18 (± 2.111)	-0.96 (± 2.381)	-1.11 (± 1.681)	-0.70 (± 2.227)
Change at Week 60 (n=9,11,10,30,20,20,16,17,21)	-1.19 (± 1.259)	-0.52 (± 2.427)	-1.17 (± 2.435)	-0.64 (± 2.236)
Change at Week 64 (n=10,11,10,28,21,22,17,17,17)	-0.85 (± 1.481)	-1.03 (± 1.776)	-1.66 (± 1.908)	-0.77 (± 2.162)

End point values	PF-06480605 150 mg (Induction) to PF-06480605 (Chronic) 50 mg	PF-06480605 150 mg (Induction) to PF-06480605 (Chronic) 150 mg	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 50 mg	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 150 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	27	30	26	26
Units: log2-transformed mg/L				
arithmetic mean (standard deviation)				
Baseline (n=12,14,14,46,27,30,26,26,29)	1.35 (± 1.638)	1.22 (± 1.865)	1.23 (± 1.687)	1.91 (± 1.948)
Change at Week 4 (n=12,14,14,45,27,29,26,25,29)	-0.85 (± 1.585)	-0.73 (± 1.967)	-1.10 (± 1.645)	-1.40 (± 1.382)
Change at Week 8 (n=12,13,14,46,26,29,26,25,29)	-0.85 (± 2.109)	-1.14 (± 2.198)	-0.97 (± 1.980)	-1.48 (± 1.391)
Change at Week 12 (n=11,13,14,42,22,29,25,25,28)	-1.45 (± 1.768)	-1.18 (± 1.814)	-0.93 (± 2.133)	-1.50 (± 1.646)
Change at Week 14 (n=12,14,14,46,26,30,26,26,29)	-1.05 (± 2.045)	-1.10 (± 2.086)	-0.74 (± 1.750)	-1.35 (± 1.720)
Change at Week 16 (n=12,12,13,45,26,30,25,25,29)	-0.61 (± 1.931)	-1.06 (± 2.098)	-0.98 (± 2.030)	-1.50 (± 1.432)
Change at Week 20 (n=12,14,14,42,26,29,25,25,29)	-0.83 (± 2.158)	-0.52 (± 2.399)	-0.98 (± 1.957)	-0.61 (± 2.365)
Change at Week 24 (n=12,14,14,42,24,28,24,26,27)	-0.80 (± 1.811)	-0.97 (± 1.911)	-1.03 (± 1.963)	-1.48 (± 1.517)
Change at Week 28 (n=11,13,12,39,23,28,22,24,26)	-0.73 (± 2.143)	-0.76 (± 1.867)	-0.87 (± 2.125)	-1.60 (± 1.558)

Change at Week 32 (n=11,14,13,40,25,25,23,24,24)	-0.79 (± 2.136)	-0.57 (± 2.027)	-1.35 (± 1.743)	-1.15 (± 1.853)
Change at Week 36 (n=11,14,13,36,23,25,21,24,22)	-1.03 (± 2.015)	-0.95 (± 1.900)	-1.21 (± 2.006)	-1.07 (± 1.441)
Change at Week40 (n=11,13,12,33,21,25,19,23,23)	-1.37 (± 2.262)	-0.84 (± 2.009)	-1.06 (± 1.992)	-1.19 (± 1.390)
Change at Week 44 (n=11,12,12,34,22,22,18,22,22)	-1.47 (± 1.876)	-0.37 (± 2.008)	-0.71 (± 1.841)	-1.03 (± 1.411)
Change at Week 48 (n=10,12,12,33,22,23,18,21,23)	-1.07 (± 1.671)	-0.78 (± 2.213)	-0.84 (± 1.802)	-1.12 (± 1.478)
Change at Week 52 (n=11,12,12,33,21,23,19,20,22)	-1.29 (± 1.756)	-1.13 (± 1.951)	-0.52 (± 1.730)	-1.22 (± 1.456)
Change at Week 56 (n=10,10,10,29,20,21,16,19,22)	-1.12 (± 2.293)	-0.71 (± 2.434)	-0.05 (± 1.966)	-0.82 (± 1.648)
Change at Week 60 (n=9,11,10,30,20,20,16,17,21)	-0.34 (± 2.332)	-0.82 (± 2.135)	-0.88 (± 2.060)	-1.71 (± 1.670)
Change at Week 64 (n=10,11,10,28,21,22,17,17,17)	-1.05 (± 1.950)	-1.22 (± 1.981)	-0.44 (± 1.778)	-1.07 (± 1.870)

End point values	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 450 mg			
Subject group type	Reporting group			
Number of subjects analysed	29			
Units: log2-transformed mg/L				
arithmetic mean (standard deviation)				
Baseline (n=12,14,14,46,27,30,26,26,29)	2.53 (± 1.803)			
Change at Week 4 (n=12,14,14,45,27,29,26,25,29)	-0.97 (± 1.656)			
Change at Week 8 (n=12,13,14,46,26,29,26,25,29)	-1.02 (± 1.695)			
Change at Week 12 (n=11,13,14,42,22,29,25,25,28)	-0.95 (± 1.646)			
Change at Week 14 (n=12,14,14,46,26,30,26,26,29)	-0.98 (± 1.603)			
Change at Week 16 (n=12,12,13,45,26,30,25,25,29)	-1.09 (± 1.783)			
Change at Week 20 (n=12,14,14,42,26,29,25,25,29)	-1.16 (± 1.718)			
Change at Week 24 (n=12,14,14,42,24,28,24,26,27)	-1.14 (± 1.639)			
Change at Week 28 (n=11,13,12,39,23,28,22,24,26)	-1.18 (± 1.844)			
Change at Week 32 (n=11,14,13,40,25,25,23,24,24)	-1.31 (± 1.988)			
Change at Week 36 (n=11,14,13,36,23,25,21,24,22)	-1.18 (± 1.915)			
Change at Week40 (n=11,13,12,33,21,25,19,23,23)	-1.60 (± 1.802)			
Change at Week 44 (n=11,12,12,34,22,22,18,22,22)	-1.69 (± 1.423)			
Change at Week 48 (n=10,12,12,33,22,23,18,21,23)	-1.47 (± 1.670)			

Change at Week 52 (n=11,12,12,33,21,23,19,20,22)	-1.54 (± 1.863)			
Change at Week 56 (n=10,10,10,29,20,21,16,19,22)	-1.32 (± 2.070)			
Change at Week 60 (n=9,11,10,30,20,20,16,17,21)	-1.91 (± 2.213)			
Change at Week 64 (n=10,11,10,28,21,22,17,17,17)	-1.69 (± 2.336)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Serum sTL1A Through the End of Study

End point title	Change From Baseline in Serum sTL1A Through the End of Study
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End point description:

Evaluable mITT population included all participants randomly assigned to IP and who took at least one dose of IP in chronic period. Number analyzed is the number of participants with data available for analysis. n= number of participants with data available for analysis at the specified time point. As pre-specified in the SAP, data is presented using the treatment sequence in the chronic period.

End point type	Secondary
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End point timeframe:

Baseline, Weeks 4, 8, 12, 14, 16, 20, 24, 28, 32, 36, 40, 44, 48, 52, 56, 60, and 64

End point values	Placebo (Induction) to PF-06480605 (Chronic) 50 mg	Placebo (Induction) to PF-06480605 (Chronic) 150 mg	Placebo (Induction) to PF-06480605 (Chronic) 450 mg	PF-06480605 50 mg (Induction) to PF-06480605 (Chronic) 50 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	14	13	41
Units: pg/mL				
arithmetic mean (standard deviation)				
Baseline (n=12,14,13,41,26,27,24,25,29)	6.76 (± 0.524)	6.93 (± 0.300)	6.89 (± 0.499)	6.73 (± 0.503)
Change at Week 4 (n=12,14,13,39,25,27,24,24,29)	0.09 (± 0.458)	-0.01 (± 0.349)	-0.02 (± 0.221)	3.50 (± 1.051)
Change at Week 8 (n=12,14,13,41,25,27,24,24,29)	-0.10 (± 0.908)	0.02 (± 0.329)	-0.10 (± 0.267)	3.18 (± 1.331)
Change at Week 12 (n=11,12,13,39,23,27,23,25,29)	0.14 (± 0.383)	-0.01 (± 0.329)	-0.17 (± 0.365)	2.93 (± 1.629)
Change at Week 14 (n=12,13,13,41,25,27,23,25,29)	0.08 (± 0.474)	0.28 (± 1.209)	-0.23 (± 0.329)	2.97 (± 1.598)
Change at Week 16 (n=11,12,13,39,24,26,23,25,29)	-0.05 (± 0.708)	0.56 (± 1.384)	-0.11 (± 0.305)	2.99 (± 1.697)
Change at Week 20 (n=12,14,13,39,26,27,22,25,29)	4.05 (± 0.978)	3.75 (± 1.543)	5.19 (± 0.861)	3.01 (± 1.710)
Change at Week 24 (n=12,13,13,37,22,25,22,24,27)	2.94 (± 1.140)	4.17 (± 1.415)	5.41 (± 0.771)	2.86 (± 1.881)
Change at Week 28 (n=12,13,11,36,24,25,21,23,26)	3.04 (± 1.182)	4.06 (± 1.536)	5.67 (± 0.742)	2.87 (± 1.992)

Change at Week 32 (n=11,14,12,36,23,23,21,23,24)	3.29 (± 1.500)	3.99 (± 1.497)	5.62 (± 0.620)	2.82 (± 1.903)
Change at Week 36 (n=10,14,12,33,23,22,20,21,23)	3.47 (± 1.247)	3.90 (± 1.564)	5.55 (± 0.842)	2.96 (± 1.813)
Change at Week 40 (n=11,13,11,32,21,23,18,22,24)	3.56 (± 1.130)	3.65 (± 1.865)	5.44 (± 0.951)	3.04 (± 1.839)
Change at Week 44 (n=11,12,11,33,22,22,18,21,24)	3.53 (± 1.172)	3.67 (± 1.671)	5.34 (± 1.093)	2.98 (± 1.762)
Change at Week 48 (n=11,12,11,32,22,22,17,20,23)	3.47 (± 1.156)	3.42 (± 1.682)	5.46 (± 1.019)	2.99 (± 1.684)
Change at Week 52 (n=11,12,11,31,22,21,18,19,25)	3.70 (± 1.262)	3.43 (± 1.928)	5.43 (± 1.211)	2.94 (± 1.668)
Change at Week 56 (n=10,12,9,28,19,21,16,18,23)	3.83 (± 1.308)	3.31 (± 1.961)	5.35 (± 1.132)	3.08 (± 1.445)
Change at Week 60 (n=9,11,9,30,20,19,15,15,22)	3.08 (± 1.718)	3.51 (± 1.742)	5.07 (± 1.553)	2.98 (± 1.710)
Change at Week 64 (n=10,11,8,27,21,20,15,17,21)	3.31 (± 1.611)	3.48 (± 1.919)	4.50 (± 1.900)	2.64 (± 2.059)

End point values	PF-06480605 150 mg (Induction) to PF-06480605 (Chronic) 50 mg	PF-06480605 150 mg (Induction) to PF-06480605 (Chronic) 150 mg	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 50 mg	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 150 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	27	24	25
Units: pg/mL				
arithmetic mean (standard deviation)				
Baseline (n=12,14,13,41,26,27,24,25,29)	6.77 (± 0.520)	6.69 (± 0.520)	6.83 (± 0.706)	6.65 (± 0.467)
Change at Week 4 (n=12,14,13,39,25,27,24,24,29)	3.73 (± 1.445)	3.97 (± 1.218)	4.88 (± 0.987)	5.29 (± 0.829)
Change at Week 8 (n=12,14,13,41,25,27,24,24,29)	3.98 (± 1.561)	3.76 (± 1.443)	4.87 (± 1.691)	4.98 (± 1.434)
Change at Week 12 (n=11,12,13,39,23,27,23,25,29)	3.84 (± 1.613)	3.75 (± 1.471)	4.34 (± 2.700)	4.59 (± 1.840)
Change at Week 14 (n=12,13,13,41,25,27,23,25,29)	3.95 (± 1.664)	3.97 (± 1.419)	4.37 (± 2.724)	4.68 (± 1.872)
Change at Week 16 (n=11,12,13,39,24,26,23,25,29)	3.55 (± 1.849)	3.96 (± 1.406)	4.40 (± 2.472)	4.42 (± 2.181)
Change at Week 20 (n=12,14,13,39,26,27,22,25,29)	3.46 (± 1.678)	3.96 (± 1.338)	4.12 (± 2.459)	3.92 (± 2.248)
Change at Week 24 (n=12,13,13,37,22,25,22,24,27)	3.57 (± 1.608)	3.60 (± 2.046)	3.74 (± 2.346)	3.69 (± 2.117)
Change at Week 28 (n=12,13,11,36,24,25,21,23,26)	3.20 (± 1.715)	3.61 (± 2.155)	3.55 (± 2.220)	3.68 (± 2.141)
Change at Week 32 (n=11,14,12,36,23,23,21,23,24)	3.09 (± 1.760)	3.92 (± 1.535)	3.23 (± 2.089)	3.67 (± 2.044)
Change at Week 36 (n=10,14,12,33,23,22,20,21,23)	3.25 (± 1.637)	3.99 (± 1.460)	3.12 (± 1.854)	3.83 (± 2.020)
Change at Week 40 (n=11,13,11,32,21,23,18,22,24)	3.02 (± 1.644)	4.07 (± 1.582)	2.95 (± 1.914)	3.84 (± 2.007)
Change at Week 44 (n=11,12,11,33,22,22,18,21,24)	2.97 (± 1.769)	3.89 (± 1.421)	2.90 (± 1.893)	4.05 (± 1.823)
Change at Week 48 (n=11,12,11,32,22,22,17,20,23)	3.01 (± 1.695)	4.25 (± 1.438)	3.28 (± 1.789)	4.11 (± 1.802)

Change at Week 52 (n=11,12,11,31,22,21,18,19,25)	3.16 (± 1.573)	4.26 (± 1.325)	3.10 (± 1.725)	4.00 (± 2.021)
Change at Week 56 (n=10,12,9,28,19,21,16,18,23)	3.00 (± 1.719)	4.24 (± 1.510)	3.10 (± 1.605)	4.49 (± 1.553)
Change at Week 60 (n=9,11,9,30,20,19,15,15,22)	3.31 (± 1.714)	3.70 (± 1.401)	3.26 (± 1.672)	3.72 (± 1.928)
Change at Week 64 (n=10,11,8,27,21,20,15,17,21)	3.30 (± 1.657)	3.75 (± 1.383)	2.85 (± 2.115)	3.69 (± 2.218)

End point values	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 450 mg			
Subject group type	Reporting group			
Number of subjects analysed	29			
Units: pg/mL				
arithmetic mean (standard deviation)				
Baseline (n=12,14,13,41,26,27,24,25,29)	6.83 (± 0.428)			
Change at Week 4 (n=12,14,13,39,25,27,24,24,29)	4.65 (± 0.686)			
Change at Week 8 (n=12,14,13,41,25,27,24,24,29)	4.74 (± 0.891)			
Change at Week 12 (n=11,12,13,39,23,27,23,25,29)	5.03 (± 1.221)			
Change at Week 14 (n=12,13,13,41,25,27,23,25,29)	5.00 (± 0.902)			
Change at Week 16 (n=11,12,13,39,24,26,23,25,29)	4.66 (± 1.069)			
Change at Week 20 (n=12,14,13,39,26,27,22,25,29)	4.40 (± 1.365)			
Change at Week 24 (n=12,13,13,37,22,25,22,24,27)	4.33 (± 1.483)			
Change at Week 28 (n=12,13,11,36,24,25,21,23,26)	4.42 (± 1.548)			
Change at Week 32 (n=11,14,12,36,23,23,21,23,24)	4.39 (± 1.452)			
Change at Week 36 (n=10,14,12,33,23,22,20,21,23)	4.58 (± 1.209)			
Change at Week 40 (n=11,13,11,32,21,23,18,22,24)	4.42 (± 1.450)			
Change at Week 44 (n=11,12,11,33,22,22,18,21,24)	4.57 (± 1.276)			
Change at Week 48 (n=11,12,11,32,22,22,17,20,23)	4.61 (± 1.428)			
Change at Week 52 (n=11,12,11,31,22,21,18,19,25)	4.53 (± 1.565)			
Change at Week 56 (n=10,12,9,28,19,21,16,18,23)	4.74 (± 1.405)			
Change at Week 60 (n=9,11,9,30,20,19,15,15,22)	4.42 (± 1.254)			
Change at Week 64 (n=10,11,8,27,21,20,15,17,21)	4.39 (± 1.118)			

Statistical analyses

No statistical analyses for this end point

Secondary: Chronic Period: Number of Participants With ADA and NAbS to PF-06480605

End point title	Chronic Period: Number of Participants With ADA and NAbS to PF-06480605
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End point description:

Samples were considered to be positive for ADA against PF-06480605 if the titer was ≥ 60 , and an ADA sample was considered to be negative if the titer was < 60 . Samples were considered to be positive for NAb against PF-06480605 if the titer was ≥ 5 , and an NAb sample was considered to be negative if the titer was < 5 . Evaluation of NAb is generally relevant only in participants who are positive for ADA. Evaluable mITT population included all participants randomly assigned to IP and who took at least one dose of IP in the chronic period. Number analyzed is the number of participants with data available for analysis. n= number of participants with data available for analysis at the specified timepoints. 9999 = No participants were analyzed at the specified timepoint.

End point type	Secondary
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End point timeframe:

Weeks 16, 20, 24, 28, 32, 36, 40, 44, 48, 52, 56, 60 and 64

End point values	Placebo (Induction) to PF-06480605 (Chronic) 50 mg	Placebo (Induction) to PF-06480605 (Chronic) 150 mg	Placebo (Induction) to PF-06480605 (Chronic) 450 mg	PF-06480605 50 mg (Induction) to PF-06480605 (Chronic) 50 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	14	14	43
Units: participants				
ADA at Week 16 (n=11,13,14,42,24,28,25,25,29)	0	0	0	38
NAb at Week 16 (n=0,0,0,39,18,24,11,18,18)	9999	9999	9999	16
ADA at Week 20 (n=12,13,13,43,26,28,22,26,29)	9	9	4	39
NAb at Week 20 (n=10,9,5,40,21,24,15,20,16)	0	0	0	12
ADA at Week 24 (n=12,13,11,40,23,28,24,25,26)	10	9	6	36
NAb at Week 24 (n=11,10,7,38,23,22,22,19,18)	1	2	0	11
ADA at Week 28 (n=11,14,12,38,24,27,20,24,25)	11	12	5	35
NAb at Week 28 (n=11,13,6,37,22,25,18,19,16)	4	3	0	13
ADA at Week 32 (n=11,14,13,37,23,25,21,24,24)	11	14	6	34

NAb at Week 32 (n=11,14,7,35,22,24,20,19,18)	4	3	0	10
ADA at Week 36 (n=11,14,12,35,20,22,20,22,23)	11	14	6	33
NAb at Week 36 (n=11,14,7,33,17,20,19,20,18)	3	3	1	10
ADA at Week 40 (n=11,11,12,35,21,24,18,21,24)	11	11	5	34
NAb at Week 40 (n=11,11,5,34,19,22,17,20,18)	3	1	1	8
ADA at Week 44 (n=10,12,12,35,21,24,18,20,24)	10	12	6	30
NAb at Week 44 (n=10,12,6,31,19,22,18,18,16)	3	1	1	7
ADA at Week 48 (n=11,12,11,34,22,24,18,20,22)	11	12	5	29
NAb at Week 48 (n=11,12,5,30,18,20,17,18,16)	2	1	1	7
ADA at Week 52 (n=11,12,12,32,22,23,18,20,23)	11	11	5	28
NAb at Week 52 (n=11,11,5,30,19,20,16,17,15)	2	2	1	8
ADA at Week 56 (n=10,12,10,30,19,22,17,19,23)	10	11	4	28
NAb at Week 56 (n=10,11,4,29,18,21,16,14,13)	2	1	1	6
ADA at Week 60 (n=9,12,10,32,20,21,14,17,22)	9	11	6	27
NAb at Week 60 (n=9,12,7,28,18,19,14,16,17)	2	0	2	5
ADA at Week 64 (n=10,11,10,29,21,20,17,16,20)	10	11	10	28
NAb at Week 64 (n=10,11,10,29,19,20,17,16,17)	0	1	1	7

End point values	PF-06480605 150 mg (Induction) to PF-06480605 (Chronic) 50 mg	PF-06480605 150 mg (Induction) to PF-06480605 (Chronic) 150 mg	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 50 mg	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 150 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	28	25	26
Units: participants				
ADA at Week 16 (n=11,13,14,42,24,28,25,25,29)	18	24	10	17
NAb at Week 16 (n=0,0,0,39,18,24,11,18,18)	7	3	1	3
ADA at Week 20 (n=12,13,13,43,26,28,22,26,29)	20	23	14	18
NAb at Week 20 (n=10,9,5,40,21,24,15,20,16)	7	4	0	5
ADA at Week 24 (n=12,13,11,40,23,28,24,25,26)	21	22	20	18
NAb at Week 24 (n=11,10,7,38,23,22,22,19,18)	4	2	1	4
ADA at Week 28 (n=11,14,12,38,24,27,20,24,25)	22	24	18	19

NAb at Week 28 (n=11,13,6,37,22,25,18,19,16)	5	4	1	4
ADA at Week 32 (n=11,14,13,37,23,25,21,24,24)	21	23	18	19
NAb at Week 32 (n=11,14,7,35,22,24,20,19,18)	4	1	0	3
ADA at Week 36 (n=11,14,12,35,20,22,20,22,23)	17	20	19	19
NAb at Week 36 (n=11,14,7,33,17,20,19,20,18)	2	3	0	5
ADA at Week 40 (n=11,11,12,35,21,24,18,21,24)	19	22	17	18
NAb at Week 40 (n=11,11,5,34,19,22,17,20,18)	3	2	0	2
ADA at Week 44 (n=10,12,12,35,21,24,18,20,24)	18	20	18	16
NAb at Week 44 (n=10,12,6,31,19,22,18,18,16)	4	3	0	1
ADA at Week 48 (n=11,12,11,34,22,24,18,20,22)	19	20	18	17
NAb at Week 48 (n=11,12,5,30,18,20,17,18,16)	3	3	0	1
ADA at Week 52 (n=11,12,12,32,22,23,18,20,23)	19	17	16	17
NAb at Week 52 (n=11,11,5,30,19,20,16,17,15)	5	2	1	1
ADA at Week 56 (n=10,12,10,30,19,22,17,19,23)	16	21	16	15
NAb at Week 56 (n=10,11,4,29,18,21,16,14,13)	5	2	0	2
ADA at Week 60 (n=9,12,10,32,20,21,14,17,22)	18	19	13	16
NAb at Week 60 (n=9,12,7,28,18,19,14,16,17)	3	3	0	3
ADA at Week 64 (n=10,11,10,29,21,20,17,16,20)	18	20	17	16
NAb at Week 64 (n=10,11,10,29,19,20,17,16,17)	4	2	1	3

End point values	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 450 mg			
Subject group type	Reporting group			
Number of subjects analysed	29			
Units: participants				
ADA at Week 16 (n=11,13,14,42,24,28,25,25,29)	15			
NAb at Week 16 (n=0,0,0,39,18,24,11,18,18)	1			
ADA at Week 20 (n=12,13,13,43,26,28,22,26,29)	16			
NAb at Week 20 (n=10,9,5,40,21,24,15,20,16)	1			
ADA at Week 24 (n=12,13,11,40,23,28,24,25,26)	16			

NAb at Week 24 (n=11,10,7,38,23,22,22,19,18)	0			
ADA at Week 28 (n=11,14,12,38,24,27,20,24,25)	15			
NAb at Week 28 (n=11,13,6,37,22,25,18,19,16)	0			
ADA at Week 32 (n=11,14,13,37,23,25,21,24,24)	18			
NAb at Week 32 (n=11,14,7,35,22,24,20,19,18)	1			
ADA at Week 36 (n=11,14,12,35,20,22,20,22,23)	16			
NAb at Week 36 (n=11,14,7,33,17,20,19,20,18)	0			
ADA at Week 40 (n=11,11,12,35,21,24,18,21,24)	18			
NAb at Week 40 (n=11,11,5,34,19,22,17,20,18)	0			
ADA at Week 44 (n=10,12,12,35,21,24,18,20,24)	15			
NAb at Week 44 (n=10,12,6,31,19,22,18,18,16)	0			
ADA at Week 48 (n=11,12,11,34,22,24,18,20,22)	14			
NAb at Week 48 (n=11,12,5,30,18,20,17,18,16)	1			
ADA at Week 52 (n=11,12,12,32,22,23,18,20,23)	13			
NAb at Week 52 (n=11,11,5,30,19,20,16,17,15)	0			
ADA at Week 56 (n=10,12,10,30,19,22,17,19,23)	13			
NAb at Week 56 (n=10,11,4,29,18,21,16,14,13)	0			
ADA at Week 60 (n=9,12,10,32,20,21,14,17,22)	16			
NAb at Week 60 (n=9,12,7,28,18,19,14,16,17)	0			
ADA at Week 64 (n=10,11,10,29,21,20,17,16,20)	17			
NAb at Week 64 (n=10,11,10,29,19,20,17,16,17)	0			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Induction Period: Study treatment initiation to the first chronic dose or safety follow-up end, whichever is first. (~16 wks + 12 wk safety FU).

Chronic Period: First chronic dose to safety follow-up end. (~40 wks + 12 wk safety FU).

Adverse event reporting additional description:

Safety Population: All participants who took ≥ 1 dose of IP during induction. Evaluable mITT

Population: All randomized participants who took $\geq$ dose of IP in the chronic period.

Induction: data may differ from publications using Week 14 as the AE reporting end. Chronic: data may differ from publications using Week 56 as the AE reporting end.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
Dictionary version	25.1

Reporting groups

Reporting group title	Induction Period: Placebo
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Reporting group description:

Participants received PF-06480605 matching placebo, as a SC injection, Q4W up to Week 12.

Reporting group title	Placebo (Induction) to PF-06480605 (Chronic) 150 mg
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Reporting group description:

Participants who received placebo and completed the 12-week induction period received PF-06480605, 150 mg, as a SC injection, Q4W from Week 16 to Week 52 in the chronic period.

Reporting group title	Placebo (Induction) to PF-06480605 (Chronic) 50 mg
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Reporting group description:

Participants who received placebo and completed the 12-week induction period received PF-06480605, 50 mg, as a SC injection, Q4W from Week 16 to Week 52 in the chronic period.

Reporting group title	Induction Period: PF-06480605 450 mg
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Reporting group description:

Participants received PF-06480605, 450 mg, as a SC injection, Q4W up to Week 12.

Reporting group title	Induction Period: PF-06480605 150 mg
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Reporting group description:

Participants received PF-06480605, 150 mg, as a SC injection, Q4W up to Week 12.

Reporting group title	Induction Period: PF-06480605 50 mg
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Reporting group description:

Participants received PF-06480605, 50 mg, as a SC injection, Q4W up to Week 12.

Reporting group title	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 150 mg
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Reporting group description:

Participants who received PF-06480605, 450 mg, and completed the 12-week induction period received PF-06480605, 150 mg, as a SC injection, Q4W from Week 16 to Week 52 in the chronic period.

Reporting group title	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 50 mg
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Reporting group description:

Participants who received PF-06480605, 450 mg, and completed the 12-week induction period received PF-06480605, 50 mg, as a SC injection, Q4W from Week 16 to Week 52 in the chronic period.

Reporting group title	PF-06480605 150 mg (Induction) to PF-06480605 (Chronic) 150 mg
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Reporting group description:

Participants who received PF-06480605, 150 mg, and completed the 12-week induction period received PF-06480605, 150 mg, as a SC injection, Q4W from Week 16 to Week 52 in the chronic period.

Reporting group title	PF-06480605 150 mg (Induction) to PF-06480605 (Chronic) 50 mg
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Reporting group description:

Participants who received PF-06480605, 150 mg, and completed the 12-week induction period received PF-06480605, 50 mg, as a SC injection, Q4W from Week 16 to Week 52 in the chronic period.

Reporting group title	PF-06480605 50 mg (Induction) to PF-06480605 (Chronic) 50 mg
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Reporting group description:

Participants who received PF-06480605, 50 mg, and completed the 12-week induction period received PF-06480605, 50 mg, as a SC injection, Q4W from Week 16 to Week 52 in the chronic period.

Reporting group title	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 450 mg
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Reporting group description:

Participants who received PF-06480605, 450 mg, and completed the 12-week induction period received PF-06480605, 450 mg, as a SC injection, Q4W from Week 16 to Week 52 in the chronic period.

Reporting group title	Placebo (Induction) to PF-06480605 (Chronic) 450mg
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Reporting group description:

Participants who received placebo and completed the 12-week induction period received PF-06480605, 450 mg, as a SC injection, Q4W from Week 16 to Week 52 in the chronic period.

Serious adverse events	Induction Period: Placebo	Placebo (Induction) to PF-06480605 (Chronic) 150 mg	Placebo (Induction) to PF-06480605 (Chronic) 50 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 45 (8.89%)	0 / 14 (0.00%)	0 / 12 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Investigations			
SARS-CoV-2 test positive			
subjects affected / exposed	1 / 45 (2.22%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Neoplasm of appendix			
subjects affected / exposed	0 / 45 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Tibia fracture			
subjects affected / exposed	0 / 45 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Embolism			

subjects affected / exposed	0 / 45 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Coronary artery stenosis			
subjects affected / exposed	0 / 45 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Haemorrhoid operation			
subjects affected / exposed	0 / 45 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous complete			
subjects affected / exposed	0 / 45 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 45 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypereosinophilic syndrome			
subjects affected / exposed	1 / 45 (2.22%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Drug ineffective			
subjects affected / exposed	0 / 45 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Intestinal perforation			

subjects affected / exposed	0 / 45 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer haemorrhage			
subjects affected / exposed	0 / 45 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ulcerative			
subjects affected / exposed	1 / 45 (2.22%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	1 / 45 (2.22%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 45 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 45 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
COVID-19 pneumonia			
subjects affected / exposed	0 / 45 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus infection			
subjects affected / exposed	0 / 45 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Induction Period: PF-06480605 450 mg	Induction Period: PF-06480605 150 mg	Induction Period: PF-06480605 50 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 91 (4.40%)	1 / 62 (1.61%)	3 / 47 (6.38%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Investigations			
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 91 (0.00%)	0 / 62 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Neoplasm of appendix			
subjects affected / exposed	1 / 91 (1.10%)	0 / 62 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Tibia fracture			
subjects affected / exposed	0 / 91 (0.00%)	0 / 62 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Embolism			
subjects affected / exposed	1 / 91 (1.10%)	0 / 62 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Coronary artery stenosis			
subjects affected / exposed	0 / 91 (0.00%)	0 / 62 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Haemorrhoid operation			
subjects affected / exposed	0 / 91 (0.00%)	0 / 62 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous complete			
subjects affected / exposed	0 / 91 (0.00%)	0 / 62 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 91 (0.00%)	0 / 62 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypereosinophilic syndrome			
subjects affected / exposed	0 / 91 (0.00%)	0 / 62 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Drug ineffective			
subjects affected / exposed	0 / 91 (0.00%)	0 / 62 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Intestinal perforation			
subjects affected / exposed	0 / 91 (0.00%)	0 / 62 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer haemorrhage			
subjects affected / exposed	0 / 91 (0.00%)	0 / 62 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ulcerative			
subjects affected / exposed	1 / 91 (1.10%)	1 / 62 (1.61%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			

subjects affected / exposed	0 / 91 (0.00%)	0 / 62 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 91 (0.00%)	0 / 62 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 91 (0.00%)	0 / 62 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
COVID-19 pneumonia			
subjects affected / exposed	0 / 91 (0.00%)	0 / 62 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus infection			
subjects affected / exposed	1 / 91 (1.10%)	0 / 62 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 150 mg	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 50 mg	PF-06480605 150 mg (Induction) to PF-06480605 (Chronic) 150 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 26 (3.85%)	2 / 26 (7.69%)	0 / 30 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Investigations			
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 26 (0.00%)	0 / 26 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Neoplasm of appendix			
subjects affected / exposed	0 / 26 (0.00%)	0 / 26 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Tibia fracture			
subjects affected / exposed	0 / 26 (0.00%)	0 / 26 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 26 (0.00%)	0 / 26 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Coronary artery stenosis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 26 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Haemorrhoid operation			
subjects affected / exposed	1 / 26 (3.85%)	0 / 26 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous complete			
subjects affected / exposed	0 / 26 (0.00%)	0 / 26 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 26 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypereosinophilic syndrome			

subjects affected / exposed	0 / 26 (0.00%)	0 / 26 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Drug ineffective			
subjects affected / exposed	0 / 26 (0.00%)	0 / 26 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Intestinal perforation			
subjects affected / exposed	0 / 26 (0.00%)	0 / 26 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer haemorrhage			
subjects affected / exposed	0 / 26 (0.00%)	0 / 26 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ulcerative			
subjects affected / exposed	0 / 26 (0.00%)	1 / 26 (3.85%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 26 (0.00%)	0 / 26 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 26 (0.00%)	0 / 26 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 26 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Infections and infestations			
COVID-19 pneumonia			
subjects affected / exposed	0 / 26 (0.00%)	1 / 26 (3.85%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus infection			
subjects affected / exposed	0 / 26 (0.00%)	0 / 26 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	PF-06480605 150 mg (Induction) to PF-06480605 (Chronic) 50 mg	PF-06480605 50 mg (Induction) to PF-06480605 (Chronic) 50 mg	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 450 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 27 (3.70%)	5 / 46 (10.87%)	4 / 29 (13.79%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Investigations			
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 27 (0.00%)	0 / 46 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Neoplasm of appendix			
subjects affected / exposed	0 / 27 (0.00%)	0 / 46 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Tibia fracture			
subjects affected / exposed	0 / 27 (0.00%)	1 / 46 (2.17%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Embolism			

subjects affected / exposed	0 / 27 (0.00%)	0 / 46 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Coronary artery stenosis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 46 (0.00%)	1 / 29 (3.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Haemorrhoid operation			
subjects affected / exposed	0 / 27 (0.00%)	0 / 46 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous complete			
subjects affected / exposed	1 / 27 (3.70%)	0 / 46 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 27 (0.00%)	0 / 46 (0.00%)	1 / 29 (3.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypereosinophilic syndrome			
subjects affected / exposed	0 / 27 (0.00%)	0 / 46 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Drug ineffective			
subjects affected / exposed	0 / 27 (0.00%)	1 / 46 (2.17%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Intestinal perforation			

subjects affected / exposed	0 / 27 (0.00%)	0 / 46 (0.00%)	1 / 29 (3.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer haemorrhage			
subjects affected / exposed	0 / 27 (0.00%)	1 / 46 (2.17%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ulcerative			
subjects affected / exposed	0 / 27 (0.00%)	1 / 46 (2.17%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 27 (0.00%)	0 / 46 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 27 (0.00%)	0 / 46 (0.00%)	1 / 29 (3.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 27 (0.00%)	1 / 46 (2.17%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
COVID-19 pneumonia			
subjects affected / exposed	0 / 27 (0.00%)	0 / 46 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus infection			
subjects affected / exposed	0 / 27 (0.00%)	0 / 46 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Placebo (Induction) to PF-06480605 (Chronic) 450mg		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 14 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Investigations			
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Neoplasm of appendix			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Tibia fracture			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Embolism			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Coronary artery stenosis			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Surgical and medical procedures			
Haemorrhoid operation			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Pregnancy, puerperium and perinatal conditions Abortion spontaneous complete subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	 0 / 14 (0.00%) 0 / 0 0 / 0		
Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	 0 / 14 (0.00%) 0 / 0 0 / 0		
Hypereosinophilic syndrome subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	 0 / 14 (0.00%) 0 / 0 0 / 0		
General disorders and administration site conditions Drug ineffective subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	 0 / 14 (0.00%) 0 / 0 0 / 0		
Gastrointestinal disorders Intestinal perforation subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	 0 / 14 (0.00%) 0 / 0 0 / 0		
Duodenal ulcer haemorrhage subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	 0 / 14 (0.00%) 0 / 0 0 / 0		
Colitis ulcerative subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	 0 / 14 (0.00%) 0 / 0 0 / 0		
Vomiting			

subjects affected / exposed	0 / 14 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
COVID-19 pneumonia			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cytomegalovirus infection			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Induction Period: Placebo	Placebo (Induction) to PF-06480605 (Chronic) 150 mg	Placebo (Induction) to PF-06480605 (Chronic) 50 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	16 / 45 (35.56%)	9 / 14 (64.29%)	5 / 12 (41.67%)
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	2 / 45 (4.44%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
SARS-CoV-2 antibody test positive			
subjects affected / exposed	0 / 45 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Electrocardiogram QT prolonged subjects affected / exposed occurrences (all)	0 / 45 (0.00%) 0	0 / 14 (0.00%) 0	1 / 12 (8.33%) 1
Blood pressure increased subjects affected / exposed occurrences (all)	0 / 45 (0.00%) 0	1 / 14 (7.14%) 3	0 / 12 (0.00%) 0
SARS-CoV-2 test positive subjects affected / exposed occurrences (all)	0 / 45 (0.00%) 0	2 / 14 (14.29%) 2	1 / 12 (8.33%) 1
Injury, poisoning and procedural complications			
Thermal burn subjects affected / exposed occurrences (all)	0 / 45 (0.00%) 0	0 / 14 (0.00%) 0	1 / 12 (8.33%) 1
Skin abrasion subjects affected / exposed occurrences (all)	0 / 45 (0.00%) 0	0 / 14 (0.00%) 0	0 / 12 (0.00%) 0
Arthropod bite subjects affected / exposed occurrences (all)	0 / 45 (0.00%) 0	1 / 14 (7.14%) 1	0 / 12 (0.00%) 0
Cardiac disorders			
Tachycardia subjects affected / exposed occurrences (all)	1 / 45 (2.22%) 1	0 / 14 (0.00%) 0	1 / 12 (8.33%) 1
Nervous system disorders			
Dizziness subjects affected / exposed occurrences (all)	0 / 45 (0.00%) 0	0 / 14 (0.00%) 0	1 / 12 (8.33%) 1
Headache subjects affected / exposed occurrences (all)	1 / 45 (2.22%) 1	1 / 14 (7.14%) 1	1 / 12 (8.33%) 1
Blood and lymphatic system disorders			
Anaemia subjects affected / exposed occurrences (all)	4 / 45 (8.89%) 4	2 / 14 (14.29%) 2	1 / 12 (8.33%) 1
Iron deficiency anaemia			

subjects affected / exposed occurrences (all)	0 / 45 (0.00%) 0	1 / 14 (7.14%) 1	0 / 12 (0.00%) 0
General disorders and administration site conditions			
Pain			
subjects affected / exposed occurrences (all)	0 / 45 (0.00%) 0	0 / 14 (0.00%) 0	0 / 12 (0.00%) 0
Oedema			
subjects affected / exposed occurrences (all)	0 / 45 (0.00%) 0	1 / 14 (7.14%) 1	0 / 12 (0.00%) 0
Injection site reaction			
subjects affected / exposed occurrences (all)	1 / 45 (2.22%) 1	0 / 14 (0.00%) 0	0 / 12 (0.00%) 0
Fatigue			
subjects affected / exposed occurrences (all)	0 / 45 (0.00%) 0	0 / 14 (0.00%) 0	0 / 12 (0.00%) 0
Pyrexia			
subjects affected / exposed occurrences (all)	1 / 45 (2.22%) 1	1 / 14 (7.14%) 1	2 / 12 (16.67%) 2
Peripheral swelling			
subjects affected / exposed occurrences (all)	0 / 45 (0.00%) 0	0 / 14 (0.00%) 0	0 / 12 (0.00%) 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed occurrences (all)	0 / 45 (0.00%) 0	0 / 14 (0.00%) 0	0 / 12 (0.00%) 0
Gastritis			
subjects affected / exposed occurrences (all)	0 / 45 (0.00%) 0	0 / 14 (0.00%) 0	1 / 12 (8.33%) 1
Nausea			
subjects affected / exposed occurrences (all)	1 / 45 (2.22%) 1	0 / 14 (0.00%) 0	0 / 12 (0.00%) 0
Stomatitis			
subjects affected / exposed occurrences (all)	0 / 45 (0.00%) 0	1 / 14 (7.14%) 1	0 / 12 (0.00%) 0
Diarrhoea			

subjects affected / exposed	0 / 45 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Umbilical hernia			
subjects affected / exposed	0 / 45 (0.00%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Angular cheilitis			
subjects affected / exposed	0 / 45 (0.00%)	0 / 14 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Colitis ulcerative			
subjects affected / exposed	0 / 45 (0.00%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Vomiting			
subjects affected / exposed	1 / 45 (2.22%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Proctitis			
subjects affected / exposed	1 / 45 (2.22%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Toothache			
subjects affected / exposed	0 / 45 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Adnexa uteri pain			
subjects affected / exposed	0 / 45 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 45 (0.00%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Epistaxis			
subjects affected / exposed	0 / 45 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 45 (2.22%)	0 / 14 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
Skin and subcutaneous tissue disorders			

Alopecia			
subjects affected / exposed	0 / 45 (0.00%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Dermatitis atopic			
subjects affected / exposed	0 / 45 (0.00%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Dry skin			
subjects affected / exposed	0 / 45 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hand dermatitis			
subjects affected / exposed	0 / 45 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 45 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dermatitis psoriasiform			
subjects affected / exposed	0 / 45 (0.00%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Acne			
subjects affected / exposed	0 / 45 (0.00%)	0 / 14 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 45 (2.22%)	0 / 14 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
Back pain			
subjects affected / exposed	0 / 45 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Coccydynia			
subjects affected / exposed	0 / 45 (0.00%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Neck pain			
subjects affected / exposed	0 / 45 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			

COVID-19			
subjects affected / exposed	0 / 45 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 45 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 45 (0.00%)	0 / 14 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Nasopharyngitis			
subjects affected / exposed	2 / 45 (4.44%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Chorioretinitis			
subjects affected / exposed	0 / 45 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 45 (0.00%)	0 / 14 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Upper respiratory tract infection			
subjects affected / exposed	0 / 45 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Induction Period: PF-06480605 450 mg	Induction Period: PF- 06480605 150 mg	Induction Period: PF-06480605 50 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	34 / 91 (37.36%)	20 / 62 (32.26%)	11 / 47 (23.40%)
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 91 (1.10%)	1 / 62 (1.61%)	1 / 47 (2.13%)
occurrences (all)	1	1	1
SARS-CoV-2 antibody test positive			
subjects affected / exposed	0 / 91 (0.00%)	1 / 62 (1.61%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 91 (0.00%)	0 / 62 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Blood pressure increased			

subjects affected / exposed occurrences (all)	0 / 91 (0.00%) 0	0 / 62 (0.00%) 0	0 / 47 (0.00%) 0
SARS-CoV-2 test positive subjects affected / exposed occurrences (all)	1 / 91 (1.10%) 1	2 / 62 (3.23%) 2	0 / 47 (0.00%) 0
Injury, poisoning and procedural complications			
Thermal burn subjects affected / exposed occurrences (all)	0 / 91 (0.00%) 0	0 / 62 (0.00%) 0	0 / 47 (0.00%) 0
Skin abrasion subjects affected / exposed occurrences (all)	0 / 91 (0.00%) 0	0 / 62 (0.00%) 0	0 / 47 (0.00%) 0
Arthropod bite subjects affected / exposed occurrences (all)	0 / 91 (0.00%) 0	0 / 62 (0.00%) 0	0 / 47 (0.00%) 0
Cardiac disorders			
Tachycardia subjects affected / exposed occurrences (all)	0 / 91 (0.00%) 0	0 / 62 (0.00%) 0	0 / 47 (0.00%) 0
Nervous system disorders			
Dizziness subjects affected / exposed occurrences (all)	3 / 91 (3.30%) 3	1 / 62 (1.61%) 1	1 / 47 (2.13%) 3
Headache subjects affected / exposed occurrences (all)	9 / 91 (9.89%) 13	2 / 62 (3.23%) 2	2 / 47 (4.26%) 2
Blood and lymphatic system disorders			
Anaemia subjects affected / exposed occurrences (all)	2 / 91 (2.20%) 2	5 / 62 (8.06%) 5	2 / 47 (4.26%) 2
Iron deficiency anaemia subjects affected / exposed occurrences (all)	2 / 91 (2.20%) 2	0 / 62 (0.00%) 0	0 / 47 (0.00%) 0
General disorders and administration site conditions			
Pain			

subjects affected / exposed	0 / 91 (0.00%)	0 / 62 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 91 (0.00%)	0 / 62 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Injection site reaction			
subjects affected / exposed	2 / 91 (2.20%)	3 / 62 (4.84%)	1 / 47 (2.13%)
occurrences (all)	2	4	2
Fatigue			
subjects affected / exposed	5 / 91 (5.49%)	1 / 62 (1.61%)	0 / 47 (0.00%)
occurrences (all)	6	1	0
Pyrexia			
subjects affected / exposed	5 / 91 (5.49%)	1 / 62 (1.61%)	0 / 47 (0.00%)
occurrences (all)	9	1	0
Peripheral swelling			
subjects affected / exposed	0 / 91 (0.00%)	0 / 62 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	4 / 91 (4.40%)	1 / 62 (1.61%)	0 / 47 (0.00%)
occurrences (all)	4	1	0
Gastritis			
subjects affected / exposed	0 / 91 (0.00%)	0 / 62 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	2 / 91 (2.20%)	2 / 62 (3.23%)	3 / 47 (6.38%)
occurrences (all)	2	2	3
Stomatitis			
subjects affected / exposed	0 / 91 (0.00%)	0 / 62 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 91 (0.00%)	1 / 62 (1.61%)	2 / 47 (4.26%)
occurrences (all)	0	1	2
Umbilical hernia			
subjects affected / exposed	0 / 91 (0.00%)	0 / 62 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0

Angular cheilitis subjects affected / exposed occurrences (all)	0 / 91 (0.00%) 0	0 / 62 (0.00%) 0	0 / 47 (0.00%) 0
Colitis ulcerative subjects affected / exposed occurrences (all)	3 / 91 (3.30%) 3	1 / 62 (1.61%) 1	2 / 47 (4.26%) 2
Vomiting subjects affected / exposed occurrences (all)	0 / 91 (0.00%) 0	0 / 62 (0.00%) 0	1 / 47 (2.13%) 1
Proctitis subjects affected / exposed occurrences (all)	0 / 91 (0.00%) 0	0 / 62 (0.00%) 0	0 / 47 (0.00%) 0
Toothache subjects affected / exposed occurrences (all)	0 / 91 (0.00%) 0	0 / 62 (0.00%) 0	0 / 47 (0.00%) 0
Reproductive system and breast disorders Adnexa uteri pain subjects affected / exposed occurrences (all)	0 / 91 (0.00%) 0	0 / 62 (0.00%) 0	0 / 47 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	1 / 91 (1.10%) 1	0 / 62 (0.00%) 0	0 / 47 (0.00%) 0
Epistaxis subjects affected / exposed occurrences (all)	0 / 91 (0.00%) 0	0 / 62 (0.00%) 0	0 / 47 (0.00%) 0
Oropharyngeal pain subjects affected / exposed occurrences (all)	2 / 91 (2.20%) 3	0 / 62 (0.00%) 0	0 / 47 (0.00%) 0
Skin and subcutaneous tissue disorders Alopecia subjects affected / exposed occurrences (all)	1 / 91 (1.10%) 1	0 / 62 (0.00%) 0	0 / 47 (0.00%) 0
Dermatitis atopic subjects affected / exposed occurrences (all)	0 / 91 (0.00%) 0	0 / 62 (0.00%) 0	0 / 47 (0.00%) 0

Dry skin			
subjects affected / exposed	1 / 91 (1.10%)	0 / 62 (0.00%)	0 / 47 (0.00%)
occurrences (all)	1	0	0
Hand dermatitis			
subjects affected / exposed	0 / 91 (0.00%)	0 / 62 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	2 / 91 (2.20%)	0 / 62 (0.00%)	0 / 47 (0.00%)
occurrences (all)	4	0	0
Dermatitis psoriasiform			
subjects affected / exposed	0 / 91 (0.00%)	0 / 62 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Acne			
subjects affected / exposed	1 / 91 (1.10%)	0 / 62 (0.00%)	0 / 47 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	4 / 91 (4.40%)	0 / 62 (0.00%)	0 / 47 (0.00%)
occurrences (all)	5	0	0
Back pain			
subjects affected / exposed	1 / 91 (1.10%)	0 / 62 (0.00%)	0 / 47 (0.00%)
occurrences (all)	1	0	0
Coccydynia			
subjects affected / exposed	0 / 91 (0.00%)	0 / 62 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 91 (0.00%)	0 / 62 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 91 (0.00%)	1 / 62 (1.61%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
Sinusitis			
subjects affected / exposed	0 / 91 (0.00%)	1 / 62 (1.61%)	1 / 47 (2.13%)
occurrences (all)	0	1	1
Pharyngitis			

subjects affected / exposed	0 / 91 (0.00%)	0 / 62 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	2 / 91 (2.20%)	1 / 62 (1.61%)	1 / 47 (2.13%)
occurrences (all)	2	1	1
Chorioretinitis			
subjects affected / exposed	0 / 91 (0.00%)	0 / 62 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	2 / 91 (2.20%)	0 / 62 (0.00%)	3 / 47 (6.38%)
occurrences (all)	2	0	3
Upper respiratory tract infection			
subjects affected / exposed	0 / 91 (0.00%)	2 / 62 (3.23%)	0 / 47 (0.00%)
occurrences (all)	0	2	0

Non-serious adverse events	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 150 mg	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 50 mg	PF-06480605 150 mg (Induction) to PF-06480605 (Chronic) 150 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	15 / 26 (57.69%)	14 / 26 (53.85%)	12 / 30 (40.00%)
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 26 (3.85%)	1 / 26 (3.85%)	0 / 30 (0.00%)
occurrences (all)	1	1	0
SARS-CoV-2 antibody test positive			
subjects affected / exposed	2 / 26 (7.69%)	1 / 26 (3.85%)	1 / 30 (3.33%)
occurrences (all)	2	1	1
Electrocardiogram QT prolonged			
subjects affected / exposed	1 / 26 (3.85%)	0 / 26 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
Blood pressure increased			
subjects affected / exposed	0 / 26 (0.00%)	0 / 26 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
SARS-CoV-2 test positive			
subjects affected / exposed	3 / 26 (11.54%)	4 / 26 (15.38%)	3 / 30 (10.00%)
occurrences (all)	3	4	3
Injury, poisoning and procedural			

complications			
Thermal burn			
subjects affected / exposed	0 / 26 (0.00%)	1 / 26 (3.85%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Skin abrasion			
subjects affected / exposed	0 / 26 (0.00%)	0 / 26 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	0 / 26 (0.00%)	0 / 26 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 26 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 26 (0.00%)	0 / 26 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	2 / 26 (7.69%)	2 / 26 (7.69%)	0 / 30 (0.00%)
occurrences (all)	3	3	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 26 (11.54%)	3 / 26 (11.54%)	0 / 30 (0.00%)
occurrences (all)	3	3	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 26 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Pain			
subjects affected / exposed	0 / 26 (0.00%)	0 / 26 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 26 (0.00%)	0 / 26 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Injection site reaction			

subjects affected / exposed	0 / 26 (0.00%)	1 / 26 (3.85%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Fatigue			
subjects affected / exposed	0 / 26 (0.00%)	0 / 26 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 26 (0.00%)	3 / 26 (11.54%)	2 / 30 (6.67%)
occurrences (all)	0	4	2
Peripheral swelling			
subjects affected / exposed	0 / 26 (0.00%)	0 / 26 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 26 (3.85%)	1 / 26 (3.85%)	1 / 30 (3.33%)
occurrences (all)	1	1	1
Gastritis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 26 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 26 (3.85%)	2 / 26 (7.69%)	3 / 30 (10.00%)
occurrences (all)	1	2	3
Stomatitis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 26 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 26 (0.00%)	1 / 26 (3.85%)	0 / 30 (0.00%)
occurrences (all)	0	2	0
Umbilical hernia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 26 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Angular cheilitis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 26 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Colitis ulcerative			
subjects affected / exposed	3 / 26 (11.54%)	6 / 26 (23.08%)	2 / 30 (6.67%)
occurrences (all)	3	6	2

Vomiting subjects affected / exposed occurrences (all)	1 / 26 (3.85%) 1	0 / 26 (0.00%) 0	0 / 30 (0.00%) 0
Proctitis subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 26 (0.00%) 0	0 / 30 (0.00%) 0
Toothache subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	2 / 26 (7.69%) 2	0 / 30 (0.00%) 0
Reproductive system and breast disorders Adnexa uteri pain subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 26 (0.00%) 0	0 / 30 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	1 / 26 (3.85%) 1	1 / 30 (3.33%) 1
Epistaxis subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 26 (0.00%) 0	0 / 30 (0.00%) 0
Oropharyngeal pain subjects affected / exposed occurrences (all)	1 / 26 (3.85%) 1	0 / 26 (0.00%) 0	3 / 30 (10.00%) 3
Skin and subcutaneous tissue disorders Alopecia subjects affected / exposed occurrences (all)	1 / 26 (3.85%) 1	0 / 26 (0.00%) 0	0 / 30 (0.00%) 0
Dermatitis atopic subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 26 (0.00%) 0	0 / 30 (0.00%) 0
Dry skin subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 26 (0.00%) 0	0 / 30 (0.00%) 0
Hand dermatitis subjects affected / exposed occurrences (all)	0 / 26 (0.00%) 0	0 / 26 (0.00%) 0	0 / 30 (0.00%) 0

Rash			
subjects affected / exposed	0 / 26 (0.00%)	2 / 26 (7.69%)	0 / 30 (0.00%)
occurrences (all)	0	2	0
Dermatitis psoriasiform			
subjects affected / exposed	0 / 26 (0.00%)	0 / 26 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Acne			
subjects affected / exposed	0 / 26 (0.00%)	0 / 26 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 26 (3.85%)	2 / 26 (7.69%)	1 / 30 (3.33%)
occurrences (all)	1	3	1
Back pain			
subjects affected / exposed	1 / 26 (3.85%)	2 / 26 (7.69%)	0 / 30 (0.00%)
occurrences (all)	1	2	0
Coccydynia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 26 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 26 (0.00%)	0 / 26 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
COVID-19			
subjects affected / exposed	1 / 26 (3.85%)	1 / 26 (3.85%)	1 / 30 (3.33%)
occurrences (all)	1	1	1
Sinusitis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 26 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1
Pharyngitis			
subjects affected / exposed	0 / 26 (0.00%)	1 / 26 (3.85%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Nasopharyngitis			
subjects affected / exposed	1 / 26 (3.85%)	0 / 26 (0.00%)	2 / 30 (6.67%)
occurrences (all)	1	0	3
Chorioretinitis			

subjects affected / exposed	0 / 26 (0.00%)	0 / 26 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 26 (0.00%)	2 / 26 (7.69%)	0 / 30 (0.00%)
occurrences (all)	0	3	0
Upper respiratory tract infection			
subjects affected / exposed	2 / 26 (7.69%)	1 / 26 (3.85%)	0 / 30 (0.00%)
occurrences (all)	3	1	0

Non-serious adverse events	PF-06480605 150 mg (Induction) to PF-06480605 (Chronic) 50 mg	PF-06480605 50 mg (Induction) to PF-06480605 (Chronic) 50 mg	PF-06480605 450 mg (Induction) to PF-06480605 (Chronic) 450 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	15 / 27 (55.56%)	24 / 46 (52.17%)	14 / 29 (48.28%)
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 27 (0.00%)	3 / 46 (6.52%)	3 / 29 (10.34%)
occurrences (all)	0	3	3
SARS-CoV-2 antibody test positive			
subjects affected / exposed	0 / 27 (0.00%)	1 / 46 (2.17%)	0 / 29 (0.00%)
occurrences (all)	0	1	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 27 (0.00%)	0 / 46 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Blood pressure increased			
subjects affected / exposed	0 / 27 (0.00%)	0 / 46 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
SARS-CoV-2 test positive			
subjects affected / exposed	5 / 27 (18.52%)	1 / 46 (2.17%)	2 / 29 (6.90%)
occurrences (all)	5	1	2
Injury, poisoning and procedural complications			
Thermal burn			
subjects affected / exposed	0 / 27 (0.00%)	0 / 46 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			

subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0	0 / 46 (0.00%) 0	0 / 29 (0.00%) 0
Arthropod bite subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0	0 / 46 (0.00%) 0	0 / 29 (0.00%) 0
Cardiac disorders Tachycardia subjects affected / exposed occurrences (all)	1 / 27 (3.70%) 1	0 / 46 (0.00%) 0	0 / 29 (0.00%) 0
Nervous system disorders Dizziness subjects affected / exposed occurrences (all)	2 / 27 (7.41%) 3	2 / 46 (4.35%) 7	0 / 29 (0.00%) 0
Headache subjects affected / exposed occurrences (all)	2 / 27 (7.41%) 2	3 / 46 (6.52%) 3	1 / 29 (3.45%) 1
Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all)	1 / 27 (3.70%) 1	4 / 46 (8.70%) 4	2 / 29 (6.90%) 2
Iron deficiency anaemia subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0	0 / 46 (0.00%) 0	1 / 29 (3.45%) 1
General disorders and administration site conditions Pain subjects affected / exposed occurrences (all)	2 / 27 (7.41%) 2	0 / 46 (0.00%) 0	0 / 29 (0.00%) 0
Oedema subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0	0 / 46 (0.00%) 0	0 / 29 (0.00%) 0
Injection site reaction subjects affected / exposed occurrences (all)	3 / 27 (11.11%) 3	1 / 46 (2.17%) 5	0 / 29 (0.00%) 0
Fatigue subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0	0 / 46 (0.00%) 0	1 / 29 (3.45%) 1

Pyrexia			
subjects affected / exposed	2 / 27 (7.41%)	2 / 46 (4.35%)	1 / 29 (3.45%)
occurrences (all)	2	4	1
Peripheral swelling			
subjects affected / exposed	0 / 27 (0.00%)	0 / 46 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 27 (0.00%)	2 / 46 (4.35%)	0 / 29 (0.00%)
occurrences (all)	0	3	0
Gastritis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 46 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	2 / 27 (7.41%)	1 / 46 (2.17%)	0 / 29 (0.00%)
occurrences (all)	2	4	0
Stomatitis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 46 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	1 / 27 (3.70%)	1 / 46 (2.17%)	0 / 29 (0.00%)
occurrences (all)	1	1	0
Umbilical hernia			
subjects affected / exposed	0 / 27 (0.00%)	0 / 46 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Angular cheilitis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 46 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Colitis ulcerative			
subjects affected / exposed	4 / 27 (14.81%)	8 / 46 (17.39%)	1 / 29 (3.45%)
occurrences (all)	4	8	2
Vomiting			
subjects affected / exposed	0 / 27 (0.00%)	0 / 46 (0.00%)	1 / 29 (3.45%)
occurrences (all)	0	0	1
Proctitis			

subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0	0 / 46 (0.00%) 0	0 / 29 (0.00%) 0
Toothache subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0	0 / 46 (0.00%) 0	0 / 29 (0.00%) 0
Reproductive system and breast disorders Adnexa uteri pain subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0	0 / 46 (0.00%) 0	0 / 29 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0	0 / 46 (0.00%) 0	1 / 29 (3.45%) 1
Epistaxis subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0	0 / 46 (0.00%) 0	0 / 29 (0.00%) 0
Oropharyngeal pain subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0	0 / 46 (0.00%) 0	0 / 29 (0.00%) 0
Skin and subcutaneous tissue disorders Alopecia subjects affected / exposed occurrences (all)	1 / 27 (3.70%) 1	0 / 46 (0.00%) 0	1 / 29 (3.45%) 1
Dermatitis atopic subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0	0 / 46 (0.00%) 0	0 / 29 (0.00%) 0
Dry skin subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0	0 / 46 (0.00%) 0	2 / 29 (6.90%) 2
Hand dermatitis subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0	0 / 46 (0.00%) 0	0 / 29 (0.00%) 0
Rash subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0	1 / 46 (2.17%) 2	0 / 29 (0.00%) 0
Dermatitis psoriasiform			

subjects affected / exposed	0 / 27 (0.00%)	0 / 46 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Acne			
subjects affected / exposed	0 / 27 (0.00%)	0 / 46 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 27 (3.70%)	0 / 46 (0.00%)	1 / 29 (3.45%)
occurrences (all)	1	0	1
Back pain			
subjects affected / exposed	0 / 27 (0.00%)	1 / 46 (2.17%)	0 / 29 (0.00%)
occurrences (all)	0	1	0
Coccydynia			
subjects affected / exposed	0 / 27 (0.00%)	0 / 46 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 27 (0.00%)	0 / 46 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 27 (0.00%)	2 / 46 (4.35%)	2 / 29 (6.90%)
occurrences (all)	0	2	2
Sinusitis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 46 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	1 / 27 (3.70%)	1 / 46 (2.17%)	0 / 29 (0.00%)
occurrences (all)	1	1	0
Nasopharyngitis			
subjects affected / exposed	1 / 27 (3.70%)	3 / 46 (6.52%)	2 / 29 (6.90%)
occurrences (all)	3	3	2
Chorioretinitis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 46 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			

subjects affected / exposed	2 / 27 (7.41%)	1 / 46 (2.17%)	0 / 29 (0.00%)
occurrences (all)	2	1	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 27 (0.00%)	0 / 46 (0.00%)	2 / 29 (6.90%)
occurrences (all)	0	0	3

Non-serious adverse events	Placebo (Induction) to PF-06480605 (Chronic) 450mg		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	9 / 14 (64.29%)		
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
SARS-CoV-2 antibody test positive			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Blood pressure increased			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
SARS-CoV-2 test positive			
subjects affected / exposed	2 / 14 (14.29%)		
occurrences (all)	2		
Injury, poisoning and procedural complications			
Thermal burn			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Skin abrasion			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	2		
Arthropod bite			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		

Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Headache			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Iron deficiency anaemia			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Pain			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Oedema			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Injection site reaction			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	3		
Fatigue			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Pyrexia			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Peripheral swelling			

subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Gastritis			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Nausea			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Stomatitis			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Diarrhoea			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Umbilical hernia			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Angular cheilitis			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Colitis ulcerative			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Vomiting			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Proctitis			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Toothache			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		

Reproductive system and breast disorders			
Adnexa uteri pain			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Epistaxis			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Oropharyngeal pain			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Dermatitis atopic			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Dry skin			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Hand dermatitis			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Rash			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Dermatitis psoriasiform			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		
Acne			
subjects affected / exposed	0 / 14 (0.00%)		
occurrences (all)	0		

Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed 0 / 14 (0.00%) occurrences (all) 0 Back pain subjects affected / exposed 0 / 14 (0.00%) occurrences (all) 0 Coccydynia subjects affected / exposed 0 / 14 (0.00%) occurrences (all) 0 Neck pain subjects affected / exposed 1 / 14 (7.14%) occurrences (all) 1			
Infections and infestations COVID-19 subjects affected / exposed 1 / 14 (7.14%) occurrences (all) 1 Sinusitis subjects affected / exposed 1 / 14 (7.14%) occurrences (all) 1 Pharyngitis subjects affected / exposed 0 / 14 (0.00%) occurrences (all) 0 Nasopharyngitis subjects affected / exposed 1 / 14 (7.14%) occurrences (all) 1 Chorioretinitis subjects affected / exposed 1 / 14 (7.14%) occurrences (all) 1 Urinary tract infection subjects affected / exposed 0 / 14 (0.00%) occurrences (all) 0 Upper respiratory tract infection subjects affected / exposed 0 / 14 (0.00%) occurrences (all) 0			

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
01 September 2020	1. Estimands regarding primary induction and chronic therapy period, related to what is considered a non-responder regarding early treatment discontinuation were clarified. Estimands section updated to reflect and clarify how a participants who discontinues study treatment prior to week 12 will be allocated regarding responder and non-responder. 2. Various changes were implemented in the Schedule of Activities. 3. Inclusion criterion weight, body mass index (BMI) was removed as the investigational drug was not dosed based on weight. 4. Time period for collecting AE and SAE information: Protocol wording states, "through and including Visit 20; this was corrected to Visit 18. 5. Mayo Scoring system for assessment of ulcerative colitis was updated: the modified endoscopic scoring system was used in this study. Friability was removed from endoscopic subscore of 1 and placed into the endoscopic subscore 2.
15 March 2022	1. Modified estimands to permit exclusion of participants with missed visits due to COVID-19 from analysis. 2. Chronic Therapy Period secondary endpoint change from baseline for fecal calprotectin, hsCRP, and sTL1A biomarkers in order to better understand the full trajectory over time was added. 3. Tertiary endpoint for the Inflammatory Bowel Disease Questionnaire (IBDQ) to assess the impact of drug on a clinically meaningful threshold and more details around histopathology endpoints was added. 4. Language was modified to clarify participants who withdraw from the treatment period should be followed for 3 study visits (one being the Early Withdrawal Visit) for a total of 12 weeks from the last dose of IP. 4. Analysis methods were modified to align with similar analysis of binary endpoints, and to allow comparison with historical data from other studies and publications with similar endpoints on treatment effect-Return stool diary data collection tool from Early Withdrawal visit due to administrative error was removed 6. Evaluable Population was updated to include ITT and mITT in order to distinguish between Induction and Chronic Period, and clarification was provided for Biomarker Analysis Population and clarified biomarker analysis population.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported