



## Clinical trial results:

### A Phase 2b, DoubleBlind, Randomized, PlaceboControlled, Parallel Group, Dose Ranging Study of Oral PF06651600 and PF06700841 as Induction and Chronic Therapy in Subjects With Moderate to Severe Ulcerative Colitis

#### Summary

EudraCT number	2016-003708-29
Trial protocol	SK LT DK DE AT PL HU ES NL BG IT
Global end of trial date	10 May 2021

#### Results information

Result version number	v1
This version publication date	25 May 2022
First version publication date	25 May 2022

#### Trial information

##### Trial identification

Sponsor protocol code	B7981005
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##### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02958865
WHO universal trial number (UTN)	-

Notes:

#### Sponsors

Sponsor organisation name	Pfizer, Inc.
Sponsor organisation address	235 E 42nd Street, New York, United States, NY 10017
Public contact	Pfizer ClinicalTrials.gov Call Center, Pfizer, Inc., +1 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer ClinicalTrials.gov Call Center, Pfizer, Inc., +1 8007181021, ClinicalTrials.gov_Inquiries@pfizer.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	10 May 2021
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	10 May 2021
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

This multicenter, multiple arm, dose ranging, placebo controlled (in the induction period only) study was to evaluate the efficacy (based on total Mayo score), safety, tolerability, PK, and PD of multiple doses of PF-06651600 (20, 70, and 200 mg doses) and PF-06700841 (10, 30, and 60 mg doses) during an 8-week induction period, followed by a chronic dosing period at doses of 50 mg and 30 mg of PF-06651600 and PF-06700841, respectively, for 24 weeks.

Protection of trial subjects:

This study was conducted in compliance with the ethical principles originating in or derived from the Declaration of Helsinki and in compliance with all International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Good Clinical Practice (GCP) Guidelines. In addition, all local regulatory requirements were followed, in particular, those affording greater protection to the safety of trial subjects.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	03 February 2017
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

## Population of trial subjects

### Subjects enrolled per country

Country: Number of subjects enrolled	Bulgaria: 8
Country: Number of subjects enrolled	Czechia: 5
Country: Number of subjects enrolled	Denmark: 12
Country: Number of subjects enrolled	Georgia: 2
Country: Number of subjects enrolled	Germany: 23
Country: Number of subjects enrolled	Hungary: 20
Country: Number of subjects enrolled	Israel: 3
Country: Number of subjects enrolled	Italy: 29
Country: Number of subjects enrolled	Korea, Republic of: 8
Country: Number of subjects enrolled	Poland: 77
Country: Number of subjects enrolled	Romania: 1
Country: Number of subjects enrolled	Russian Federation: 31
Country: Number of subjects enrolled	Serbia: 8
Country: Number of subjects enrolled	Slovakia: 6
Country: Number of subjects enrolled	Spain: 10
Country: Number of subjects enrolled	Turkey: 18
Country: Number of subjects enrolled	Ukraine: 23

Country: Number of subjects enrolled	United States: 33
Worldwide total number of subjects	317
EEA total number of subjects	191

Notes:

<b>Subjects enrolled per age group</b>	
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)	304
From 65 to 84 years	13
85 years and over	0

## Subject disposition

### Recruitment

Recruitment details:

The study consisted of a screening period of up to 6 weeks, an 8 week double blind induction period, an additional 24 week open label active chronic dosing period followed by a 4 week follow up period after the last dose of investigational product for a total of 36 weeks.

### Pre-assignment

Screening details:

A total of 319 subjects were randomized and 317 subjects were treated.

### 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
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<b>Arm title</b>	Placebo (Induction: 0 to 8 weeks)
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Arm description:

The placebo was administered orally once daily (QD) from Day 1 to Week 8.

Arm type	Placebo
Investigational medicinal product name	Matching placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received Placebo QD from Day 1 to Week 8.

<b>Arm title</b>	PF-06651600 20 mg (Induction)
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Arm description:

PF-06651600 tablet was administered orally at 20 mg QD from Day 1 to Week 8.

Arm type	Experimental
Investigational medicinal product name	PF-06651600
Investigational medicinal product code	
Other name	Ritlecitinib
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received PF-06651600 20 mg QD from Day 1 to Week 8.

<b>Arm title</b>	PF-06651600 70 mg (Induction)
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Arm description:

PF-06651600 tablet was administered orally at 70 mg QD from Day 1 to Week 8.

Arm type	Experimental
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Investigational medicinal product name	PF-06651600
Investigational medicinal product code	
Other name	Ritlecitinib
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Subjects received PF-06651600 70 mg QD from Day 1 to Week 8.	
<b>Arm title</b>	PF-06651600 200 mg (Induction)
Arm description:	
PF-06651600 tablet was administered orally at 200 mg QD from Day 1 to Week 8.	
Arm type	Experimental
Investigational medicinal product name	PF-06651600
Investigational medicinal product code	
Other name	Ritlecitinib
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Subjects received PF-06651600 200 mg QD from Day 1 to Week 8.	
<b>Arm title</b>	PF-06700841 10 mg (Induction)
Arm description:	
PF-06700841 tablet was administered orally at 10 mg QD from Day 1 to Week 8.	
Arm type	Experimental
Investigational medicinal product name	PF-06700841
Investigational medicinal product code	
Other name	Brepocitinib
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Subjects received PF-06700841 10 mg QD from Day 1 to Week 8.	
<b>Arm title</b>	PF-06700841 30 mg (Induction)
Arm description:	
PF-06700841 tablet was administered orally at 30 mg QD from Day 1 to Week 8.	
Arm type	Experimental
Investigational medicinal product name	PF-06700841
Investigational medicinal product code	
Other name	Brepocitinib
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Subjects received PF-06700841 30 mg QD from Day 1 to Week 8.	
<b>Arm title</b>	PF-06700841 60 mg (Induction)
Arm description:	
PF-06700841 tablet was administered orally at 60 mg QD from Day 1 to Week 8.	
Arm type	Experimental
Investigational medicinal product name	PF-06700841
Investigational medicinal product code	
Other name	Brepocitinib
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received PF-06700841 60 mg QD from Day 1 to Week 8.

<b>Number of subjects in period 1</b>	Placebo (Induction: 0 to 8 weeks)	PF-06651600 20 mg (Induction)	PF-06651600 70 mg (Induction)
Started	25	51	49
Completed	21	44	43
Not completed	4	7	6
Physician decision	1	1	-
Consent withdrawn by subject	2	-	3
Adverse event, non-fatal	-	2	-
ADVERSE EVENT, serious non-fatal	-	2	-
No longer meets eligibility criteria	-	-	-
Death	-	1	-
other	-	-	1
Lost to follow-up	-	-	-
Lack of efficacy	1	1	1
Protocol deviation	-	-	1

<b>Number of subjects in period 1</b>	PF-06651600 200 mg (Induction)	PF-06700841 10 mg (Induction)	PF-06700841 30 mg (Induction)
Started	50	48	47
Completed	41	45	43
Not completed	9	3	4
Physician decision	-	-	-
Consent withdrawn by subject	1	1	1
Adverse event, non-fatal	3	-	1
ADVERSE EVENT, serious non-fatal	2	1	1
No longer meets eligibility criteria	1	-	-
Death	-	-	-
other	2	-	1
Lost to follow-up	-	1	-
Lack of efficacy	-	-	-
Protocol deviation	-	-	-

<b>Number of subjects in period 1</b>	PF-06700841 60 mg (Induction)
Started	47

Completed	44
Not completed	3
Physician decision	-
Consent withdrawn by subject	1
Adverse event, non-fatal	-
ADVERSE EVENT, serious non-fatal	1
No longer meets eligibility criteria	1
Death	-
other	-
Lost to follow-up	-
Lack of efficacy	-
Protocol deviation	-

## Period 2

Period 2 title	Chronic Period
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

## Arms

Are arms mutually exclusive?	Yes
<b>Arm title</b>	PF-06651600 200 mg -> PF-06651600 50 mg

Arm description:

PF-06651600 tablet was administered orally at 200 mg QD from Day 1 to Week 8 and at 50 mg QD from Week 9 to Week 32.

Arm type	Experimental
Investigational medicinal product name	PF-06651600
Investigational medicinal product code	
Other name	Ritlecitinib
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received PF-06651600 50 mg QD from Week 8 to Week 32.

<b>Arm title</b>	PF-06651600 70 mg -> PF-06651600 50 mg
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Arm description:

PF-06651600 tablet was administered orally at 70 mg QD from Day 1 to Week 8 and at 50 mg QD from Week 9 to Week 32.

Arm type	Experimental
Investigational medicinal product name	PF-06651600
Investigational medicinal product code	
Other name	Ritlecitinib
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received PF-06651600 50 mg QD from Week 8 to Week 32.

<b>Arm title</b>	PF-06651600 20 mg -> PF-06651600 50 mg
Arm description: PF-06651600 tablet was administered orally at 20 mg QD from Day 1 to Week 8 and at 50 mg QD from Week 9 to Week 32.	
Arm type	Experimental
Investigational medicinal product name	PF-06651600
Investigational medicinal product code	
Other name	Ritlecitinib
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: Subjects received PF-06651600 50 mg QD from Week 8 to Week 32.	
<b>Arm title</b>	Placebo -> PF-06651600 50 mg
Arm description: The placebo was administered orally QD from Day 1 to Week 8 and PF-06651600 was administered at 50 mg QD from Week 9 to Week 32.	
Arm type	Placebo
Investigational medicinal product name	PF-06651600
Investigational medicinal product code	
Other name	Ritlecitinib
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: Subjects received PF-06651600 50 mg QD from Week 8 to Week 32.	
<b>Arm title</b>	PF-06700841 60 mg -> PF-06700841 30 mg
Arm description: PF-06700841 tablet was administered orally at 60 mg QD from Day 1 to Week 8 and at 30 mg QD from Week 9 to Week 32.	
Arm type	Experimental
Investigational medicinal product name	PF-06700841
Investigational medicinal product code	
Other name	Brepocitinib
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: Subjects received PF-06700841 30 mg QD from Week 8 to Week 32.	
<b>Arm title</b>	PF-06700841 30 mg -> PF-06700841 30 mg
Arm description: PF-06700841 tablet was administered orally at 30 mg QD from Day 1 to Week 8 and at 30 mg QD from Week 9 to Week 32.	
Arm type	Experimental
Investigational medicinal product name	PF-06700841
Investigational medicinal product code	
Other name	Brepocitinib
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: Subjects received PF-06700841 30 mg QD from Week 8 to Week 32.	
<b>Arm title</b>	PF-06700841 10 mg -> PF-06700841 30 mg
Arm description: PF-06700841 tablet was administered orally at 10 mg QD from Day 1 to Week 8 and at 30 mg QD from Week 9 to Week 32.	



Arm type	Experimental
Investigational medicinal product name	PF-06700841
Investigational medicinal product code	
Other name	Brepocitinib
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received PF-06700841 30 mg QD from Week 8 to Week 32.

<b>Arm title</b>	Placebo -> PF-06700841 30 mg
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Arm description:

The placebo was administered orally from Day 1 to Week 8 and PF-06700841 was administered orally at 30 mg QD from Week 9 to Week 32.

Arm type	Placebo
Investigational medicinal product name	PF-06700841
Investigational medicinal product code	
Other name	Brepocitinib
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received PF-06700841 30 mg QD from Week 8 to Week 32.

<b>Arm title</b>	Pooling Placebo During Chronic
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Arm description:

The placebo was administered orally QD from Week 9 to Week 32 regardless of what was administered from Day 1 to Week 8.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received Placebo QD from Week 8 to Week 32.

<b>Number of subjects in period 2<sup>[1]</sup></b>	PF-06651600 200 mg -> PF-06651600 50 mg	PF-06651600 70 mg -> PF-06651600 50 mg	PF-06651600 20 mg -> PF-06651600 50 mg
Started	35	36	39
Completed	33	33	33
Not completed	2	3	6
Consent withdrawn by subject	-	-	-
ADVERSE EVENT, serious non-fatal	1	1	1
Adverse event, non-fatal	-	-	1
No longer meets eligibility criteria	-	-	1
Pregnancy	-	-	1
Non-compliance with study drug	-	-	-
other	1	-	1

Lack of efficacy	-	2	1
Protocol deviation	-	-	-

Number of subjects in period 2 <sup>[1]</sup>	Placebo -> PF-06651600 50 mg	PF-06700841 60 mg -> PF-06700841 30 mg	PF-06700841 30 mg -> PF-06700841 30 mg
Started	10	38	37
Completed	10	31	26
Not completed	0	7	11
Consent withdrawn by subject	-	1	6
ADVERSE EVENT, serious non-fatal	-	1	3
Adverse event, non-fatal	-	-	1
No longer meets eligibility criteria	-	-	-
Pregnancy	-	-	-
Non-compliance with study drug	-	-	-
other	-	-	1
Lack of efficacy	-	5	-
Protocol deviation	-	-	-

Number of subjects in period 2 <sup>[1]</sup>	PF-06700841 10 mg -> PF-06700841 30 mg	Placebo -> PF-06700841 30 mg	Pooling Placebo During Chronic
Started	39	9	37
Completed	31	5	20
Not completed	8	4	17
Consent withdrawn by subject	3	3	2
ADVERSE EVENT, serious non-fatal	-	-	-
Adverse event, non-fatal	1	1	5
No longer meets eligibility criteria	-	-	-
Pregnancy	-	-	1
Non-compliance with study drug	1	-	-
other	-	-	1
Lack of efficacy	2	-	8
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: One subject who was re-randomized but not treated during chronic period was not included.

## Baseline characteristics

### Reporting groups

Reporting group title	Placebo (Induction: 0 to 8 weeks)
Reporting group description:	
The placebo was administered orally once daily (QD) from Day 1 to Week 8.	
Reporting group title	PF-06651600 20 mg (Induction)
Reporting group description:	
PF-06651600 tablet was administered orally at 20 mg QD from Day 1 to Week 8.	
Reporting group title	PF-06651600 70 mg (Induction)
Reporting group description:	
PF-06651600 tablet was administered orally at 70 mg QD from Day 1 to Week 8.	
Reporting group title	PF-06651600 200 mg (Induction)
Reporting group description:	
PF-06651600 tablet was administered orally at 200 mg QD from Day 1 to Week 8.	
Reporting group title	PF-06700841 10 mg (Induction)
Reporting group description:	
PF-06700841 tablet was administered orally at 10 mg QD from Day 1 to Week 8.	
Reporting group title	PF-06700841 30 mg (Induction)
Reporting group description:	
PF-06700841 tablet was administered orally at 30 mg QD from Day 1 to Week 8.	
Reporting group title	PF-06700841 60 mg (Induction)
Reporting group description:	
PF-06700841 tablet was administered orally at 60 mg QD from Day 1 to Week 8.	

Reporting group values	Placebo (Induction: 0 to 8 weeks)	PF-06651600 20 mg (Induction)	PF-06651600 70 mg (Induction)
Number of subjects	25	51	49
Age Categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	23	47	48
From 65-84 years	2	4	1
85 years and over	0	0	0
Age Continuous Units: years			
arithmetic mean	42.8	41.3	40.2
standard deviation	± 15.45	± 14.03	± 13.31
Gender Categorical Units: Subjects			
Male	14	34	24
Female	11	17	25

Race			
Units: Subjects			
White	22	46	46
Black or African American	1	1	2
Asian	1	3	1
Other	1	1	0
Ethnicity			
Units: Subjects			
Hispanic or Latino	0	2	0
Not Hispanic or Latino	25	49	49

Reporting group values	PF-06651600 200 mg (Induction)	PF-06700841 10 mg (Induction)	PF-06700841 30 mg (Induction)
Number of subjects	50	48	47
Age Categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	46	47	47
From 65-84 years	4	1	0
85 years and over	0	0	0
Age Continuous			
Units: years			
arithmetic mean	37.3	40.8	40.9
standard deviation	± 15.67	± 13.04	± 13.03
Gender Categorical			
Units: Subjects			
Male	32	30	23
Female	18	18	24
Race			
Units: Subjects			
White	48	44	44
Black or African American	1	0	0
Asian	0	3	3
Other	1	1	0
Ethnicity			
Units: Subjects			
Hispanic or Latino	0	0	2
Not Hispanic or Latino	50	48	45

Reporting group values	PF-06700841 60 mg (Induction)	Total	
Number of subjects	47	317	
Age Categorical			
Units: Subjects			
In utero	0	0	

Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	46	304	
From 65-84 years	1	13	
85 years and over	0	0	
Age Continuous			
Units: years			
arithmetic mean	40.3		
standard deviation	± 12.80	-	
Gender Categorical			
Units: Subjects			
Male	25	182	
Female	22	135	
Race			
Units: Subjects			
White	45	295	
Black or African American	1	6	
Asian	0	11	
Other	1	5	
Ethnicity			
Units: Subjects			
Hispanic or Latino	2	6	
Not Hispanic or Latino	45	311	

## End points

### End points reporting groups

Reporting group title	Placebo (Induction: 0 to 8 weeks)
Reporting group description: The placebo was administered orally once daily (QD) from Day 1 to Week 8.	
Reporting group title	PF-06651600 20 mg (Induction)
Reporting group description: PF-06651600 tablet was administered orally at 20 mg QD from Day 1 to Week 8.	
Reporting group title	PF-06651600 70 mg (Induction)
Reporting group description: PF-06651600 tablet was administered orally at 70 mg QD from Day 1 to Week 8.	
Reporting group title	PF-06651600 200 mg (Induction)
Reporting group description: PF-06651600 tablet was administered orally at 200 mg QD from Day 1 to Week 8.	
Reporting group title	PF-06700841 10 mg (Induction)
Reporting group description: PF-06700841 tablet was administered orally at 10 mg QD from Day 1 to Week 8.	
Reporting group title	PF-06700841 30 mg (Induction)
Reporting group description: PF-06700841 tablet was administered orally at 30 mg QD from Day 1 to Week 8.	
Reporting group title	PF-06700841 60 mg (Induction)
Reporting group description: PF-06700841 tablet was administered orally at 60 mg QD from Day 1 to Week 8.	
Reporting group title	PF-06651600 200 mg -> PF-06651600 50 mg
Reporting group description: PF-06651600 tablet was administered orally at 200 mg QD from Day 1 to Week 8 and at 50 mg QD from Week 9 to Week 32.	
Reporting group title	PF-06651600 70 mg -> PF-06651600 50 mg
Reporting group description: PF-06651600 tablet was administered orally at 70 mg QD from Day 1 to Week 8 and at 50 mg QD from Week 9 to Week 32.	
Reporting group title	PF-06651600 20 mg -> PF-06651600 50 mg
Reporting group description: PF-06651600 tablet was administered orally at 20 mg QD from Day 1 to Week 8 and at 50 mg QD from Week 9 to Week 32.	
Reporting group title	Placebo -> PF-06651600 50 mg
Reporting group description: The placebo was administered orally QD from Day 1 to Week 8 and PF-06651600 was administered at 50 mg QD from Week 9 to Week 32.	
Reporting group title	PF-06700841 60 mg -> PF-06700841 30 mg
Reporting group description: PF-06700841 tablet was administered orally at 60 mg QD from Day 1 to Week 8 and at 30 mg QD from Week 9 to Week 32.	
Reporting group title	PF-06700841 30 mg -> PF-06700841 30 mg
Reporting group description: PF-06700841 tablet was administered orally at 30 mg QD from Day 1 to Week 8 and at 30 mg QD from Week 9 to Week 32.	
Reporting group title	PF-06700841 10 mg -> PF-06700841 30 mg
Reporting group description: PF-06700841 tablet was administered orally at 10 mg QD from Day 1 to Week 8 and at 30 mg QD from Week 9 to Week 32.	
Reporting group title	Placebo -> PF-06700841 30 mg

Reporting group description:

The placebo was administered orally from Day 1 to Week 8 and PF-06700841 was administered orally at 30 mg QD from Week 9 to Week 32.

Reporting group title	Pooling Placebo During Chronic
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Reporting group description:

The placebo was administered orally QD from Week 9 to Week 32 regardless of what was administered from Day 1 to Week 8.

### Primary: Induction Period: Total Mayo Score at Week 8

End point title	Induction Period: Total Mayo Score at Week 8
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End point description:

The Mayo score ranges from 0 to 12, with higher scores indicating more severe disease. The intent-to-treat (ITT) analysis set was used to analyze this endpoint, defined as all randomized subjects who received at least 1 dose of investigational product or placebo.

End point type	Primary
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End point timeframe:

Week 8

End point values	Placebo (Induction: 0 to 8 weeks)	PF-06651600 20 mg (Induction)	PF-06651600 70 mg (Induction)	PF-06651600 200 mg (Induction)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	51	49	50
Units: Unit on a scale				
least squares mean (confidence interval 90%)	7.88 (6.95 to 8.81)	5.85 (5.18 to 6.51)	4.00 (3.33 to 4.67)	3.27 (2.58 to 3.96)

End point values	PF-06700841 10 mg (Induction)	PF-06700841 30 mg (Induction)	PF-06700841 60 mg (Induction)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	48	47	47	
Units: Unit on a scale				
least squares mean (confidence interval 90%)	6.08 (5.43 to 6.74)	5.60 (4.93 to 6.27)	4.67 (4.01 to 5.33)	

### Statistical analyses

Statistical analysis title	Placebo, PF-06651600 20 mg
Comparison groups	Placebo (Induction: 0 to 8 weeks) v PF-06651600 20 mg (Induction)

Number of subjects included in analysis	76
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0017
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Mean difference (final values)
Point estimate	-2.03
Confidence interval	
level	90 %
sides	2-sided
lower limit	-3.17
upper limit	-0.89
Variability estimate	Standard error of the mean
Dispersion value	0.69

<b>Statistical analysis title</b>	Placebo, PF-06651600 70 mg
Comparison groups	Placebo (Induction: 0 to 8 weeks) v PF-06651600 70 mg (Induction)
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Mean difference (final values)
Point estimate	-3.88
Confidence interval	
level	90 %
sides	2-sided
lower limit	-5.01
upper limit	-2.74
Variability estimate	Standard error of the mean
Dispersion value	0.69

<b>Statistical analysis title</b>	Placebo, PF-06651600 200 mg
Comparison groups	Placebo (Induction: 0 to 8 weeks) v PF-06651600 200 mg (Induction)
Number of subjects included in analysis	75
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Mean difference (final values)
Point estimate	-4.61



Confidence interval	
level	90 %
sides	2-sided
lower limit	-5.76
upper limit	-3.46
Variability estimate	Standard error of the mean
Dispersion value	0.7

<b>Statistical analysis title</b>	Placebo, PF-06700841 10 mg
Comparison groups	Placebo (Induction: 0 to 8 weeks) v PF-06700841 10 mg (Induction)
Number of subjects included in analysis	73
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0045
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Mean difference (final values)
Point estimate	-1.79
Confidence interval	
level	90 %
sides	2-sided
lower limit	-2.92
upper limit	-0.67
Variability estimate	Standard error of the mean
Dispersion value	0.68

<b>Statistical analysis title</b>	Placebo, PF-06700841 30 mg
Comparison groups	Placebo (Induction: 0 to 8 weeks) v PF-06700841 30 mg (Induction)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0005
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Mean difference (final values)
Point estimate	-2.28
Confidence interval	
level	90 %
sides	2-sided
lower limit	-3.41
upper limit	-1.14
Variability estimate	Standard error of the mean
Dispersion value	0.69

<b>Statistical analysis title</b>	Placebo, PF-06700841 60 mg
Comparison groups	Placebo (Induction: 0 to 8 weeks) v PF-06700841 60 mg (Induction)
Number of subjects included in analysis	72
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Mean difference (final values)
Point estimate	-3.21
Confidence interval	
level	90 %
sides	2-sided
lower limit	-4.34
upper limit	-2.08
Variability estimate	Standard error of the mean
Dispersion value	0.69

**Primary: Chronic Period: Number of subjects with Treatment-Emergent Adverse Events (AEs), Serious Adverse Events (SAEs) and with withdrawals due to adverse events**

End point title	Chronic Period: Number of subjects with Treatment-Emergent Adverse Events (AEs), Serious Adverse Events (SAEs) and with withdrawals due to adverse events <sup>[1]</sup>
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End point description:

An AE is any untoward medical occurrence in a study subjects administered a product or medical device; the event need not necessarily have a causal relationship with the treatment or usage. An SAE is any untoward medical occurrence at any dose that: results in death; is life threatening (immediate risk of death); requires inpatient hospitalization or prolongation of existing hospitalization; results in persistent or significant disability/incapacity (substantial disruption of the ability to conduct normal life functions); results in congenital anomaly/birth defect; or that is considered to be an important medical event that may jeopardize the subject or may require intervention to prevent one of the other AE outcomes. Treatment-emergent AEs were those with initial onset or that worsen in severity after the first dose of the study medication. All AEs in the table below were treatment-emergent AEs. All subjects who received at least one dose of the randomized study treatment.

End point type	Primary
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End point timeframe:

Baseline of Chronic period (Week 8) to Week 36

Notes:

[1] - 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 statistical analysis was planned for this endpoint.

<b>End point values</b>	PF-06651600 200 mg -> PF- 06651600 50 mg	PF-06651600 70 mg -> PF- 06651600 50 mg	PF-06651600 20 mg -> PF- 06651600 50 mg	Placebo -> PF- 06651600 50 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	35	36	39	10
Units: Subjects				
subjects with AEs	18	27	18	8
Subjects with SAEs	3	1	1	0
Subjects with severe adverse events	2	1	3	0

Subjects discontinued from study due to AEs	1	1	3	1
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End point values	PF-06700841 60 mg -> PF-06700841 30 mg	PF-06700841 30 mg -> PF-06700841 30 mg	PF-06700841 10 mg -> PF-06700841 30 mg	Placebo -> PF-06700841 30 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	37	39	9
Units: Subjects				
subjects with AEs	21	23	26	4
Subjects with SAEs	2	4	2	0
Subjects with severe adverse events	3	4	4	1
Subjects discontinued from study due to AEs	1	4	1	1

End point values	Pooling Placebo During Chronic			
Subject group type	Reporting group			
Number of subjects analysed	37			
Units: Subjects				
subjects with AEs	18			
Subjects with SAEs	0			
Subjects with severe adverse events	4			
Subjects discontinued from study due to AEs	6			

## Statistical analyses

No statistical analyses for this end point

### Primary: Chronic Period: Number of subjects with Laboratory Abnormalities without regard to baseline values - Hematology

End point title	Chronic Period: Number of subjects with Laboratory Abnormalities without regard to baseline values - Hematology <sup>[2]</sup>
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End point description:

Following parameters were analyzed for laboratory examination: hemoglobin, hematocrit, erythrocytes, reticulocytes, ery. Mean Corpuscular Volume, platelets, Reticulocytes/Erythrocytes, Leukocytes, Lymphocytes, Neutrophils, Basophils, Eosinophils, Monocytes, Activated Partial Thromboplastin Time, Prothrombin Time, Prothrombin Intl. Normalized Ratio. The analysis population included all enrolled participants who received at least one dose of study medication.

End point type	Primary
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End point timeframe:

Baseline of Chronic period (Week 8) to Week 36

Notes:

[2] - 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 statistical analysis was planned for this endpoint.

End point values	PF-06651600 200 mg -> PF- 06651600 50 mg	PF-06651600 70 mg -> PF- 06651600 50 mg	PF-06651600 20 mg -> PF- 06651600 50 mg	Placebo -> PF- 06651600 50 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	35	35	39	10
Units: Subjects				
Hemoglobin(g/dL)<0.8x LLN	2	2	1	1
Hematocrit(%)<0.8x LLN	0	2	1	0
Erythrocytes(10 <sup>6</sup> /mm <sup>3</sup> )<0.8x LLN	0	1	1	0
Reticulocytes (ABSOLUTE) (10 <sup>3</sup> /mm <sup>3</sup> )<0.5x LLN	0	0	0	0
Reticulocytes (ABSOLUTE) (10 <sup>3</sup> /mm <sup>3</sup> )>1.5x ULN	0	0	1	0
Ery. Mean Corpuscular Volume (10 <sup>-15</sup> L)<0.9x LLN	0	0	1	0
Ery. Mean Corpuscular Volume (10 <sup>-15</sup> L)>1.1x ULN	0	0	0	0
Platelets (10 <sup>3</sup> /mm <sup>3</sup> )<0.5xLLN	0	0	0	0
Platelets (10 <sup>3</sup> /mm <sup>3</sup> )>1.75xULN	0	0	0	0
Reticulocytes/Erythrocytes (%)<0.5xLLN	0	0	0	0
Reticulocytes/Erythrocytes (%)>1.5xULN	1	1	2	0
Leukocytes (10 <sup>3</sup> /mm <sup>3</sup> )<0.6xLLN	0	0	0	0
Leukocytes (10 <sup>3</sup> /mm <sup>3</sup> )>1.5xULN	0	0	1	1
Lymphocytes (ABSOLUTE) (10 <sup>3</sup> /mm <sup>3</sup> )<0.8xLLN	7	6	6	1
Lymphocytes (ABSOLUTE) (10 <sup>3</sup> /mm <sup>3</sup> )>1.2xULN	0	0	0	0
Neutrophils (ABSOLUTE) (10 <sup>3</sup> /mm <sup>3</sup> )<0.8xLLN	1	2	0	0
Neutrophils (ABSOLUTE) (10 <sup>3</sup> /mm <sup>3</sup> )>1.2xULN	3	8	11	1
Basophils (ABSOLUTE)(10 <sup>3</sup> /mm <sup>3</sup> )>1.2xULN	0	0	0	0
Eosinophils (ABSOLUTE) (10 <sup>3</sup> /mm <sup>3</sup> )>1.2xULN	0	0	0	0
Monocytes (ABSOLUTE) (10 <sup>3</sup> /mm <sup>3</sup> )>1.2xULN	0	0	0	0
ActivatedPartialThromboplastinTime (sec)>1.1xULN	0	3	1	0
Prothrombin Time (sec)>1.1xULN	2	3	2	0
Prothrombin Intl. Normalized Ratio>1.1xULN	2	3	2	0

End point values	PF-06700841 60 mg -> PF- 06700841 30 mg	PF-06700841 30 mg -> PF- 06700841 30 mg	PF-06700841 10 mg -> PF- 06700841 30 mg	Placebo -> PF- 06700841 30 mg
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Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	37	39	9
Units: Subjects				
Hemoglobin(g/dL)<0.8x LLN	3	3	6	2
Hematocrit(%)<0.8x LLN	1	1	1	1
Erythrocytes(10 <sup>6</sup> /mm <sup>3</sup> )<0.8x LLN	1	0	1	1
Reticulocytes (ABSOLUTE) (10 <sup>3</sup> /mm <sup>3</sup> )<0.5x LLN	0	0	0	0
Reticulocytes (ABSOLUTE) (10 <sup>3</sup> /mm <sup>3</sup> )>1.5x ULN	0	0	0	0
Ery. Mean Corpuscular Volume (10 <sup>-15</sup> L)<0.9x LLN	0	1	0	0
Ery. Mean Corpuscular Volume (10 <sup>-15</sup> L)>1.1x ULN	0	0	0	0
Platelets (10 <sup>3</sup> /mm <sup>3</sup> )<0.5xLLN	0	0	0	0
Platelets (10 <sup>3</sup> /mm <sup>3</sup> )>1.75xULN	3	1	2	0
Reticulocytes/Erythrocytes (%)<0.5xLLN	0	0	0	0
Reticulocytes/Erythrocytes (%)>1.5xULN	1	1	0	0
Leukocytes (10 <sup>3</sup> /mm <sup>3</sup> )<0.6xLLN	0	0	0	0
Leukocytes (10 <sup>3</sup> /mm <sup>3</sup> )>1.5xULN	1	1	1	1
Lymphocytes (ABSOLUTE) (10 <sup>3</sup> /mm <sup>3</sup> )<0.8xLLN	0	0	3	0
Lymphocytes (ABSOLUTE) (10 <sup>3</sup> /mm <sup>3</sup> )>1.2xULN	0	0	0	1
Neutrophils (ABSOLUTE) (10 <sup>3</sup> /mm <sup>3</sup> )<0.8xLLN	3	1	2	1
Neutrophils (ABSOLUTE) (10 <sup>3</sup> /mm <sup>3</sup> )>1.2xULN	8	6	6	3
Basophils (ABSOLUTE)(10 <sup>3</sup> /mm <sup>3</sup> )>1.2xULN	2	1	0	0
Eosinophils (ABSOLUTE) (10 <sup>3</sup> /mm <sup>3</sup> )>1.2xULN	2	1	0	0
Monocytes (ABSOLUTE) (10 <sup>3</sup> /mm <sup>3</sup> )>1.2xULN	2	2	0	0
ActivatedPartialThromboplastinTime (sec)>1.1xULN	2	0	0	0
Prothrombin Time (sec)>1.1xULN	2	2	0	0
Prothrombin Intl. Normalized Ratio>1.1xULN	2	1	0	0

End point values	Pooling Placebo During Chronic			
Subject group type	Reporting group			
Number of subjects analysed	37			
Units: Subjects				
Hemoglobin(g/dL)<0.8x LLN	3			
Hematocrit(%)<0.8x LLN	2			
Erythrocytes(10 <sup>6</sup> /mm <sup>3</sup> )<0.8x LLN	1			
Reticulocytes (ABSOLUTE) (10 <sup>3</sup> /mm <sup>3</sup> )<0.5x LLN	0			
Reticulocytes (ABSOLUTE) (10 <sup>3</sup> /mm <sup>3</sup> )>1.5x ULN	0			

Ery. Mean Corpuscular Volume (10 <sup>-15</sup> L)<0.9x LLN	0			
Ery. Mean Corpuscular Volume (10 <sup>-15</sup> L)>1.1x ULN	0			
Platelets (10 <sup>3</sup> /mm <sup>3</sup> )<0.5xLLN	0			
Platelets (10 <sup>3</sup> /mm <sup>3</sup> )>1.75xULN	2			
Reticulocytes/Erythrocytes (%)<0.5xLLN	0			
Reticulocytes/Erythrocytes (%)>1.5xULN	1			
Leukocytes (10 <sup>3</sup> /mm <sup>3</sup> )<0.6xLLN	0			
Leukocytes (10 <sup>3</sup> /mm <sup>3</sup> )>1.5xULN	1			
Lymphocytes (ABSOLUTE) (10 <sup>3</sup> /mm <sup>3</sup> )<0.8xLLN	3			
Lymphocytes (ABSOLUTE) (10 <sup>3</sup> /mm <sup>3</sup> )>1.2xULN	0			
Neutrophils (ABSOLUTE) (10 <sup>3</sup> /mm <sup>3</sup> )<0.8xLLN	1			
Neutrophils (ABSOLUTE) (10 <sup>3</sup> /mm <sup>3</sup> )>1.2xULN	6			
Basophils (ABSOLUTE)(10 <sup>3</sup> /mm <sup>3</sup> )>1.2xULN	1			
Eosinophils (ABSOLUTE) (10 <sup>3</sup> /mm <sup>3</sup> )>1.2xULN	2			
Monocytes (ABSOLUTE) (10 <sup>3</sup> /mm <sup>3</sup> )>1.2xULN	0			
ActivatedPartialThromboplastinTime (sec)>1.1xULN	0			
Prothrombin Time (sec)>1.1xULN	0			
Prothrombin Intl. Normalized Ratio>1.1xULN	0			

## Statistical analyses

No statistical analyses for this end point

## Primary: Chronic Period: Number of subjects with Laboratory Abnormalities without regard to baseline values - Clinical Chemistry

End point title	Chronic Period: Number of subjects with Laboratory Abnormalities without regard to baseline values - Clinical Chemistry <sup>[3]</sup>
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End point description:

Following parameters were analyzed for laboratory examination: Bilirubin, Direct Bilirubin, Indirect Bilirubin, Aspartate Aminotransferase, Alanine Aminotransferase, Gamma Glutamyl Transferase, Alkaline Phosphatase, Protein, Albumin, Urea Nitrogen, Creatinine, Urate, HDL Cholesterol, LDL Cholesterol, Triglycerides, Sodium, Potassium, Chloride, Calcium, Glucose, Hemoglobin A1C, Creatine Kinase, Cholesterol. The analysis population included all enrolled participants who received at least one dose of study medication.

End point type	Primary
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End point timeframe:

Baseline of Chronic period (Week 8) to Week 36

Notes:

[3] - 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 statistical analysis was planned for this endpoint.

End point values	PF-06651600 200 mg -> PF- 06651600 50 mg	PF-06651600 70 mg -> PF- 06651600 50 mg	PF-06651600 20 mg -> PF- 06651600 50 mg	Placebo -> PF- 06651600 50 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	35	35	39	10
Units: Subjects				
Bilirubin (mg/dL)>1.5x ULN	1	0	1	0
Direct Bilirubin (mg/dL)>1.5x ULN	0	0	0	0
Indirect Bilirubin (mg/dL)>1.5x ULN	0	0	0	0
Aspartate Aminotransferase (U/L)>3.0x ULN	0	0	2	0
Alanine Aminotransferase (U/L)>3.0x ULN	1	0	1	0
Gamma Glutamyl Transferase (U/L)>3.0x ULN	0	0	0	0
Alkaline Phosphatase (U/L)>3.0x ULN	0	0	1	0
Protein (g/dL)<0.8x LLN	0	0	0	0
Protein (g/dL)>1.2x ULN	0	0	0	0
Albumin (g/dL)<0.8x LLN	0	0	0	0
Albumin (g/dL)>1.2x ULN	0	0	0	0
Urea Nitrogen (mg/dL)>1.3x ULN	0	1	0	0
Creatinine (mg/dL)>1.3x ULN	0	1	0	0
Urate (mg/dL)>1.2x ULN	0	2	0	0
HDL Cholesterol (mg/dL)<0.8x LLN	1	0	0	0
LDL Cholesterol (mg/dL)>1.2x ULN	1	1	0	0
Triglycerides (mg/dL)>1.3x ULN	3	2	1	0
Sodium (Meq/L)<0.95x LLN	0	0	0	0
Sodium (Meq/L)>1.05x ULN	0	0	0	0
Potassium (Meq/L)<0.9x LLN	0	0	0	0
Potassium (Meq/L)>1.1x ULN	1	0	0	0
Chloride (Meq/L)<0.9x LLN	0	0	0	0
Chloride (Meq/L)>1.1x ULN	0	0	0	0
Calcium (mg/dL)<0.9x LLN	0	0	0	0
Calcium (mg/dL)>1.1x ULN	0	0	0	0
Glucose (mg/dL)<0.6x LLN	0	0	0	0
Glucose (mg/dL)>1.5x ULN	1	3	3	0
Hemoglobin A1C (%)>1.3x ULN	0	0	0	0
Creatine Kinase (U/L)>2.0x ULN	1	3	2	1
Cholesterol (mg/dl)>1.3x ULN	0	1	0	0

End point values	PF-06700841 60 mg -> PF- 06700841 30 mg	PF-06700841 30 mg -> PF- 06700841 30 mg	PF-06700841 10 mg -> PF- 06700841 30 mg	Placebo -> PF- 06700841 30 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	37	39	9
Units: Subjects				
Bilirubin (mg/dL)>1.5x ULN	1	0	1	0
Direct Bilirubin (mg/dL)>1.5x ULN	0	0	0	0
Indirect Bilirubin (mg/dL)>1.5x ULN	0	0	0	0

Aspartate Aminotransferase (U/L)>3.0x ULN	0	0	0	0
Alanine Aminotransferase (U/L)>3.0x ULN	0	0	2	0
Gamma Glutamyl Transferase (U/L)>3.0x ULN	0	0	0	0
Alkaline Phosphatase (U/L)>3.0x ULN	0	0	0	0
Protein (g/dL)<0.8x LLN	0	0	0	0
Protein (g/dL)>1.2x ULN	0	0	0	0
Albumin (g/dL)<0.8x LLN	0	0	0	0
Albumin (g/dL)>1.2x ULN	0	0	0	0
Urea Nitrogen (mg/dL)>1.3x ULN	0	0	0	0
Creatinine (mg/dL)>1.3x ULN	0	1	1	0
Urate (mg/dL)>1.2x ULN	0	1	1	0
HDL Cholesterol (mg/dL)<0.8x LLN	0	0	1	0
LDL Cholesterol (mg/dL)>1.2x ULN	1	0	2	1
Triglycerides (mg/dL)>1.3x ULN	2	2	1	0
Sodium (Meq/L)<0.95x LLN	0	0	0	0
Sodium (Meq/L)>1.05x ULN	0	0	0	0
Potassium (Meq/L)<0.9x LLN	0	1	0	0
Potassium (Meq/L)>1.1x ULN	2	0	0	0
Chloride (Meq/L)<0.9x LLN	0	0	0	0
Chloride (Meq/L)>1.1x ULN	0	0	0	0
Calcium (mg/dL)<0.9x LLN	0	1	0	0
Calcium (mg/dL)>1.1x ULN	0	0	0	0
Glucose (mg/dL)<0.6x LLN	0	0	0	0
Glucose (mg/dL)>1.5x ULN	1	2	0	0
Hemoglobin A1C (%)>1.3x ULN	0	0	0	0
Creatine Kinase (U/L)>2.0x ULN	3	10	2	0
Cholesterol (mg/dl)>1.3x ULN	0	0	1	0

End point values	Pooling Placebo During Chronic			
Subject group type	Reporting group			
Number of subjects analysed	37			
Units: Subjects				
Bilirubin (mg/dL)>1.5x ULN	1			
Direct Bilirubin (mg/dL)>1.5x ULN	0			
Indirect Bilirubin (mg/dL)>1.5x ULN	0			
Aspartate Aminotransferase (U/L)>3.0x ULN	0			
Alanine Aminotransferase (U/L)>3.0x ULN	0			
Gamma Glutamyl Transferase (U/L)>3.0x ULN	0			
Alkaline Phosphatase (U/L)>3.0x ULN	0			
Protein (g/dL)<0.8x LLN	0			
Protein (g/dL)>1.2x ULN	0			
Albumin (g/dL)<0.8x LLN	0			
Albumin (g/dL)>1.2x ULN	0			
Urea Nitrogen (mg/dL)>1.3x ULN	0			



Creatinine (mg/dL)>1.3x ULN	0			
Urate (mg/dL)>1.2x ULN	0			
HDL Cholesterol (mg/dL)<0.8x LLN	0			
LDL Cholesterol (mg/dL)>1.2x ULN	0			
Triglycerides (mg/dL)>1.3x ULN	1			
Sodium (Meq/L)<0.95x LLN	0			
Sodium (Meq/L)>1.05x ULN	0			
Potassium (Meq/L)<0.9x LLN	0			
Potassium (Meq/L)>1.1x ULN	0			
Chloride (Meq/L)<0.9x LLN	0			
Chloride (Meq/L)>1.1x ULN	0			
Calcium (mg/dL)<0.9x LLN	0			
Calcium (mg/dL)>1.1x ULN	0			
Glucose (mg/dL)<0.6x LLN	0			
Glucose (mg/dL)>1.5x ULN	0			
Hemoglobin A1C (%)>1.3x ULN	0			
Creatine Kinase (U/L)>2.0x ULN	1			
Cholesterol (mg/dl)>1.3x ULN	0			

## Statistical analyses

No statistical analyses for this end point

### Primary: Chronic Period: Number of subjects with Laboratory Abnormalities without regard to baseline values - Urinalysis

End point title	Chronic Period: Number of subjects with Laboratory Abnormalities without regard to baseline values - Urinalysis <sup>[4]</sup>
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End point description:

Following parameters were analyzed for laboratory examination: pH, URINE Glucose, Ketones, URINE Protein, URINE Hemoglobin, Nitrite, Leukocyte Esterase, URINE Erythrocytes, URINE Leukocytes, Hyaline Casts, WBC Casts, Bacteria. The analysis population included all enrolled participants who received at least one dose of study medication.

End point type	Primary
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End point timeframe:

Baseline of Chronic period (Week 8) to Week 36

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 statistical analysis was planned for this endpoint.

End point values	PF-06651600 200 mg -> PF- 06651600 50 mg	PF-06651600 70 mg -> PF- 06651600 50 mg	PF-06651600 20 mg -> PF- 06651600 50 mg	Placebo -> PF- 06651600 50 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	35	36	39	10
Units: Subjects				
pH (scalar)<4.5	0	0	0	0
pH (scalar)>8	0	0	0	0
URINE Glucose (No Unit)>=1	1	2	1	1
Ketones (No Unit)>=1	4	3	8	2
URINE Protein (No Unit)>=1	0	1	3	0

URINE Hemoglobin (No Unit)>=1	7	4	5	1
Nitrite (No Unit)>=1	2	2	0	2
Leukocyte Esterase (No Unit)>=1	8	13	11	1
URINE Erythrocytes (/HPF)>=20	1	1	4	1
URINE Leukocytes (/HPF)>=20	0	2	3	1
Hyaline Casts (/LPF)>1	5	0	6	2
WBC Casts (/LPF)>1	0	0	0	0
Bacteria (No Unit)>20	0	0	0	0

<b>End point values</b>	PF-06700841 60 mg -> PF- 06700841 30 mg	PF-06700841 30 mg -> PF- 06700841 30 mg	PF-06700841 10 mg -> PF- 06700841 30 mg	Placebo -> PF- 06700841 30 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	37	39	9
Units: Subjects				
pH (scalar)<4.5	0	0	0	0
pH (scalar)>8	0	0	0	0
URINE Glucose (No Unit)>=1	1	1	0	0
Ketones (No Unit)>=1	4	1	3	0
URINE Protein (No Unit)>=1	1	0	2	0
URINE Hemoglobin (No Unit)>=1	7	9	9	0
Nitrite (No Unit)>=1	1	1	1	0
Leukocyte Esterase (No Unit)>=1	14	7	8	1
URINE Erythrocytes (/HPF)>=20	2	3	5	0
URINE Leukocytes (/HPF)>=20	3	1	1	0
Hyaline Casts (/LPF)>1	4	1	2	1
WBC Casts (/LPF)>1	0	0	0	0
Bacteria (No Unit)>20	0	0	1	0

<b>End point values</b>	Pooling Placebo During Chronic			
Subject group type	Reporting group			
Number of subjects analysed	37			
Units: Subjects				
pH (scalar)<4.5	0			
pH (scalar)>8	0			
URINE Glucose (No Unit)>=1	1			
Ketones (No Unit)>=1	2			
URINE Protein (No Unit)>=1	1			
URINE Hemoglobin (No Unit)>=1	9			
Nitrite (No Unit)>=1	1			
Leukocyte Esterase (No Unit)>=1	9			
URINE Erythrocytes (/HPF)>=20	1			
URINE Leukocytes (/HPF)>=20	4			
Hyaline Casts (/LPF)>1	2			
WBC Casts (/LPF)>1	1			
Bacteria (No Unit)>20	0			

## Statistical analyses

No statistical analyses for this end point

### Primary: Chronic Period: Number of subjects with abnormal electrocardiogram findings

End point title	Chronic Period: Number of subjects with abnormal electrocardiogram findings <sup>[5]</sup>
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End point description:

The analysis population included all enrolled participants who received at least one dose of study medication. The criteria of test abnormality is defined as one of the following conditions was met: 1)Associated with accompanying symptoms; 2)Test result requires additional diagnostic testing or medical/surgical intervention; 3)Test result leads to a change in study dosing (outside of any protocol specified dose adjustments) or discontinuation from the study, significant additional concomitant drug treatment, or other therapy; 4)Test result is considered to be an AE by the investigator or sponsor.

End point type	Primary
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End point timeframe:

Baseline of Chronic period (Week 8) to Week 36

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 statistical analysis was planned for this endpoint.

End point values	PF-06651600 200 mg -> PF- 06651600 50 mg	PF-06651600 70 mg -> PF- 06651600 50 mg	PF-06651600 20 mg -> PF- 06651600 50 mg	Placebo -> PF- 06651600 50 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	33	34	37	10
Units: Subjects				
NORMAL	30	28	35	9
ABNORMAL, NOT CLINICALLY SIGNIFICANT	3	6	2	1
ABNORMAL, CLINICALLY SIGNIFICANT	0	0	0	0

End point values	PF-06700841 60 mg -> PF- 06700841 30 mg	PF-06700841 30 mg -> PF- 06700841 30 mg	PF-06700841 10 mg -> PF- 06700841 30 mg	Placebo -> PF- 06700841 30 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	32	30	36	9
Units: Subjects				
NORMAL	31	28	32	7
ABNORMAL, NOT CLINICALLY SIGNIFICANT	1	2	4	2
ABNORMAL, CLINICALLY SIGNIFICANT	0	0	0	0

<b>End point values</b>	Pooling Placebo During Chronic			
Subject group type	Reporting group			
Number of subjects analysed	33			
Units: Subjects				
NORMAL	29			
ABNORMAL, NOT CLINICALLY SIGNIFICANT	4			
ABNORMAL, CLINICALLY SIGNIFICANT	0			

## Statistical analyses

No statistical analyses for this end point

### Primary: Chronic Period: Number of subjects with Serious Infection

End point title	Chronic Period: Number of subjects with Serious Infection <sup>[6]</sup>
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End point description:

Serious infections are treated infections that: Require parenteral antimicrobial therapy and present with positive pre-treatment culture; and either Require hospitalization for treatment; or Meet other criteria that require the infection to be classified as a SAE. The analysis population included all enrolled participants who received at least one dose of study medication.

End point type	Primary
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End point timeframe:

Baseline of Chronic period (Week 8) to Week 36

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 statistical analysis was planned for this endpoint.

<b>End point values</b>	PF-06651600 200 mg -> PF- 06651600 50 mg	PF-06651600 70 mg -> PF- 06651600 50 mg	PF-06651600 20 mg -> PF- 06651600 50 mg	Placebo -> PF- 06651600 50 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	35	36	39	10
Units: Subjects				
COVID 19 pneumonia	0	0	0	0
viral infection	0	0	0	0

<b>End point values</b>	PF-06700841 60 mg -> PF- 06700841 30 mg	PF-06700841 30 mg -> PF- 06700841 30 mg	PF-06700841 10 mg -> PF- 06700841 30 mg	Placebo -> PF- 06700841 30 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	37	39	9
Units: Subjects				
COVID 19 pneumonia	0	0	1	0

viral infection	1	0	0	0
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<b>End point values</b>	Pooling Placebo During Chronic			
Subject group type	Reporting group			
Number of subjects analysed	37			
Units: Subjects				
COVID 19 pneumonia	0			
viral infection	0			

## Statistical analyses

No statistical analyses for this end point

## Secondary: Induction Period: Percentage of subjects achieving remission based on total Mayo score

End point title	Induction Period: Percentage of subjects achieving remission based on total Mayo score
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End point description:

Remission excludes friability and is based on total Mayo score of less than/equal to 2 with no individual subscore greater than 1 and a rectal bleeding subscore of 0 at Week 8. The ITT analysis set was used to analyze this endpoint, defined as all randomized subjects who received at least 1 dose of investigational product or placebo.

End point type	Secondary
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End point timeframe:

Week 8

<b>End point values</b>	Placebo (Induction: 0 to 8 weeks)	PF-06651600 20 mg (Induction)	PF-06651600 70 mg (Induction)	PF-06651600 200 mg (Induction)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	51	49	50
Units: Percentage of subjects				
number (confidence interval 90%)	0 (0.0 to 11.0)	9.8 (4.8 to 19.1)	28.6 (19.0 to 40.4)	34.0 (24.0 to 45.4)

<b>End point values</b>	PF-06700841 10 mg (Induction)	PF-06700841 30 mg (Induction)	PF-06700841 60 mg (Induction)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	48	47	47	
Units: Percentage of subjects				
number (confidence interval 90%)	8.3 (3.7 to 16.8)	23.4 (14.8 to 34.5)	23.4 (14.8 to 34.5)	

## Statistical analyses

No statistical analyses for this end point

### Secondary: Induction Period: Percentage of subjects achieving improvement in endoscopic appearance at Week 8

End point title	Induction Period: Percentage of subjects achieving improvement in endoscopic appearance at Week 8
End point description: Improvement of endoscopic appearance is defined as a Mayo endoscopic subscore of less than/equal to 1. The ITT analysis set was used to analyze this endpoint, defined as all randomized subjects who received at least 1 dose of investigational product or placebo.	
End point type	Secondary
End point timeframe: Week 8	

End point values	Placebo (Induction: 0 to 8 weeks)	PF-06651600 20 mg (Induction)	PF-06651600 70 mg (Induction)	PF-06651600 200 mg (Induction)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	51	49	50
Units: Percengate of subjects				
number (confidence interval 90%)	0 (0.0 to 11.0)	21.6 (13.5 to 33.1)	34.7 (24.4 to 46.4)	42.0 (30.3 to 54.6)

End point values	PF-06700841 10 mg (Induction)	PF-06700841 30 mg (Induction)	PF-06700841 60 mg (Induction)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	48	47	47	
Units: Percengate of subjects				
number (confidence interval 90%)	20.8 (11.8 to 31.5)	31.9 (20.8 to 44.4)	29.8 (19.9 to 42.3)	

## Statistical analyses

No statistical analyses for this end point

### Secondary: Induction Period: Percentage of subjects achieving clinical response at Week 8

End point title	Induction Period: Percentage of subjects achieving clinical response at Week 8
End point description: Clinical response is defined as a decrease from baseline in total Mayo score of at least 3 points and at least 30%, with an accompanying decrease in the subscore for rectal bleeding of at least 1 point or absolute subscore for rectal bleeding of 0 or 1. The ITT analysis set was used to analyze this endpoint, defined as all randomized subjects who received at least 1 dose of investigational product or placebo.	
End point type	Secondary
End point timeframe: Week 8	

End point values	Placebo (Induction: 0 to 8 weeks)	PF-06651600 20 mg (Induction)	PF-06651600 70 mg (Induction)	PF-06651600 200 mg (Induction)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	51	49	50
Units: Percentage of subjects				
number (confidence interval 90%)	24.0 (11.0 to 41.7)	41.2 (29.9 to 53.6)	69.4 (57.6 to 80.1)	68.0 (56.6 to 78.8)

End point values	PF-06700841 10 mg (Induction)	PF-06700841 30 mg (Induction)	PF-06700841 60 mg (Induction)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	48	47	47	
Units: Percentage of subjects				
number (confidence interval 90%)	41.7 (29.6 to 54.5)	53.2 (40.3 to 65.5)	61.7 (48.7 to 72.9)	

## Statistical analyses

No statistical analyses for this end point

## Secondary: Induction Period: Percentage of subjects in endoscopic remission at Week 8

End point title	Induction Period: Percentage of subjects in endoscopic remission at Week 8
End point description: Endoscopic remission is defined as an endoscopic subscore of 0. The ITT analysis set was used to analyze this endpoint, defined as all randomized subjects who received at least 1 dose of investigational product or placebo.	
End point type	Secondary
End point timeframe: Week 8	

End point values	Placebo (Induction: 0 to 8 weeks)	PF-06651600 20 mg (Induction)	PF-06651600 70 mg (Induction)	PF-06651600 200 mg (Induction)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	51	49	50
Units: Percentage of subjects				
number (confidence interval 90%)	0 (0.0 to 11.0)	3.9 (1.0 to 11.0)	8.2 (3.6 to 16.5)	12.0 (5.4 to 21.2)

End point values	PF-06700841 10 mg (Induction)	PF-06700841 30 mg (Induction)	PF-06700841 60 mg (Induction)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	48	47	47	
Units: Percentage of subjects				
number (confidence interval 90%)	2.1 (0.2 to 8.6)	17.0 (8.8 to 28.3)	8.5 (3.8 to 17.2)	

### Statistical analyses

No statistical analyses for this end point

### Secondary: Induction Period: Percentage of subjects in symptomatic remission at Week 8

End point title	Induction Period: Percentage of subjects in symptomatic remission at Week 8
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End point description:

Symptomatic remission is defined as a total Mayo score of 2 points or lower, with no individual subscore exceeding 1 point, and both rectal bleeding and stool frequency subscores of 0. The ITT analysis set was used to analyze this endpoint, defined as all randomized subjects who received at least 1 dose of investigational product or placebo.

End point type	Secondary
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End point timeframe:

Week 8

End point values	Placebo (Induction: 0 to 8 weeks)	PF-06651600 20 mg (Induction)	PF-06651600 70 mg (Induction)	PF-06651600 200 mg (Induction)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	51	49	50
Units: Percentage of subjects				
number (confidence interval 90%)	0 (0.0 to 11.0)	7.8 (3.5 to 15.9)	16.3 (8.4 to 27.1)	26.0 (16.2 to 37.6)

End point values	PF-06700841 10 mg	PF-06700841 30 mg	PF-06700841 60 mg	
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	(Induction)	(Induction)	(Induction)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	48	47	47	
Units: Percentage of subjects				
number (confidence interval 90%)	6.3 (2.3 to 15.1)	14.9 (8.0 to 25.1)	14.9 (8.0 to 25.1)	

## Statistical analyses

No statistical analyses for this end point

### Secondary: Induction Period: Percentage of subjects achieving deep remission at Week 8

End point title	Induction Period: Percentage of subjects achieving deep remission at Week 8
End point description:	
Deep remission is defined as a total Mayo score of 2 points or lower, with no individual subscore exceeding 1 point and a 0 on both endoscopic and rectal bleeding subscores. The ITT analysis set was used to analyze this endpoint, defined as all randomized subjects who received at least 1 dose of investigational product or placebo.	
End point type	Secondary
End point timeframe:	
Week 8	

End point values	Placebo (Induction: 0 to 8 weeks)	PF-06651600 20 mg (Induction)	PF-06651600 70 mg (Induction)	PF-06651600 200 mg (Induction)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	51	49	50
Units: Percentage of subjects				
number (confidence interval 90%)	0 (0.0 to 11.0)	3.9 (1.0 to 11.0)	8.2 (3.6 to 16.5)	12.0 (5.4 to 21.2)

End point values	PF-06700841 10 mg (Induction)	PF-06700841 30 mg (Induction)	PF-06700841 60 mg (Induction)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	48	47	47	
Units: Percentage of subjects				
number (confidence interval 90%)	0 (0.0 to 5.6)	14.9 (8.0 to 25.1)	6.4 (2.4 to 15.4)	

## Statistical analyses

**Secondary: Induction Period: Partial Mayo Scores and changes from baseline at Weeks 2,4,and 8**

End point title	Induction Period: Partial Mayo Scores and changes from baseline at Weeks 2,4,and 8
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## End point description:

A partial Mayo Score (Mayo Score without endoscopic subscore) ranges from 0 to 9, with higher scores indicating more severe disease. Baseline value is defined as the last non-missing measurement collected prior to the first administration of study drug at Day 1. ITT analysis set was defined as all randomized subjects who received at least 1 dose of investigational product or placebo. The subjects in the ITT analysis set who had partial Mayo score at each specified time point was used to analyze this endpoint.

End point type	Secondary
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## End point timeframe:

Weeks 2,4,and 8

End point values	Placebo (Induction: 0 to 8 weeks)	PF-06651600 20 mg (Induction)	PF-06651600 70 mg (Induction)	PF-06651600 200 mg (Induction)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	51	49	50
Units: Unit on a scale				
least squares mean (standard error)				
Week 2	-0.66 (± 0.37)	-1.65 (± 0.26)	-2.56 (± 0.26)	-3.19 (± 0.27)
Week 4	-1.64 (± 0.42)	-2.24 (± 0.29)	-3.29 (± 0.30)	-4.24 (± 0.31)
Week 8	-1.15 (± 0.43)	-2.54 (± 0.30)	-4.06 (± 0.30)	-4.69 (± 0.32)

End point values	PF-06700841 10 mg (Induction)	PF-06700841 30 mg (Induction)	PF-06700841 60 mg (Induction)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	48	47	47	
Units: Unit on a scale				
least squares mean (standard error)				
Week 2	-1.60 (± 0.27)	-1.64 (± 0.27)	-2.45 (± 0.27)	
Week 4	-2.31 (± 0.30)	-2.06 (± 0.30)	-2.95 (± 0.30)	
Week 8	-2.51 (± 0.30)	-2.71 (± 0.31)	-3.47 (± 0.31)	

**Statistical analyses**

No statistical analyses for this end point

**Secondary: Induction Period: Change from baseline in total Mayo score**

End point title	Induction Period: Change from baseline in total Mayo score
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## End point description:

Total Mayo Score ranges from 0 to 12, with higher scores indicating more severe disease. Baseline value

is defined as the last non-missing measurement collected prior to the first administration of study drug at Day 1. The ITT analysis set was used to analyze this endpoint, defined as all randomized subjects who received at least 1 dose of investigational product or placebo.

End point type	Secondary
End point timeframe:	
Week 8	

End point values	Placebo (Induction: 0 to 8 weeks)	PF-06651600 20 mg (Induction)	PF-06651600 70 mg (Induction)	PF-06651600 200 mg (Induction)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	51	49	50
Units: Units on a scale				
least squares mean (confidence interval 90%)	-1.14 (-2.06 to -0.22)	-3.17 (-3.83 to -2.51)	-5.02 (-5.68 to -4.36)	-5.74 (-6.43 to -5.06)

End point values	PF-06700841 10 mg (Induction)	PF-06700841 30 mg (Induction)	PF-06700841 60 mg (Induction)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	48	47	47	
Units: Units on a scale				
least squares mean (confidence interval 90%)	-2.93 (-3.58 to -2.29)	-3.42 (-4.08 to -2.76)	-4.35 (-5.00 to -3.69)	

## Statistical analyses

No statistical analyses for this end point

## Secondary: Induction Period: Changes from baseline in Inflammatory Bowel Disease Questionnaire (IBDQ) total score at Weeks 4 and 8

End point title	Induction Period: Changes from baseline in Inflammatory Bowel Disease Questionnaire (IBDQ) total score at Weeks 4 and 8
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End point description:

IBDQ is a psychometrically validated PRO instrument for measuring the disease-specific quality of life in subjects with IBD, including UC. A score of at least 170 corresponds to clinical remission and an increase of at least 16 points is considered to indicate a clinically meaningful improvement.

End point type	Secondary
End point timeframe:	
Weeks 4 and 8	

End point values	Placebo (Induction: 0 to 8 weeks)	PF-06651600 20 mg (Induction)	PF-06651600 70 mg (Induction)	PF-06651600 200 mg (Induction)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	51	49	50
Units: Units on a scale				
least squares mean (confidence interval 90%)				
Week 4	30.30 (19.56 to 41.05)	33.71 (26.12 to 41.30)	51.12 (43.52 to 58.72)	57.01 (49.12 to 64.90)
Week 8	24.23 (12.02 to 36.45)	37.91 (29.41 to 46.42)	59.20 (50.56 to 67.83)	62.17 (53.14 to 71.20)

End point values	PF-06700841 10 mg (Induction)	PF-06700841 30 mg (Induction)	PF-06700841 60 mg (Induction)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	48	47	47	
Units: Units on a scale				
least squares mean (confidence interval 90%)				
Week 4	28.45 (20.73 to 36.17)	37.94 (30.16 to 45.72)	49.79 (41.99 to 57.60)	
Week 8	36.6 (27.87 to 45.33)	48.81 (40.01 to 57.61)	56.39 (47.60 to 65.18)	

## Statistical analyses

No statistical analyses for this end point

## Secondary: Induction Period: Percentage of subjects with IBDQ total score greater than/equal to 170 at Weeks 4 and 8

End point title	Induction Period: Percentage of subjects with IBDQ total score greater than/equal to 170 at Weeks 4 and 8
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End point description:

IBDQ is a psychometrically validated PRO instrument for measuring the disease-specific quality of life in subjects with IBD, including UC. A score of at least 170 corresponds to clinical remission and an increase of at least 16 points is considered to indicate a clinically meaningful improvement.

End point type	Secondary
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End point timeframe:

Weeks 4 and 8

End point values	Placebo (Induction: 0 to 8 weeks)	PF-06651600 20 mg (Induction)	PF-06651600 70 mg (Induction)	PF-06651600 200 mg (Induction)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	51	49	50
Units: Percentage of subjects				
number (confidence interval 90%)				
Week 4	24.0 (11.0 to 41.7)	21.6 (13.5 to 33.1)	40.8 (28.9 to 53.6)	46.0 (34.2 to 58.5)
Week 8	20.0 (10.1 to 36.2)	29.4 (19.1 to 40.6)	57.1 (44.4 to 69.2)	44.0 (33.0 to 56.6)

End point values	PF-06700841 10 mg (Induction)	PF-06700841 30 mg (Induction)	PF-06700841 60 mg (Induction)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	48	47	47	
Units: Percentage of subjects				
number (confidence interval 90%)				
Week 4	27.1 (16.8 to 39.4)	27.7 (17.2 to 40.3)	38.3 (27.1 to 51.3)	
Week 8	31.3 (20.4 to 43.4)	40.4 (28.3 to 53.5)	51.1 (38.9 to 62.8)	

## Statistical analyses

No statistical analyses for this end point

## Secondary: Induction Period: Percentage of subjects with greater than/equal to 16 point increase in IBDQ total score from baseline at Weeks 4 and 8

End point title	Induction Period: Percentage of subjects with greater than/equal to 16 point increase in IBDQ total score from baseline at Weeks 4 and 8
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End point description:

IBDQ is a psychometrically validated PRO instrument for measuring the disease-specific quality of life in subjects with IBD, including UC. A score of at least 170 corresponds to clinical remission and an increase of at least 16 points is considered to indicate a clinically meaningful improvement.

End point type	Secondary
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End point timeframe:

Weeks 4 and 8

End point values	Placebo (Induction: 0 to 8 weeks)	PF-06651600 20 mg (Induction)	PF-06651600 70 mg (Induction)	PF-06651600 200 mg (Induction)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	51	49	50
Units: Percentage of subjects				
number (confidence interval 90%)				

Week 4	48.0 (30.7 to 64.0)	60.8 (48.4 to 72.3)	83.7 (72.9 to 91.6)	80.0 (69.7 to 88.7)
Week 8	56.0 (38.9 to 73.0)	54.9 (42.5 to 66.9)	79.6 (69.2 to 88.5)	70.0 (58.5 to 80.5)

End point values	PF-06700841 10 mg (Induction)	PF-06700841 30 mg (Induction)	PF-06700841 60 mg (Induction)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	48	47	47	
Units: Percentage of subjects				
number (confidence interval 90%)				
Week 4	64.6 (52.5 to 75.3)	78.7 (67.8 to 88.0)	72.3 (59.7 to 82.8)	
Week 8	62.5 (50.0 to 73.6)	80.9 (69.7 to 88.8)	78.7 (67.8 to 88.0)	

## Statistical analyses

No statistical analyses for this end point

## Secondary: Indction Period: Percentage of subjects with improvement in IBDQ bowel symptom domain at Weeks 4 and 8

End point title	Indction Period: Percentage of subjects with improvement in IBDQ bowel symptom domain at Weeks 4 and 8
End point description:	
Improvement is defined as an increase of at least 1.2 points from baseline in average score among IBDQ bowel symptom domain (items 1, 5, 9, 13, 17, 20, 22, 24, 26, 29).	
End point type	Secondary
End point timeframe:	
Weeks 4 and 8	

End point values	Placebo (Induction: 0 to 8 weeks)	PF-06651600 20 mg (Induction)	PF-06651600 70 mg (Induction)	PF-06651600 200 mg (Induction)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	51	49	50
Units: Percentage of subjects				
number (confidence interval 90%)				
Week 4	20.0 (10.1 to 36.2)	51.0 (38.7 to 63.2)	65.3 (53.6 to 75.6)	64.0 (52.6 to 75.1)
Week 8	24.0 (11.0 to 41.7)	47.1 (35.0 to 59.4)	69.4 (57.6 to 80.1)	62.0 (50.0 to 73.5)

End point values	PF-06700841	PF-06700841	PF-06700841	
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	10 mg (Induction)	30 mg (Induction)	60 mg (Induction)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	48	47	47	
Units: Percentage of subjects				
number (confidence interval 90%)				
Week 4	37.5 (26.4 to 50.0)	53.2 (40.3 to 65.5)	57.4 (44.4 to 69.7)	
Week 8	50.0 (37.6 to 62.4)	63.8 (51.3 to 74.9)	66.0 (53.5 to 77.3)	

## Statistical analyses

No statistical analyses for this end point

## Secondary: Induction Period: Changes from baseline in Short Form 36 version 2 (SF-36 v2) at Weeks 4 and 8

End point title	Induction Period: Changes from baseline in Short Form 36 version 2 (SF-36 v2) at Weeks 4 and 8
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End point description:

SF-36 physical and mental component summary scores: physical health component summary score (PCS) and mental health component summary score (MCS) are calculated from the 8 domain scores. Higher scores indicate a better health-related quality of life.

End point type	Secondary
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End point timeframe:

Weeks 4 and 8

End point values	Placebo (Induction: 0 to 8 weeks)	PF-06651600 20 mg (Induction)	PF-06651600 70 mg (Induction)	PF-06651600 200 mg (Induction)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	51	49	50
Units: Units on a scale				
least squares mean (confidence interval 90%)				
PCS at Week 4	4.69 (2.59 to 6.80)	5.90 (4.41 to 7.39)	6.36 (4.88 to 7.85)	9.21 (7.67 to 10.76)
MCS at Week 4	7.83 (4.59 to 11.06)	4.95 (2.67 to 7.23)	7.79 (5.50 to 10.07)	8.81 (6.43 to 11.18)
PCS at Week 8	5.37 (2.96 to 7.77)	5.85 (4.19 to 7.52)	8.66 (6.97 to 10.35)	10.86 (9.08 to 12.64)
MCS at Week 8	4.24 (0.69 to 7.78)	5.18 (2.72 to 7.64)	9.72 (7.22 to 12.22)	9.41 (6.79 to 12.03)

End point values	PF-06700841 10 mg (Induction)	PF-06700841 30 mg (Induction)	PF-06700841 60 mg (Induction)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	48	47	47	

Units: Units on a scale				
least squares mean (confidence interval 90%)				
PCS at Week 4	5.67 (4.16 to 7.19)	5.85 (4.31 to 7.38)	6.40 (4.87 to 7.93)	
MCS at Week 4	2.44 (0.13 to 4.74)	7.46 (5.11 to 9.82)	9.28 (6.93 to 11.62)	
PCS at Week 8	6.29 (4.57 to 8.02)	8.21 (6.47 to 9.95)	8.55 (6.83 to 10.27)	
MCS at Week 8	5.22 (2.70 to 7.75)	8.04 (5.48 to 10.61)	10.01 (7.47 to 12.55)	

## Statistical analyses

No statistical analyses for this end point

## Secondary: Induction Period: Changes from baseline in EuroQoL-5 Dimensions at Weeks 4 and 8

End point title	Induction Period: Changes from baseline in EuroQoL-5 Dimensions at Weeks 4 and 8
End point description:	
The EQ 5D-3L consists of 5 domains: mobility, self care, usual activities, pain/discomfort, and anxiety/depression. The utility score (index value) is calculated based on the 5 domain scores. The EQ 5D Visual Analog Scale (VAS) records the respondent's self rated health on a scale from 0 (worst imaginable health state) to 100 (best imaginable health state).	
End point type	Secondary
End point timeframe:	
Weeks 4 and 8	

End point values	Placebo (Induction: 0 to 8 weeks)	PF-06651600 20 mg (Induction)	PF-06651600 70 mg (Induction)	PF-06651600 200 mg (Induction)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	51	49	50
Units: Units on a scale				
least squares mean (confidence interval 90%)				
EQ5D01-Index Value at week 4	0.11 (0.06 to 0.16)	0.07 (0.04 to 0.11)	0.12 (0.09 to 0.15)	0.13 (0.10 to 0.17)
EQ5D01-Index Value at Week 8	0.08 (0.03 to 0.13)	0.08 (0.05 to 0.12)	0.15 (0.11 to 0.18)	0.15 (0.12 to 0.19)
EQ5D01-EQ VAS Score at Week 4	8.41 (2.18 to 14.63)	13.6 (9.20 to 18.00)	16.35 (11.96 to 20.74)	17.45 (12.88 to 22.02)
EQ5D01-EQ VAS Score at Week 8	13.17 (6.48 to 19.85)	13.11 (8.48 to 17.74)	18.88 (14.17 to 23.60)	22.54 (17.60 to 27.49)

End point values	PF-06700841 10 mg (Induction)	PF-06700841 30 mg (Induction)	PF-06700841 60 mg (Induction)	
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Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	48	47	47	
Units: Units on a scale				
least squares mean (confidence interval 90%)				
EQ5D01-Index Value at week 4	0.07 (0.03 to 0.10)	0.11 (0.08 to 0.14)	0.12 (0.09 to 0.15)	
EQ5D01-Index Value at Week 8	0.09 (0.05 to 0.13)	0.13 (0.10 to 0.17)	0.14 (0.11 to 0.18)	
EQ5D01-EQ VAS Score at Week 4	10.48 (6.04 to 14.92)	12.24 (7.72 to 16.77)	14.44 (9.90 to 18.97)	
EQ5D01-EQ VAS Score at Week 8	10.35 (5.58 to 15.12)	17.11 (12.28 to 21.94)	20.01 (15.21 to 24.81)	

## Statistical analyses

No statistical analyses for this end point

### Secondary: Induction Period: Number of subjects with Treatment-Emergent Adverse Events (AEs), Serious Adverse Events (SAEs) and with withdrawals due to adverse events (All-Causalities)

End point title	Induction Period: Number of subjects with Treatment-Emergent Adverse Events (AEs), Serious Adverse Events (SAEs) and with withdrawals due to adverse events (All-Causalities)
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End point description:

An AE is any untoward medical occurrence in a study subjects administered a product or medical device; the event need not necessarily have a causal relationship with the treatment or usage. An SAE is any untoward medical occurrence at any dose that: results in death; is life threatening (immediate risk of death); requires inpatient hospitalization or prolongation of existing hospitalization; results in persistent or significant disability/incapacity (substantial disruption of the ability to conduct normal life functions); results in congenital anomaly/birth defect; or that is considered to be an important medical event that may jeopardize the subject or may require intervention to prevent one of the other AE outcomes. Treatment-emergent AEs were those with initial onset or that worsen in severity after the first dose of the study medication.

End point type	Secondary
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End point timeframe:

Baseline, Week 8

End point values	Placebo (Induction: 0 to 8 weeks)	PF-06651600 20 mg (Induction)	PF-06651600 70 mg (Induction)	PF-06651600 200 mg (Induction)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	51	49	50
Units: Subjects				
Subjects with AEs	13	23	21	21
Subjects with SAEs	0	3	0	3
Subjects with severe AEs	0	2	0	1
Subjects discontinued from study due to AEs	0	5	0	5

<b>End point values</b>	PF-06700841 10 mg (Induction)	PF-06700841 30 mg (Induction)	PF-06700841 60 mg (Induction)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	48	47	47	
Units: Subjects				
Subjects with AEs	19	26	23	
Subjects with SAEs	1	3	1	
Subjects with severe AEs	0	1	1	
Subjects discontinued from study due to AEs	1	2	1	

## Statistical analyses

No statistical analyses for this end point

## Secondary: Induction Period: Number of subjects with Laboratory Abnormalities without regard to baseline values - Hematology

End point title	Induction Period: Number of subjects with Laboratory Abnormalities without regard to baseline values - Hematology
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End point description:

Following parameters were analyzed for laboratory examination: hemoglobin, hematocrit, erythrocytes, reticulocytes, ery. Mean Corpuscular Volume, platelets, Reticulocytes/Erythrocytes, Leukocytes, Lymphocytes, Neutrophils, Basophils, Eosinophils, Monocytes, Activated Partial Thromboplastin Time, Prothrombin Time, Prothrombin Intl. Normalized Ratio. The ITT analysis set was used to analyze this endpoint, defined as all randomized subjects who received at least 1 dose of investigational product or placebo.

End point type	Secondary
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End point timeframe:

Baseline, Week 8

<b>End point values</b>	Placebo (Induction: 0 to 8 weeks)	PF-06651600 20 mg (Induction)	PF-06651600 70 mg (Induction)	PF-06651600 200 mg (Induction)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	51	49	50
Units: Subjects				
Hemoglobin (g/dL) < 0.8x LLN	3	2	5	9
Hematocrit (%) < 0.8x LLN	2	0	3	4
Erythrocytes (10 <sup>6</sup> /mm <sup>3</sup> ) < 0.8x LLN	0	0	4	3
Reticulocytes (ABSOLUTE) (10 <sup>3</sup> /mm <sup>3</sup> ) < 0.5x LLN	0	0	0	0
Reticulocytes (ABSOLUTE) (10 <sup>3</sup> /mm <sup>3</sup> ) > 1.5x ULN	1	1	2	2
Ery. Mean Corpuscular Volume (10 <sup>-15</sup> L) < 0.9x LLN	0	0	0	0

Ery. Mean Corpuscular Volume ( $10^{-15}$ L)>1.1x ULN	0	0	0	0
Platelets ( $10^3$ /mm <sup>3</sup> )<0.5x LLN	0	0	0	0
Platelets ( $10^3$ /mm <sup>3</sup> )>1.75x ULN	1	0	0	0
Reticulocytes/Erythrocytes (%)<0.5x LLN	0	0	0	0
Reticulocytes/Erythrocytes (%)>1.5x ULN	1	2	3	3
Leukocytes ( $10^3$ /mm <sup>3</sup> )<0.6x LLN	0	0	0	0
Leukocytes ( $10^3$ /mm <sup>3</sup> )>1.5x ULN	0	3	0	3
Lymphocytes (ABSOLUTE) ( $10^3$ /mm <sup>3</sup> )<0.8x LLN	3	2	4	11
Lymphocytes (ABSOLUTE) ( $10^3$ /mm <sup>3</sup> )>1.2x ULN	0	1	0	0
Neutrophils (ABSOLUTE) ( $10^3$ /mm <sup>3</sup> )<0.8x LLN	1	0	0	0
Neutrophils (ABSOLUTE) ( $10^3$ /mm <sup>3</sup> )>1.2x ULN	7	13	7	9
Basophils (ABSOLUTE) ( $10^3$ /mm <sup>3</sup> )>1.2x ULN	0	0	1	0
Eosinophils (ABSOLUTE) ( $10^3$ /mm <sup>3</sup> )>1.2x ULN	2	3	1	1
Monocytes (ABSOLUTE) ( $10^3$ /mm <sup>3</sup> )>1.2x ULN	2	2	0	2
Activated Partial Thromboplastin Time>1.1x ULN	1	0	1	0
Prothrombin Time (sec)>1.1x ULN	1	2	1	1
Prothrombin Intl. Normalized Ratio>1.1x ULN	1	2	1	1

End point values	PF-06700841 10 mg (Induction)	PF-06700841 30 mg (Induction)	PF-06700841 60 mg (Induction)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	48	47	47	
Units: Subjects				
Hemoglobin (g/dL)<0.8x LLN	4	4	5	
Hematocrit (%)<0.8x LLN	1	1	0	
Erythrocytes ( $10^6$ /mm <sup>3</sup> )<0.8x LLN	1	1	2	
Reticulocytes (ABSOLUTE) ( $10^3$ /mm <sup>3</sup> )<0.5x LLN	0	0	0	
Reticulocytes (ABSOLUTE) ( $10^3$ /mm <sup>3</sup> )>1.5x ULN	0	0	0	
Ery. Mean Corpuscular Volume ( $10^{-15}$ L)<0.9x LLN	0	0	0	
Ery. Mean Corpuscular Volume ( $10^{-15}$ L)>1.1x ULN	0	0	0	
Platelets ( $10^3$ /mm <sup>3</sup> )<0.5x LLN	0	0	0	
Platelets ( $10^3$ /mm <sup>3</sup> )>1.75x ULN	2	2	5	
Reticulocytes/Erythrocytes (%)<0.5x LLN	0	0	0	
Reticulocytes/Erythrocytes (%)>1.5x ULN	0	0	2	
Leukocytes ( $10^3$ /mm <sup>3</sup> )<0.6x LLN	1	0	0	
Leukocytes ( $10^3$ /mm <sup>3</sup> )>1.5x ULN	2	2	1	

Lymphocytes (ABSOLUTE) (10 <sup>3</sup> /mm <sup>3</sup> )<0.8x LLN	2	1	2	
Lymphocytes (ABSOLUTE) (10 <sup>3</sup> /mm <sup>3</sup> )>1.2x ULN	1	1	1	
Neutrophils (ABSOLUTE) (10 <sup>3</sup> /mm <sup>3</sup> )<0.8x LLN	2	3	2	
Neutrophils (ABSOLUTE) (10 <sup>3</sup> /mm <sup>3</sup> )>1.2x ULN	7	7	11	
Basophils (ABSOLUTE) (10 <sup>3</sup> /mm <sup>3</sup> )>1.2x ULN	1	1	0	
Eosinophils (ABSOLUTE) (10 <sup>3</sup> /mm <sup>3</sup> )>1.2x ULN	1	3	2	
Monocytes (ABSOLUTE) (10 <sup>3</sup> /mm <sup>3</sup> )>1.2x ULN	1	1	2	
Activated Partial Thromboplastin Time>1.1x ULN	0	0	0	
Prothrombin Time (sec)>1.1x ULN	0	0	0	
Prothrombin Intl. Normalized Ratio>1.1x ULN	0	0	0	

## Statistical analyses

No statistical analyses for this end point

## Secondary: Induction Period: Number of subjects with Laboratory Abnormalities without regard to baseline values - Clinical Chemistry

End point title	Induction Period: Number of subjects with Laboratory Abnormalities without regard to baseline values - Clinical Chemistry
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End point description:

Following parameters were analyzed for laboratory examination: Bilirubin, Direct Bilirubin, Indirect Bilirubin, Aspartate Aminotransferase, Alanine Aminotransferase, Gamma Glutamyl Transferase, Alkaline Phosphatase, Protein, Albumin, Urea Nitrogen, Creatinine, Urate, HDL Cholesterol, LDL Cholesterol, Triglycerides, Sodium, Potassium, Chloride, Calcium, Glucose, Hemoglobin A1C, Creatine Kinase, Cholesterol. The analysis population included all enrolled participants who received at least one dose of study medication.

End point type	Secondary
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End point timeframe:

Baseline through Week 8

End point values	Placebo (Induction: 0 to 8 weeks)	PF-06651600 20 mg (Induction)	PF-06651600 70 mg (Induction)	PF-06651600 200 mg (Induction)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	51	48	50
Units: Subjects				
Bilirubin (mg/dL)>1.5x ULN	0	1	0	1
Direct Bilirubin (mg/dL)>1.5x ULN	0	0	0	0
Indirect Bilirubin (mg/dL)>1.5x ULN	0	0	0	0
Aspartate Aminotransferase (U/L)>3.0x ULN	0	0	0	0
Alanine Aminotransferase (U/L)>3.0x ULN	0	0	0	0

Gamma Glutamyl Transferase (U/L)>3.0x ULN	0	0	0	0
Alkaline Phosphatase (U/L)>3.0x ULN	0	1	0	0
Protein (g/dL)<0.8x LLN	0	0	0	0
Protein (g/dL)>1.2x ULN	0	0	0	0
Albumin (g/dL)<0.8x LLN	0	0	0	0
Albumin (g/dL)>1.2x ULN	0	0	0	0
Urea Nitrogen (mg/dL)>1.3x ULN	0	0	0	0
Creatinine (mg/dL)>1.3x ULN	0	0	0	0
Urate (mg/dL)>1.2x ULN	0	0	1	0
HDL Cholesterol (mg/dL)<0.8x LLN	0	0	0	0
LDL Cholesterol (mg/dL)>1.2x ULN	0	0	1	0
Triglycerides (mg/dL)>1.3x ULN	1	1	1	3
Sodium (Meq/L)<0.95x LLN	0	0	0	0
Sodium (Meq/L)>1.05xULN	0	0	0	0
Potassium (Meq/L)<0.9x LLN	0	0	0	0
Potassium (Meq/L)>1.1x ULN	0	0	1	0
Chloride (Meq/L)<0.9x LLN	0	0	0	0
Chloride (Meq/L)>1.1x ULN	0	0	0	0
Calcium (mg/dL)<0.9x LLN	0	0	0	0
Calcium (mg/dL)>1.1x ULN	0	0	0	0
Glucose (mg/dL)<0.6x LLN	0	0	0	0
Glucose (mg/dL)>1.5x ULN	0	1	2	1
Hemoglobin A1C (%)>1.3x ULN	0	0	0	0
Creatine Kinase (U/L)>2.0x ULN	2	0	2	3
Cholesterol (mg/dl)>1.3x ULN	0	0	1	0

<b>End point values</b>	PF-06700841 10 mg (Induction)	PF-06700841 30 mg (Induction)	PF-06700841 60 mg (Induction)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	48	47	47	
Units: Subjects				
Bilirubin (mg/dL)>1.5x ULN	2	2	1	
Direct Bilirubin (mg/dL)>1.5x ULN	0	0	0	
Indirect Bilirubin (mg/dL)>1.5x ULN	0	0	0	
Aspartate Aminotransferase (U/L)>3.0x ULN	0	0	0	
Alanine Aminotransferase (U/L)>3.0x ULN	2	0	0	
Gamma Glutamyl Transferase (U/L)>3.0x ULN	0	0	0	
Alkaline Phosphatase (U/L)>3.0x ULN	0	0	0	
Protein (g/dL)<0.8x LLN	0	0	0	
Protein (g/dL)>1.2x ULN	0	0	0	
Albumin (g/dL)<0.8x LLN	0	0	0	
Albumin (g/dL)>1.2x ULN	0	0	0	
Urea Nitrogen (mg/dL)>1.3x ULN	0	0	0	
Creatinine (mg/dL)>1.3x ULN	0	1	0	
Urate (mg/dL)>1.2x ULN	0	0	0	
HDL Cholesterol (mg/dL)<0.8x LLN	0	0	0	

LDL Cholesterol (mg/dL)>1.2x ULN	0	0	1	
Triglycerides (mg/dL)>1.3x ULN	1	2	5	
Sodium (Meq/L)<0.95x LLN	0	0	0	
Sodium (Meq/L)>1.05xULN	0	0	0	
Potassium (Meq/L)<0.9x LLN	0	0	0	
Potassium (Meq/L)>1.1x ULN	0	0	0	
Chloride (Meq/L)<0.9x LLN	0	0	0	
Chloride (Meq/L)>1.1x ULN	0	0	0	
Calcium (mg/dL)<0.9x LLN	0	0	0	
Calcium (mg/dL)>1.1x ULN	0	0	0	
Glucose (mg/dL)<0.6x LLN	0	0	0	
Glucose (mg/dL)>1.5x ULN	1	0	2	
Hemoglobin A1C (%)>1.3x ULN	0	0	0	
Creatine Kinase (U/L)>2.0x ULN	2	3	6	
Cholesterol (mg/dl)>1.3x ULN	0	1	0	

### Statistical analyses

No statistical analyses for this end point

### Secondary: Induction Period: Number of subjects with Laboratory Abnormalities without regard to baseline values - Urinalysis

End point title	Induction Period: Number of subjects with Laboratory Abnormalities without regard to baseline values - Urinalysis
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End point description:

Following parameters were analyzed for laboratory examination: pH, URINE Glucose, Ketones, URINE Protein, URINE Hemoglobin, Nitrite, Leukocyte Esterase, URINE Erythrocytes, URINE Leukocytes, Hyaline Casts, WBC Casts, Bacteria. The analysis population included all enrolled participants who received at least one dose of study medication.

End point type	Secondary
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End point timeframe:

Baseline through Week 8

End point values	Placebo (Induction: 0 to 8 weeks)	PF-06651600 20 mg (Induction)	PF-06651600 70 mg (Induction)	PF-06651600 200 mg (Induction)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	49	48	50
Units: Subjects				
pH (scalar)<4.5	0	0	0	0
pH (scalar)>8	0	0	0	0
URINE Glucose (No Unit)>=1	0	1	4	1
Ketones (No Unit)>=1	1	4	1	1
URINE Protein (No Unit)>=1	0	2	0	1
URINE Hemoglobin (No Unit)>=1	2	4	4	4
Nitrite (No Unit)>=1	1	1	2	1
Leukocyte Esterase (No Unit)>=1	3	11	4	10
URINE Erythrocytes (/HPF)>=20	0	0	1	1

URINE Leukocytes (/HPF)>=20	1	2	1	4
Granular Casts (/LPF)>1	1	0	0	1
Hyaline Casts (/LPF)>1	3	2	2	4
WBC Casts (/LPF)>1	0	0	1	0
Bacteria (No Unit)>20	0	0	0	0

End point values	PF-06700841 10 mg (Induction)	PF-06700841 30 mg (Induction)	PF-06700841 60 mg (Induction)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	48	47	47	
Units: Subjects				
pH (scalar)<4.5	0	0	0	
pH (scalar)>8	0	0	0	
URINE Glucose (No Unit)>=1	0	1	1	
Ketones (No Unit)>=1	7	4	4	
URINE Protein (No Unit)>=1	1	2	0	
URINE Hemoglobin (No Unit)>=1	5	8	4	
Nitrite (No Unit)>=1	2	0	1	
Leukocyte Esterase (No Unit)>=1	7	8	14	
URINE Erythrocytes (/HPF)>=20	0	0	0	
URINE Leukocytes (/HPF)>=20	3	1	3	
Granular Casts (/LPF)>1	0	0	0	
Hyaline Casts (/LPF)>1	4	2	1	
WBC Casts (/LPF)>1	0	0	0	
Bacteria (No Unit)>20	0	0	0	

## Statistical analyses

No statistical analyses for this end point

## Secondary: Induction Period: Number of subjects with abnormal electrocardiogram findings

End point title	Induction Period: Number of subjects with abnormal electrocardiogram findings
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End point description:

The analysis population included all enrolled participants who received at least one dose of study medication.

End point type	Secondary
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End point timeframe:

Baseline through Week 8

End point values	Placebo (Induction: 0 to 8 weeks)	PF-06651600 20 mg (Induction)	PF-06651600 70 mg (Induction)	PF-06651600 200 mg (Induction)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	42	42	40
Units: Subjects				
NORMAL	18	35	34	35
ABNORMAL, NOT CLINICALLY SIGNIFICANT	2	7	8	4
ABNORMAL, CLINICALLY SIGNIFICANT	0	0	0	1
NOT EVALUABLE	0	0	0	0

End point values	PF-06700841 10 mg (Induction)	PF-06700841 30 mg (Induction)	PF-06700841 60 mg (Induction)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	44	42	43	
Units: Subjects				
NORMAL	39	37	40	
ABNORMAL, NOT CLINICALLY SIGNIFICANT	5	4	3	
ABNORMAL, CLINICALLY SIGNIFICANT	0	0	0	
NOT EVALUABLE	0	1	0	

### Statistical analyses

No statistical analyses for this end point

### Secondary: Induction Period: Number of subjects with Serious Infection

End point title	Induction Period: Number of subjects with Serious Infection
End point description:	
Serious infections are treated infections that: Require parenteral antimicrobial therapy and present with positive pre-treatment culture; and either Require hospitalization for treatment; or Meet other criteria that require the infection to be classified as a SAE. The analysis population included all enrolled participants who received at least one dose of study medication.	
End point type	Secondary
End point timeframe:	
Baseline through Week 8	

End point values	Placebo (Induction: 0 to 8 weeks)	PF-06651600 20 mg (Induction)	PF-06651600 70 mg (Induction)	PF-06651600 200 mg (Induction)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	51	49	50
Units: Subjects				
Listeria encephalitis	0	0	0	1
Pneumonia	0	1	0	0



Viral infection	0	1	0	0
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End point values	PF-06700841 10 mg (Induction)	PF-06700841 30 mg (Induction)	PF-06700841 60 mg (Induction)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	48	47	47	
Units: Subjects				
Listeria encephalitis	0	0	0	
Pneumonia	0	0	0	
Viral infection	0	0	0	

## Statistical analyses

No statistical analyses for this end point

## Secondary: Chronic Period: Total Mayo Score at Week 32

End point title	Chronic Period: Total Mayo Score at Week 32
End point description:	
The Mayo score ranges from 0 to 12, with higher scores indicating more severe disease. The ITT analysis set was used to analyze this endpoint, defined as all randomized subjects who received at least 1 dose of investigational product or placebo.	
End point type	Secondary
End point timeframe:	
Week 32	

End point values	PF-06651600 200 mg -> PF- 06651600 50 mg	PF-06651600 70 mg -> PF- 06651600 50 mg	PF-06651600 20 mg -> PF- 06651600 50 mg	Placebo -> PF- 06651600 50 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	35	36	39	10
Units: Unit on a scale				
least squares mean (confidence interval 90%)	2.89 (2.18 to 3.60)	3.46 (2.77 to 4.16)	3.47 (2.75 to 4.19)	4.13 (2.82 to 5.44)

End point values	PF-06700841 60 mg -> PF- 06700841 30 mg	PF-06700841 30 mg -> PF- 06700841 30 mg	PF-06700841 10 mg -> PF- 06700841 30 mg	Placebo -> PF- 06700841 30 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	37	39	9
Units: Unit on a scale				
least squares mean (confidence interval 90%)	3.86 (2.98 to 4.75)	3.63 (2.67 to 4.59)	3.81 (2.94 to 4.68)	4.62 (2.62 to 6.61)

## Statistical analyses

No statistical analyses for this end point

### Secondary: Chronic Period: Percentage of subjects achieving remission based on total Mayo score at Week 32

End point title	Chronic Period: Percentage of subjects achieving remission based on total Mayo score at Week 32
End point description: Remission excludes friability and is based on total Mayo score of less than/equal to 2 with no individual subscore greater than 1 and a rectal bleeding subscore of 0 at week 32. The ITT analysis set was used to analyze this endpoint, defined as all randomized subjects who received at least 1 dose of investigational product or placebo.	
End point type	Secondary
End point timeframe: Week 32	

End point values	PF-06651600 200 mg -> PF- 06651600 50 mg	PF-06651600 70 mg -> PF- 06651600 50 mg	PF-06651600 20 mg -> PF- 06651600 50 mg	Placebo -> PF- 06651600 50 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	35	36	39	10
Units: Percentage of subjects				
number (confidence interval 90%)	34.1 (22.3 to 46.5)	28.6 (17.4 to 41.0)	23.9 (15.1 to 35.0)	16.7 (4.5 to 39.8)

End point values	PF-06700841 60 mg -> PF- 06700841 30 mg	PF-06700841 30 mg -> PF- 06700841 30 mg	PF-06700841 10 mg -> PF- 06700841 30 mg	Placebo -> PF- 06700841 30 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	37	39	9
Units: Percentage of subjects				
number (confidence interval 90%)	26.8 (17.1 to 39.8)	26.8 (17.1 to 39.8)	21.4 (12.6 to 34.2)	18.2 (4.9 to 43.6)

## Statistical analyses

No statistical analyses for this end point

**Secondary: Chronic Period: Percentage of subjects achieving improvement in endoscopic appearance at Week 32**

End point title	Chronic Period: Percentage of subjects achieving improvement in endoscopic appearance at Week 32
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End point description:

Improvement of endoscopic appearance is defined as a Mayo endoscopic subscore of less than/equal to 1. The ITT analysis set was used to analyze this endpoint, defined as all randomized subjects who received at least 1 dose of investigational product or placebo.

End point type	Secondary
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End point timeframe:

Week 32

<b>End point values</b>	PF-06651600 200 mg -> PF- 06651600 50 mg	PF-06651600 70 mg -> PF- 06651600 50 mg	PF-06651600 20 mg -> PF- 06651600 50 mg	Placebo -> PF- 06651600 50 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	35	36	39	10
Units: Percentage of subjects				
number (confidence interval 90%)	34.1 (22.3 to 46.5)	40.5 (27.7 to 54.3)	26.1 (15.8 to 37.7)	33.3 (15.4 to 60.2)

<b>End point values</b>	PF-06700841 60 mg -> PF- 06700841 30 mg	PF-06700841 30 mg -> PF- 06700841 30 mg	PF-06700841 10 mg -> PF- 06700841 30 mg	Placebo -> PF- 06700841 30 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	37	39	9
Units: Percentage of subjects				
number (confidence interval 90%)	36.6 (24.6 to 50.0)	34.1 (23.0 to 46.9)	31.0 (19.4 to 43.3)	18.2 (4.9 to 43.6)

**Statistical analyses**

No statistical analyses for this end point

**Other pre-specified: Chronic Period: Change from baseline in total Mayo score**

End point title	Chronic Period: Change from baseline in total Mayo score
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End point description:

Total Mayo Score ranges from 0 to 12, with higher scores indicating more severe disease. Baseline value is defined as the last non-missing measurement collected prior to the first administration of study drug at Day 1. The ITT analysis set was used to analyze this endpoint, defined as all randomized subjects who received at least 1 dose of investigational product or placebo.

End point type	Other pre-specified
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End point timeframe:

Week 32

<b>End point values</b>	PF-06651600 200 mg -> PF- 06651600 50 mg	PF-06651600 70 mg -> PF- 06651600 50 mg	PF-06651600 20 mg -> PF- 06651600 50 mg	Placebo -> PF- 06651600 50 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	35	36	39	10
Units: Units on a scale				
least squares mean (confidence interval 90%)	-6.12 (-6.83 to -5.41)	-5.55 (-6.24 to -4.85)	-5.54 (-6.26 to -4.82)	-4.88 (-6.19 to -3.57)

<b>End point values</b>	PF-06700841 60 mg -> PF- 06700841 30 mg	PF-06700841 30 mg -> PF- 06700841 30 mg	PF-06700841 10 mg -> PF- 06700841 30 mg	Placebo -> PF- 06700841 30 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	37	39	9
Units: Units on a scale				
least squares mean (confidence interval 90%)	-5.21 (-6.09 to -4.32)	-5.44 (-6.39 to -4.48)	-5.26 (-6.12 to -4.39)	-4.45 (-6.45 to -2.45)

### Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

From the time the subject took at least 1 dose of study treatment up to 28 days after the last treatment administration. (approximately 36 Weeks)

Assessment type	Non-systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	24.0
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### Reporting groups

Reporting group title	Placebo (Induction: 0 to 8 weeks)
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Reporting group description:

The placebo was administered orally once daily (QD) from Day 1 to Week 8.

Reporting group title	PF-06651600 20 mg (Induction)
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Reporting group description:

PF-06651600 tablet was administered orally at 20 mg QD from Day 1 to Week 8.

Reporting group title	PF-06651600 70 mg (Induction)
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Reporting group description:

PF-06651600 tablet was administered orally at 70 mg QD from Day 1 to Week 8.

Reporting group title	PF-06651600 200 mg (Induction)
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Reporting group description:

PF-06651600 tablet was administered orally at 200 mg QD from Day 1 to Week 8.

Reporting group title	PF-06700841 10 mg (Induction)
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Reporting group description:

PF-06700841 tablet was administered orally at 10 mg QD from Day 1 to Week 8.

Reporting group title	PF-06700841 30 mg (Induction)
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Reporting group description:

PF-06700841 tablet was administered orally at 30 mg QD from Day 1 to Week 8.

Reporting group title	PF-06700841 60 mg (Induction)
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Reporting group description:

PF-06700841 tablet was administered orally at 60 mg QD from Day 1 to Week 8.

Reporting group title	PF-06651600 200 mg -> PF-06651600 50 mg
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Reporting group description:

PF-06651600 tablet was administered orally at 200 mg QD from Day 1 to Week 8 and at 50 mg QD from Week 9 to Week 32.

Reporting group title	PF-06651600 70 mg -> PF-06651600 50 mg
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Reporting group description:

PF-06651600 tablet was administered orally at 70 mg QD from Day 1 to Week 8 and at 50 mg QD from Week 9 to Week 32.

Reporting group title	PF-06651600 20 mg -> PF-06651600 50 mg
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Reporting group description:

PF-06651600 tablet was administered orally at 20 mg QD from Day 1 to Week 8 and at 50 mg QD from Week 9 to Week 32.

Reporting group title	Placebo -> PF-06651600 50 mg
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Reporting group description:

The placebo was administered orally QD from Day 1 to Week 8 and PF-06651600 was administered at 50 mg QD from Week 9 to Week 32.

Reporting group title	PF-06700841 60 mg -> PF-06700841 30 mg
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Reporting group description:

PF-06700841 tablet was administered orally at 60 mg QD from Day 1 to Week 8 and at 30 mg QD from Week 9 to Week 32.

Reporting group title	PF-06700841 30 mg -> PF-06700841 30 mg
Reporting group description: PF-06700841 tablet was administered orally at 30 mg QD from Day 1 to Week 8 and at 30 mg QD from Week 9 to Week 32.	
Reporting group title	PF-06700841 10 mg -> PF-06700841 30 mg
Reporting group description: PF-06700841 tablet was administered orally at 10 mg QD from Day 1 to Week 8 and at 30 mg QD from Week 9 to Week 32.	
Reporting group title	Placebo -> PF-06700841 30 mg
Reporting group description: The placebo was administered orally from Day 1 to Week 8 and PF-06700841 was administered orally at 30 mg QD from Week 9 to Week 32.	
Reporting group title	Pooling Placebo During Chronic
Reporting group description: The placebo was administered orally QD from Week 9 to Week 32 regardless of what was administered from Day 1 to Week 8.	

Serious adverse events	Placebo (Induction: 0 to 8 weeks)	PF-06651600 20 mg (Induction)	PF-06651600 70 mg (Induction)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 25 (0.00%)	3 / 51 (5.88%)	0 / 49 (0.00%)
number of deaths (all causes)	0	1	0
number of deaths resulting from adverse events	0	1	0
Injury, poisoning and procedural complications			
Ankle injury	Additional description: Ankle fracture		
subjects affected / exposed	0 / 25 (0.00%)	0 / 51 (0.00%)	0 / 49 (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
Fracture bone	Additional description: Femur fracture		
subjects affected / exposed	0 / 25 (0.00%)	0 / 51 (0.00%)	0 / 49 (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			
Peripheral vasoconstriction, necrosis and vascular insufficiency	Additional description: Peripheral artery thrombosis		
subjects affected / exposed	0 / 25 (0.00%)	0 / 51 (0.00%)	0 / 49 (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			
Myocardial infarction			

subjects affected / exposed	0 / 25 (0.00%)	1 / 51 (1.96%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Myocardial ischemia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 51 (0.00%)	0 / 49 (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	Additional description: Haemorrhoid operation		
subjects affected / exposed	0 / 25 (0.00%)	0 / 51 (0.00%)	0 / 49 (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 / 25 (0.00%)	0 / 51 (0.00%)	0 / 49 (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			
Pyrexia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 51 (0.00%)	0 / 49 (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			
Colitis ulcerative			
subjects affected / exposed	0 / 25 (0.00%)	1 / 51 (1.96%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	0 / 25 (0.00%)	0 / 51 (0.00%)	0 / 49 (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
Respiratory, thoracic and mediastinal disorders			
Interstitial lung fibrosis			

subjects affected / exposed	0 / 25 (0.00%)	0 / 51 (0.00%)	0 / 49 (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
Skin and subcutaneous tissue disorders			
Urticaria generalised			
subjects affected / exposed	0 / 25 (0.00%)	0 / 51 (0.00%)	0 / 49 (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
Renal and urinary disorders			
Kidney dysfunction			
	Additional description: Acute kidney injury		
subjects affected / exposed	0 / 25 (0.00%)	0 / 51 (0.00%)	0 / 49 (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			
Listeria encephalitis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 51 (0.00%)	0 / 49 (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
Pneumonia			
subjects affected / exposed	0 / 25 (0.00%)	1 / 51 (1.96%)	0 / 49 (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
Viral DNA test positive			
	Additional description: Viral infection		
subjects affected / exposed	0 / 25 (0.00%)	1 / 51 (1.96%)	0 / 49 (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
Pneumonia viral			
	Additional description: COVID-19		
subjects affected / exposed	0 / 25 (0.00%)	0 / 51 (0.00%)	0 / 49 (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
Metabolism and nutrition disorders			
Dehydration			



subjects affected / exposed	0 / 25 (0.00%)	0 / 51 (0.00%)	0 / 49 (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

<b>Serious adverse events</b>	PF-06651600 200 mg (Induction)	PF-06700841 10 mg (Induction)	PF-06700841 30 mg (Induction)
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 50 (6.00%)	1 / 48 (2.08%)	3 / 47 (6.38%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Ankle injury	Additional description: Ankle fracture		
subjects affected / exposed	0 / 50 (0.00%)	0 / 48 (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
Fracture bone	Additional description: Femur fracture		
subjects affected / exposed	0 / 50 (0.00%)	0 / 48 (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			
Peripheral vasoconstriction, necrosis and vascular insufficiency	Additional description: Peripheral artery thrombosis		
subjects affected / exposed	0 / 50 (0.00%)	0 / 48 (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
Cardiac disorders			
Myocardial infarction			
subjects affected / exposed	0 / 50 (0.00%)	0 / 48 (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
Myocardial ischemia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 48 (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	Additional description: Haemorrhoid operation		

subjects affected / exposed	0 / 50 (0.00%)	0 / 48 (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
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 48 (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			
Pyrexia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 48 (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
Gastrointestinal disorders			
Colitis ulcerative			
subjects affected / exposed	1 / 50 (2.00%)	1 / 48 (2.08%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	0 / 50 (0.00%)	0 / 48 (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
Respiratory, thoracic and mediastinal disorders			
Interstitial lung fibrosis			
subjects affected / exposed	1 / 50 (2.00%)	0 / 48 (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
Skin and subcutaneous tissue disorders			
Urticaria generalised			
subjects affected / exposed	0 / 50 (0.00%)	0 / 48 (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
Renal and urinary disorders			
Kidney dysfunction			
Additional description: Acute kidney injury			

subjects affected / exposed	0 / 50 (0.00%)	0 / 48 (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
<b>Infections and infestations</b>			
Listeria encephalitis			
subjects affected / exposed	1 / 50 (2.00%)	0 / 48 (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
Pneumonia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 48 (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
<b>Viral DNA test positive</b>			
Additional description: Viral infection			
subjects affected / exposed	0 / 50 (0.00%)	0 / 48 (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
<b>Pneumonia viral</b>			
Additional description: COVID-19			
subjects affected / exposed	0 / 50 (0.00%)	0 / 48 (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
<b>Metabolism and nutrition disorders</b>			
Dehydration			
subjects affected / exposed	0 / 50 (0.00%)	0 / 48 (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

<b>Serious adverse events</b>	PF-06700841 60 mg (Induction)	PF-06651600 200 mg -> PF-06651600 50 mg	PF-06651600 70 mg -> PF-06651600 50 mg
<b>Total subjects affected by serious adverse events</b>			
subjects affected / exposed	1 / 47 (2.13%)	3 / 35 (8.57%)	1 / 36 (2.78%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
<b>Injury, poisoning and procedural complications</b>			
Ankle injury			
Additional description: Ankle fracture			

subjects affected / exposed	0 / 47 (0.00%)	1 / 35 (2.86%)	0 / 36 (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
Fracture bone	Additional description: Femur fracture		
subjects affected / exposed	0 / 47 (0.00%)	1 / 35 (2.86%)	0 / 36 (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			
Peripheral vasoconstriction, necrosis and vascular insufficiency	Additional description: Peripheral artery thrombosis		
subjects affected / exposed	0 / 47 (0.00%)	0 / 35 (0.00%)	0 / 36 (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			
Myocardial infarction			
subjects affected / exposed	0 / 47 (0.00%)	0 / 35 (0.00%)	0 / 36 (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
Myocardial ischemia			
subjects affected / exposed	0 / 47 (0.00%)	0 / 35 (0.00%)	0 / 36 (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	Additional description: Haemorrhoid operation		
subjects affected / exposed	0 / 47 (0.00%)	0 / 35 (0.00%)	0 / 36 (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	1 / 47 (2.13%)	0 / 35 (0.00%)	0 / 36 (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			
Pyrexia			

subjects affected / exposed	0 / 47 (0.00%)	0 / 35 (0.00%)	0 / 36 (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			
Colitis ulcerative			
subjects affected / exposed	0 / 47 (0.00%)	0 / 35 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	0 / 47 (0.00%)	0 / 35 (0.00%)	0 / 36 (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
Respiratory, thoracic and mediastinal disorders			
Interstitial lung fibrosis			
subjects affected / exposed	0 / 47 (0.00%)	0 / 35 (0.00%)	0 / 36 (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
Skin and subcutaneous tissue disorders			
Urticaria generalised			
subjects affected / exposed	0 / 47 (0.00%)	1 / 35 (2.86%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Kidney dysfunction	Additional description: Acute kidney injury		
subjects affected / exposed	0 / 47 (0.00%)	0 / 35 (0.00%)	0 / 36 (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			
Listeria encephalitis			
subjects affected / exposed	0 / 47 (0.00%)	0 / 35 (0.00%)	0 / 36 (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
Pneumonia			

subjects affected / exposed	0 / 47 (0.00%)	0 / 35 (0.00%)	0 / 36 (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
Viral DNA test positive	Additional description: Viral infection		
subjects affected / exposed	0 / 47 (0.00%)	0 / 35 (0.00%)	0 / 36 (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
Pneumonia viral	Additional description: COVID-19		
subjects affected / exposed	0 / 47 (0.00%)	0 / 35 (0.00%)	0 / 36 (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
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 47 (0.00%)	0 / 35 (0.00%)	0 / 36 (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

<b>Serious adverse events</b>	PF-06651600 20 mg -> PF-06651600 50 mg	Placebo -> PF-06651600 50 mg	PF-06700841 60 mg -> PF-06700841 30 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 39 (2.56%)	0 / 10 (0.00%)	2 / 38 (5.26%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Ankle injury	Additional description: Ankle fracture		
subjects affected / exposed	0 / 39 (0.00%)	0 / 10 (0.00%)	0 / 38 (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
Fracture bone	Additional description: Femur fracture		
subjects affected / exposed	0 / 39 (0.00%)	0 / 10 (0.00%)	0 / 38 (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			
Peripheral vasoconstriction, necrosis and vascular insufficiency	Additional description: Peripheral artery thrombosis		

subjects affected / exposed	0 / 39 (0.00%)	0 / 10 (0.00%)	0 / 38 (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			
Myocardial infarction			
subjects affected / exposed	0 / 39 (0.00%)	0 / 10 (0.00%)	0 / 38 (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
Myocardial ischemia			
subjects affected / exposed	0 / 39 (0.00%)	0 / 10 (0.00%)	0 / 38 (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	Additional description: Haemorrhoid operation		
subjects affected / exposed	0 / 39 (0.00%)	0 / 10 (0.00%)	0 / 38 (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 / 39 (0.00%)	0 / 10 (0.00%)	0 / 38 (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			
Pyrexia			
subjects affected / exposed	0 / 39 (0.00%)	0 / 10 (0.00%)	0 / 38 (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			
Colitis ulcerative			
subjects affected / exposed	1 / 39 (2.56%)	0 / 10 (0.00%)	1 / 38 (2.63%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			

subjects affected / exposed	0 / 39 (0.00%)	0 / 10 (0.00%)	0 / 38 (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
Respiratory, thoracic and mediastinal disorders			
Interstitial lung fibrosis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 10 (0.00%)	0 / 38 (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
Skin and subcutaneous tissue disorders			
Urticaria generalised			
subjects affected / exposed	0 / 39 (0.00%)	0 / 10 (0.00%)	0 / 38 (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
Renal and urinary disorders			
Kidney dysfunction	Additional description: Acute kidney injury		
subjects affected / exposed	0 / 39 (0.00%)	0 / 10 (0.00%)	1 / 38 (2.63%)
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			
Listeria encephalitis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 10 (0.00%)	0 / 38 (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
Pneumonia			
subjects affected / exposed	0 / 39 (0.00%)	0 / 10 (0.00%)	0 / 38 (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
Viral DNA test positive	Additional description: Viral infection		
subjects affected / exposed	0 / 39 (0.00%)	0 / 10 (0.00%)	1 / 38 (2.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia viral	Additional description: COVID-19		



subjects affected / exposed	0 / 39 (0.00%)	0 / 10 (0.00%)	0 / 38 (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
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 39 (0.00%)	0 / 10 (0.00%)	1 / 38 (2.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

<b>Serious adverse events</b>	PF-06700841 30 mg -> PF-06700841 30 mg	PF-06700841 10 mg -> PF-06700841 30 mg	Placebo -> PF-06700841 30 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 37 (10.81%)	2 / 39 (5.13%)	0 / 9 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Ankle injury	Additional description: Ankle fracture		
subjects affected / exposed	0 / 37 (0.00%)	0 / 39 (0.00%)	0 / 9 (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
Fracture bone	Additional description: Femur fracture		
subjects affected / exposed	0 / 37 (0.00%)	0 / 39 (0.00%)	0 / 9 (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			
Peripheral vasoconstriction, necrosis and vascular insufficiency	Additional description: Peripheral artery thrombosis		
subjects affected / exposed	0 / 37 (0.00%)	0 / 39 (0.00%)	0 / 9 (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			
Myocardial infarction			
subjects affected / exposed	0 / 37 (0.00%)	0 / 39 (0.00%)	0 / 9 (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
Myocardial ischemia			

subjects affected / exposed	1 / 37 (2.70%)	0 / 39 (0.00%)	0 / 9 (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
Surgical and medical procedures			
Haemorrhoid	Additional description: Haemorrhoid operation		
subjects affected / exposed	0 / 37 (0.00%)	0 / 39 (0.00%)	0 / 9 (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 / 37 (0.00%)	0 / 39 (0.00%)	0 / 9 (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			
Pyrexia			
subjects affected / exposed	0 / 37 (0.00%)	0 / 39 (0.00%)	0 / 9 (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			
Colitis ulcerative			
subjects affected / exposed	2 / 37 (5.41%)	1 / 39 (2.56%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	1 / 37 (2.70%)	0 / 39 (0.00%)	0 / 9 (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
Respiratory, thoracic and mediastinal disorders			
Interstitial lung fibrosis			
subjects affected / exposed	0 / 37 (0.00%)	0 / 39 (0.00%)	0 / 9 (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
Skin and subcutaneous tissue disorders			
Urticaria generalised			

subjects affected / exposed	0 / 37 (0.00%)	0 / 39 (0.00%)	0 / 9 (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
Renal and urinary disorders			
Kidney dysfunction	Additional description: Acute kidney injury		
subjects affected / exposed	0 / 37 (0.00%)	0 / 39 (0.00%)	0 / 9 (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			
Listeria encephalitis			
subjects affected / exposed	0 / 37 (0.00%)	0 / 39 (0.00%)	0 / 9 (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
Pneumonia			
subjects affected / exposed	0 / 37 (0.00%)	0 / 39 (0.00%)	0 / 9 (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
Viral DNA test positive	Additional description: Viral infection		
subjects affected / exposed	0 / 37 (0.00%)	0 / 39 (0.00%)	0 / 9 (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
Pneumonia viral	Additional description: COVID-19		
subjects affected / exposed	0 / 37 (0.00%)	1 / 39 (2.56%)	0 / 9 (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
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 37 (0.00%)	0 / 39 (0.00%)	0 / 9 (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
<b>Serious adverse events</b>	Pooling Placebo During Chronic		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 37 (0.00%)		
number of deaths (all causes)	0		

number of deaths resulting from adverse events	0		
Injury, poisoning and procedural complications			
Ankle injury	Additional description: Ankle fracture		
subjects affected / exposed	0 / 37 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Fracture bone	Additional description: Femur fracture		
subjects affected / exposed	0 / 37 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Peripheral vasoconstriction, necrosis and vascular insufficiency	Additional description: Peripheral artery thrombosis		
subjects affected / exposed	0 / 37 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Myocardial infarction			
subjects affected / exposed	0 / 37 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myocardial ischemia			
subjects affected / exposed	0 / 37 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Surgical and medical procedures			
Haemorrhoid	Additional description: Haemorrhoid operation		
subjects affected / exposed	0 / 37 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 37 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 37 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Colitis ulcerative			
subjects affected / exposed	0 / 37 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Large intestine perforation			
subjects affected / exposed	0 / 37 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Interstitial lung fibrosis			
subjects affected / exposed	0 / 37 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Urticaria generalised			
subjects affected / exposed	0 / 37 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Kidney dysfunction	Additional description: Acute kidney injury		
subjects affected / exposed	0 / 37 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Listeria encephalitis			
subjects affected / exposed	0 / 37 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia			

subjects affected / exposed	0 / 37 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Viral DNA test positive	Additional description: Viral infection		
subjects affected / exposed	0 / 37 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia viral	Additional description: COVID-19		
subjects affected / exposed	0 / 37 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 37 (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	Placebo (Induction: 0 to 8 weeks)	PF-06651600 20 mg (Induction)	PF-06651600 70 mg (Induction)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 25 (16.00%)	8 / 51 (15.69%)	6 / 49 (12.24%)
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 25 (0.00%)	0 / 51 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Feeling hot			
subjects affected / exposed	0 / 25 (0.00%)	0 / 51 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Feeling bad	Additional description: Influenza like illness		
subjects affected / exposed	0 / 25 (0.00%)	0 / 51 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			

subjects affected / exposed	0 / 25 (0.00%)	0 / 51 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 51 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Swelling face			
subjects affected / exposed	0 / 25 (0.00%)	0 / 51 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 25 (0.00%)	0 / 51 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 25 (0.00%)	0 / 51 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 25 (0.00%)	0 / 51 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Irritable mood	Additional description: Irritability		
subjects affected / exposed	0 / 25 (0.00%)	0 / 51 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 25 (0.00%)	0 / 51 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Blood urine present			
subjects affected / exposed	0 / 25 (0.00%)	0 / 51 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Urine protein, quantitative	Additional description: Protein urine present		
subjects affected / exposed	0 / 25 (0.00%)	0 / 51 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 25 (8.00%)	3 / 51 (5.88%)	3 / 49 (6.12%)
occurrences (all)	3	3	6

Sciatica subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 51 (0.00%) 0	0 / 49 (0.00%) 0
Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all)	1 / 25 (4.00%) 1	1 / 51 (1.96%) 1	2 / 49 (4.08%) 2
Ear and labyrinth disorders Hearing loss unilateral subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 51 (0.00%) 0	0 / 49 (0.00%) 0
Eye disorders			
Visual field tests abnormal	Additional description: Visual impairment		
subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 51 (0.00%) 0	0 / 49 (0.00%) 0
Gastrointestinal disorders			
Abdominal pain subjects affected / exposed occurrences (all)	2 / 25 (8.00%) 2	1 / 51 (1.96%) 1	1 / 49 (2.04%) 1
Anal exam abnormal	Additional description: Anal fissure		
subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 51 (0.00%) 0	0 / 49 (0.00%) 0
Ulcerative colitis subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 51 (0.00%) 0	0 / 49 (0.00%) 0
Diarrhoea subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 51 (0.00%) 0	0 / 49 (0.00%) 0
Nausea subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 51 (0.00%) 0	0 / 49 (0.00%) 0
Flatulence subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 51 (0.00%) 0	0 / 49 (0.00%) 0
Dyspepsia subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 51 (0.00%) 0	0 / 49 (0.00%) 0



Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 25 (0.00%)	0 / 51 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 51 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Dermatitis atopic			
subjects affected / exposed	0 / 25 (0.00%)	0 / 51 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 25 (0.00%)	0 / 51 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 25 (0.00%)	2 / 51 (3.92%)	1 / 49 (2.04%)
occurrences (all)	0	2	1
Arthritis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 51 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Contracture of palmar fascia			
Additional description: Dupuytren's contracture			
subjects affected / exposed	0 / 25 (0.00%)	0 / 51 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 51 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Pain			
Additional description: Pain in extremity			
subjects affected / exposed	0 / 25 (0.00%)	0 / 51 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	0 / 25 (0.00%)	2 / 51 (3.92%)	0 / 49 (0.00%)
occurrences (all)	0	2	0
COVID-19			
subjects affected / exposed	0 / 25 (0.00%)	0 / 51 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0

Conjunctivitis subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 51 (0.00%) 0	0 / 49 (0.00%) 0
Herpes zoster subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 51 (0.00%) 0	0 / 49 (0.00%) 0
Influenza subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 51 (0.00%) 0	0 / 49 (0.00%) 0
Urinary tract infection subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 51 (0.00%) 0	0 / 49 (0.00%) 0
Metabolism and nutrition disorders Hypermatraemia subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 51 (0.00%) 0	0 / 49 (0.00%) 0

<b>Non-serious adverse events</b>	PF-06651600 200 mg (Induction)	PF-06700841 10 mg (Induction)	PF-06700841 30 mg (Induction)
Total subjects affected by non-serious adverse events subjects affected / exposed	5 / 50 (10.00%)	2 / 48 (4.17%)	11 / 47 (23.40%)
Vascular disorders Hypertension subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 48 (0.00%) 0	0 / 47 (0.00%) 0
General disorders and administration site conditions Feeling hot subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 48 (0.00%) 0	0 / 47 (0.00%) 0
Feeling bad subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 48 (0.00%) 0	0 / 47 (0.00%) 0
Oedema peripheral subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 48 (0.00%) 0	0 / 47 (0.00%) 0
Pyrexia			

subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 48 (0.00%) 0	0 / 47 (0.00%) 0
Swelling face subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 48 (0.00%) 0	0 / 47 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 48 (0.00%) 0	0 / 47 (0.00%) 0
Rhinorrhoea subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 48 (0.00%) 0	0 / 47 (0.00%) 0
Psychiatric disorders Anxiety subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 48 (0.00%) 0	0 / 47 (0.00%) 0
Irritable mood subjects affected / exposed occurrences (all)	Additional description: Irritability		
	0 / 50 (0.00%) 0	0 / 48 (0.00%) 0	0 / 47 (0.00%) 0
Investigations Blood creatine phosphokinase increased subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 48 (0.00%) 0	0 / 47 (0.00%) 0
Blood urine present subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 48 (0.00%) 0	0 / 47 (0.00%) 0
Urine protein, quantitative subjects affected / exposed occurrences (all)	Additional description: Protein urine present		
	0 / 50 (0.00%) 0	0 / 48 (0.00%) 0	0 / 47 (0.00%) 0
Nervous system disorders Headache subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	1 / 48 (2.08%) 1	4 / 47 (8.51%) 4
Sciatica subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 48 (0.00%) 0	0 / 47 (0.00%) 0

Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	4 / 50 (8.00%)	1 / 48 (2.08%)	1 / 47 (2.13%)
occurrences (all)	4	1	1
Ear and labyrinth disorders			
Hearing loss unilateral			
subjects affected / exposed	0 / 50 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Visual field tests abnormal	Additional description: Visual impairment		
subjects affected / exposed	0 / 50 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 50 (0.00%)	0 / 48 (0.00%)	2 / 47 (4.26%)
occurrences (all)	0	0	2
Anal exam abnormal	Additional description: Anal fissure		
subjects affected / exposed	0 / 50 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Ulcerative colitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 50 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 50 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 50 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne			

subjects affected / exposed	0 / 50 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Dermatitis atopic			
subjects affected / exposed	0 / 50 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 50 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 50 (0.00%)	1 / 48 (2.08%)	3 / 47 (6.38%)
occurrences (all)	0	1	3
Arthritis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Contracture of palmar fascia	Additional description: Dupuytren's contracture		
subjects affected / exposed	0 / 50 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Pain	Additional description: Pain in extremity		
subjects affected / exposed	0 / 50 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	1 / 50 (2.00%)	0 / 48 (0.00%)	5 / 47 (10.64%)
occurrences (all)	1	0	5
COVID-19			
subjects affected / exposed	0 / 50 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			

subjects affected / exposed	0 / 50 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 50 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 50 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 50 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hypermatraemia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 48 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0

<b>Non-serious adverse events</b>	PF-06700841 60 mg (Induction)	PF-06651600 200 mg -> PF-06651600 50 mg	PF-06651600 70 mg -> PF-06651600 50 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	9 / 47 (19.15%)	9 / 35 (25.71%)	21 / 36 (58.33%)
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 47 (0.00%)	0 / 35 (0.00%)	4 / 36 (11.11%)
occurrences (all)	0	0	4
General disorders and administration site conditions			
Feeling hot			
subjects affected / exposed	0 / 47 (0.00%)	0 / 35 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Feeling bad	Additional description: Influenza like illness		
subjects affected / exposed	0 / 47 (0.00%)	0 / 35 (0.00%)	2 / 36 (5.56%)
occurrences (all)	0	0	2
Oedema peripheral			
subjects affected / exposed	0 / 47 (0.00%)	0 / 35 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 47 (0.00%)	1 / 35 (2.86%)	2 / 36 (5.56%)
occurrences (all)	0	1	2

Swelling face subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0	1 / 35 (2.86%) 1	0 / 36 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0	0 / 35 (0.00%) 0	0 / 36 (0.00%) 0
Rhinorrhoea subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0	0 / 35 (0.00%) 0	0 / 36 (0.00%) 0
Psychiatric disorders Anxiety subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0	0 / 35 (0.00%) 0	1 / 36 (2.78%) 1
Irritable mood	Additional description: Irritability		
subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0	0 / 35 (0.00%) 0	0 / 36 (0.00%) 0
Investigations Blood creatine phosphokinase increased subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0	0 / 35 (0.00%) 0	1 / 36 (2.78%) 1
Blood urine present subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0	0 / 35 (0.00%) 0	0 / 36 (0.00%) 0
Urine protein, quantitative	Additional description: Protein urine present		
subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0	0 / 35 (0.00%) 0	0 / 36 (0.00%) 0
Nervous system disorders Headache subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0	0 / 35 (0.00%) 0	0 / 36 (0.00%) 0
Sciatica subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0	0 / 35 (0.00%) 0	0 / 36 (0.00%) 0
Blood and lymphatic system disorders			

Anaemia subjects affected / exposed occurrences (all)	4 / 47 (8.51%) 4	1 / 35 (2.86%) 1	0 / 36 (0.00%) 0
Ear and labyrinth disorders Hearing loss unilateral subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0	0 / 35 (0.00%) 0	0 / 36 (0.00%) 0
Eye disorders Visual field tests abnormal subjects affected / exposed occurrences (all)	Additional description: Visual impairment		
	0 / 47 (0.00%) 0	0 / 35 (0.00%) 0	0 / 36 (0.00%) 0
Gastrointestinal disorders Abdominal pain subjects affected / exposed occurrences (all)	2 / 47 (4.26%) 2	0 / 35 (0.00%) 0	1 / 36 (2.78%) 1
Anal exam abnormal subjects affected / exposed occurrences (all)	Additional description: Anal fissure		
	0 / 47 (0.00%) 0	0 / 35 (0.00%) 0	2 / 36 (5.56%) 2
Ulcerative colitis subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0	4 / 35 (11.43%) 5	5 / 36 (13.89%) 6
Diarrhoea subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0	1 / 35 (2.86%) 1	2 / 36 (5.56%) 3
Nausea subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0	0 / 35 (0.00%) 0	0 / 36 (0.00%) 0
Flatulence subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0	0 / 35 (0.00%) 0	1 / 36 (2.78%) 1
Dyspepsia subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0	0 / 35 (0.00%) 0	1 / 36 (2.78%) 2
Skin and subcutaneous tissue disorders Acne subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0	1 / 35 (2.86%) 1	0 / 36 (0.00%) 0



Alopecia			
subjects affected / exposed	0 / 47 (0.00%)	1 / 35 (2.86%)	1 / 36 (2.78%)
occurrences (all)	0	1	1
Dermatitis atopic			
subjects affected / exposed	0 / 47 (0.00%)	0 / 35 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 47 (0.00%)	1 / 35 (2.86%)	0 / 36 (0.00%)
occurrences (all)	0	2	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 47 (2.13%)	2 / 35 (5.71%)	1 / 36 (2.78%)
occurrences (all)	1	3	1
Arthritis			
subjects affected / exposed	0 / 47 (0.00%)	0 / 35 (0.00%)	1 / 36 (2.78%)
occurrences (all)	0	0	1
Contracture of palmar fascia	Additional description: Dupuytren's contracture		
subjects affected / exposed	0 / 47 (0.00%)	0 / 35 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	0 / 47 (0.00%)	0 / 35 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Pain	Additional description: Pain in extremity		
subjects affected / exposed	0 / 47 (0.00%)	0 / 35 (0.00%)	1 / 36 (2.78%)
occurrences (all)	0	0	1
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	3 / 47 (6.38%)	1 / 35 (2.86%)	1 / 36 (2.78%)
occurrences (all)	3	1	1
COVID-19			
subjects affected / exposed	0 / 47 (0.00%)	0 / 35 (0.00%)	1 / 36 (2.78%)
occurrences (all)	0	0	1
Conjunctivitis			
subjects affected / exposed	0 / 47 (0.00%)	0 / 35 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			

subjects affected / exposed	0 / 47 (0.00%)	0 / 35 (0.00%)	3 / 36 (8.33%)
occurrences (all)	0	0	3
Influenza			
subjects affected / exposed	0 / 47 (0.00%)	0 / 35 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 47 (0.00%)	0 / 35 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hypermatraemia			
subjects affected / exposed	0 / 47 (0.00%)	0 / 35 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0

<b>Non-serious adverse events</b>	PF-06651600 20 mg -> PF-06651600 50 mg	Placebo -> PF-06651600 50 mg	PF-06700841 60 mg -> PF-06700841 30 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	11 / 39 (28.21%)	8 / 10 (80.00%)	15 / 38 (39.47%)
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 39 (0.00%)	2 / 10 (20.00%)	0 / 38 (0.00%)
occurrences (all)	0	2	0
General disorders and administration site conditions			
Feeling hot			
subjects affected / exposed	0 / 39 (0.00%)	1 / 10 (10.00%)	0 / 38 (0.00%)
occurrences (all)	0	2	0
Feeling bad	Additional description: Influenza like illness		
subjects affected / exposed	0 / 39 (0.00%)	0 / 10 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 39 (0.00%)	1 / 10 (10.00%)	0 / 38 (0.00%)
occurrences (all)	0	2	0
Pyrexia			
subjects affected / exposed	1 / 39 (2.56%)	1 / 10 (10.00%)	1 / 38 (2.63%)
occurrences (all)	1	1	1
Swelling face			
subjects affected / exposed	0 / 39 (0.00%)	1 / 10 (10.00%)	0 / 38 (0.00%)
occurrences (all)	0	1	0

Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 39 (0.00%)	0 / 10 (0.00%)	2 / 38 (5.26%)
occurrences (all)	0	0	2
Rhinorrhoea			
subjects affected / exposed	0 / 39 (0.00%)	0 / 10 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 39 (0.00%)	0 / 10 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Irritable mood	Additional description: Irritability		
subjects affected / exposed	0 / 39 (0.00%)	0 / 10 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 39 (2.56%)	0 / 10 (0.00%)	1 / 38 (2.63%)
occurrences (all)	1	0	1
Blood urine present			
subjects affected / exposed	0 / 39 (0.00%)	0 / 10 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Urine protein, quantitative	Additional description: Protein urine present		
subjects affected / exposed	0 / 39 (0.00%)	0 / 10 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 39 (0.00%)	2 / 10 (20.00%)	1 / 38 (2.63%)
occurrences (all)	0	7	1
Sciatica			
subjects affected / exposed	0 / 39 (0.00%)	0 / 10 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 39 (0.00%)	1 / 10 (10.00%)	1 / 38 (2.63%)
occurrences (all)	0	1	1
Ear and labyrinth disorders			

Hearing loss unilateral subjects affected / exposed occurrences (all)	1 / 39 (2.56%) 2	2 / 10 (20.00%) 2	0 / 38 (0.00%) 0
Eye disorders	Additional description: Visual impairment		
Visual field tests abnormal subjects affected / exposed occurrences (all)	0 / 39 (0.00%) 0	1 / 10 (10.00%) 1	0 / 38 (0.00%) 0
Gastrointestinal disorders	Additional description: Anal fissure		
Abdominal pain subjects affected / exposed occurrences (all)	1 / 39 (2.56%) 1	0 / 10 (0.00%) 0	1 / 38 (2.63%) 1
Anal exam abnormal subjects affected / exposed occurrences (all)	0 / 39 (0.00%) 0	0 / 10 (0.00%) 0	0 / 38 (0.00%) 0
Ulcerative colitis subjects affected / exposed occurrences (all)	4 / 39 (10.26%) 4	3 / 10 (30.00%) 3	2 / 38 (5.26%) 2
Diarrhoea subjects affected / exposed occurrences (all)	0 / 39 (0.00%) 0	2 / 10 (20.00%) 2	1 / 38 (2.63%) 1
Nausea subjects affected / exposed occurrences (all)	0 / 39 (0.00%) 0	0 / 10 (0.00%) 0	1 / 38 (2.63%) 1
Flatulence subjects affected / exposed occurrences (all)	2 / 39 (5.13%) 2	0 / 10 (0.00%) 0	0 / 38 (0.00%) 0
Dyspepsia subjects affected / exposed occurrences (all)	0 / 39 (0.00%) 0	1 / 10 (10.00%) 1	0 / 38 (0.00%) 0
Skin and subcutaneous tissue disorders			
Acne subjects affected / exposed occurrences (all)	0 / 39 (0.00%) 0	1 / 10 (10.00%) 1	2 / 38 (5.26%) 2
Alopecia subjects affected / exposed occurrences (all)	1 / 39 (2.56%) 1	1 / 10 (10.00%) 1	0 / 38 (0.00%) 0
Dermatitis atopic			

subjects affected / exposed	0 / 39 (0.00%)	1 / 10 (10.00%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Rash			
subjects affected / exposed	1 / 39 (2.56%)	1 / 10 (10.00%)	0 / 38 (0.00%)
occurrences (all)	1	1	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 39 (0.00%)	1 / 10 (10.00%)	2 / 38 (5.26%)
occurrences (all)	0	1	2
Arthritis			
subjects affected / exposed	0 / 39 (0.00%)	1 / 10 (10.00%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Contracture of palmar fascia	Additional description: Dupuytren's contracture		
subjects affected / exposed	0 / 39 (0.00%)	1 / 10 (10.00%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Osteoarthritis			
subjects affected / exposed	0 / 39 (0.00%)	2 / 10 (20.00%)	0 / 38 (0.00%)
occurrences (all)	0	2	0
Pain	Additional description: Pain in extremity		
subjects affected / exposed	0 / 39 (0.00%)	1 / 10 (10.00%)	1 / 38 (2.63%)
occurrences (all)	0	2	1
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 10 (0.00%)	4 / 38 (10.53%)
occurrences (all)	0	0	5
COVID-19			
subjects affected / exposed	2 / 39 (5.13%)	0 / 10 (0.00%)	1 / 38 (2.63%)
occurrences (all)	2	0	1
Conjunctivitis			
subjects affected / exposed	0 / 39 (0.00%)	1 / 10 (10.00%)	1 / 38 (2.63%)
occurrences (all)	0	1	1
Herpes zoster			
subjects affected / exposed	0 / 39 (0.00%)	0 / 10 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Influenza			

subjects affected / exposed	2 / 39 (5.13%)	0 / 10 (0.00%)	0 / 38 (0.00%)
occurrences (all)	2	0	0
Urinary tract infection			
subjects affected / exposed	0 / 39 (0.00%)	1 / 10 (10.00%)	2 / 38 (5.26%)
occurrences (all)	0	1	2
Metabolism and nutrition disorders			
Hypermatraemia			
subjects affected / exposed	0 / 39 (0.00%)	1 / 10 (10.00%)	0 / 38 (0.00%)
occurrences (all)	0	1	0

<b>Non-serious adverse events</b>	PF-06700841 30 mg -> PF-06700841 30 mg	PF-06700841 10 mg -> PF-06700841 30 mg	Placebo -> PF-06700841 30 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	15 / 37 (40.54%)	20 / 39 (51.28%)	4 / 9 (44.44%)
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 37 (2.70%)	2 / 39 (5.13%)	0 / 9 (0.00%)
occurrences (all)	1	2	0
General disorders and administration site conditions			
Feeling hot			
subjects affected / exposed	0 / 37 (0.00%)	0 / 39 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Feeling bad	Additional description: Influenza like illness		
subjects affected / exposed	0 / 37 (0.00%)	0 / 39 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	1 / 37 (2.70%)	0 / 39 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Pyrexia			
subjects affected / exposed	0 / 37 (0.00%)	2 / 39 (5.13%)	1 / 9 (11.11%)
occurrences (all)	0	2	1
Swelling face			
subjects affected / exposed	0 / 37 (0.00%)	0 / 39 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			

Cough			
subjects affected / exposed	0 / 37 (0.00%)	0 / 39 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 37 (0.00%)	0 / 39 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 37 (0.00%)	0 / 39 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Irritable mood	Additional description: Irritability		
subjects affected / exposed	0 / 37 (0.00%)	0 / 39 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	3 / 37 (8.11%)	3 / 39 (7.69%)	0 / 9 (0.00%)
occurrences (all)	3	4	0
Blood urine present			
subjects affected / exposed	0 / 37 (0.00%)	2 / 39 (5.13%)	0 / 9 (0.00%)
occurrences (all)	0	2	0
Urine protein, quantitative	Additional description: Protein urine present		
subjects affected / exposed	0 / 37 (0.00%)	2 / 39 (5.13%)	0 / 9 (0.00%)
occurrences (all)	0	2	0
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 37 (2.70%)	2 / 39 (5.13%)	0 / 9 (0.00%)
occurrences (all)	1	2	0
Sciatica			
subjects affected / exposed	0 / 37 (0.00%)	0 / 39 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 37 (0.00%)	2 / 39 (5.13%)	1 / 9 (11.11%)
occurrences (all)	0	2	1
Ear and labyrinth disorders			

Hearing loss unilateral subjects affected / exposed occurrences (all)	0 / 37 (0.00%) 0	0 / 39 (0.00%) 0	0 / 9 (0.00%) 0
Eye disorders	Additional description: Visual impairment		
Visual field tests abnormal subjects affected / exposed occurrences (all)	0 / 37 (0.00%) 0	0 / 39 (0.00%) 0	0 / 9 (0.00%) 0
Gastrointestinal disorders	Additional description: Anal fissure		
Abdominal pain subjects affected / exposed occurrences (all)	1 / 37 (2.70%) 2	2 / 39 (5.13%) 2	0 / 9 (0.00%) 0
Anal exam abnormal subjects affected / exposed occurrences (all)	0 / 37 (0.00%) 0	0 / 39 (0.00%) 0	0 / 9 (0.00%) 0
Ulcerative colitis subjects affected / exposed occurrences (all)	2 / 37 (5.41%) 2	6 / 39 (15.38%) 6	1 / 9 (11.11%) 1
Diarrhoea subjects affected / exposed occurrences (all)	2 / 37 (5.41%) 2	0 / 39 (0.00%) 0	0 / 9 (0.00%) 0
Nausea subjects affected / exposed occurrences (all)	2 / 37 (5.41%) 2	0 / 39 (0.00%) 0	0 / 9 (0.00%) 0
Flatulence subjects affected / exposed occurrences (all)	0 / 37 (0.00%) 0	0 / 39 (0.00%) 0	0 / 9 (0.00%) 0
Dyspepsia subjects affected / exposed occurrences (all)	0 / 37 (0.00%) 0	1 / 39 (2.56%) 1	0 / 9 (0.00%) 0
Skin and subcutaneous tissue disorders			
Acne subjects affected / exposed occurrences (all)	0 / 37 (0.00%) 0	1 / 39 (2.56%) 1	0 / 9 (0.00%) 0
Alopecia subjects affected / exposed occurrences (all)	1 / 37 (2.70%) 1	0 / 39 (0.00%) 0	0 / 9 (0.00%) 0
Dermatitis atopic			



subjects affected / exposed occurrences (all)	0 / 37 (0.00%) 0	0 / 39 (0.00%) 0	0 / 9 (0.00%) 0
Rash subjects affected / exposed occurrences (all)	0 / 37 (0.00%) 0	0 / 39 (0.00%) 0	0 / 9 (0.00%) 0
Musculoskeletal and connective tissue disorders			
Arthralgia subjects affected / exposed occurrences (all)	1 / 37 (2.70%) 1	4 / 39 (10.26%) 5	0 / 9 (0.00%) 0
Arthritis subjects affected / exposed occurrences (all)	0 / 37 (0.00%) 0	0 / 39 (0.00%) 0	0 / 9 (0.00%) 0
Contracture of palmar fascia subjects affected / exposed occurrences (all)	Additional description: Dupuytren's contracture		
	0 / 37 (0.00%) 0	0 / 39 (0.00%) 0	0 / 9 (0.00%) 0
Osteoarthritis subjects affected / exposed occurrences (all)	0 / 37 (0.00%) 0	1 / 39 (2.56%) 1	0 / 9 (0.00%) 0
Pain subjects affected / exposed occurrences (all)	Additional description: Pain in extremity		
	0 / 37 (0.00%) 0	0 / 39 (0.00%) 0	0 / 9 (0.00%) 0
Infections and infestations			
Nasopharyngitis subjects affected / exposed occurrences (all)	5 / 37 (13.51%) 7	2 / 39 (5.13%) 3	1 / 9 (11.11%) 2
COVID-19 subjects affected / exposed occurrences (all)	0 / 37 (0.00%) 0	2 / 39 (5.13%) 2	0 / 9 (0.00%) 0
Conjunctivitis subjects affected / exposed occurrences (all)	0 / 37 (0.00%) 0	0 / 39 (0.00%) 0	0 / 9 (0.00%) 0
Herpes zoster subjects affected / exposed occurrences (all)	0 / 37 (0.00%) 0	1 / 39 (2.56%) 1	0 / 9 (0.00%) 0
Influenza			

subjects affected / exposed	1 / 37 (2.70%)	0 / 39 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Urinary tract infection			
subjects affected / exposed	0 / 37 (0.00%)	1 / 39 (2.56%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
Hypermatraemia			
subjects affected / exposed	0 / 37 (0.00%)	0 / 39 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

<b>Non-serious adverse events</b>	Pooling Placebo During Chronic		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	15 / 37 (40.54%)		
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 37 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Feeling hot			
subjects affected / exposed	0 / 37 (0.00%)		
occurrences (all)	0		
Feeling bad	Additional description: Influenza like illness		
subjects affected / exposed	0 / 37 (0.00%)		
occurrences (all)	0		
Oedema peripheral			
subjects affected / exposed	0 / 37 (0.00%)		
occurrences (all)	0		
Pyrexia			
subjects affected / exposed	1 / 37 (2.70%)		
occurrences (all)	1		
Swelling face			
subjects affected / exposed	0 / 37 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
Cough			

subjects affected / exposed	0 / 37 (0.00%)		
occurrences (all)	0		
Rhinorrhoea			
subjects affected / exposed	0 / 37 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 37 (0.00%)		
occurrences (all)	0		
Irritable mood	Additional description: Irritability		
subjects affected / exposed	0 / 37 (0.00%)		
occurrences (all)	0		
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 37 (0.00%)		
occurrences (all)	0		
Blood urine present			
subjects affected / exposed	0 / 37 (0.00%)		
occurrences (all)	0		
Urine protein, quantitative	Additional description: Protein urine present		
subjects affected / exposed	0 / 37 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 37 (2.70%)		
occurrences (all)	1		
Sciatica			
subjects affected / exposed	0 / 37 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 37 (5.41%)		
occurrences (all)	2		
Ear and labyrinth disorders			
Hearing loss unilateral			

subjects affected / exposed occurrences (all)	0 / 37 (0.00%) 0		
Eye disorders			
Visual field tests abnormal	Additional description: Visual impairment		
subjects affected / exposed occurrences (all)	0 / 37 (0.00%) 0		
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed occurrences (all)	1 / 37 (2.70%) 1		
Anal exam abnormal	Additional description: Anal fissure		
subjects affected / exposed occurrences (all)	0 / 37 (0.00%) 0		
Ulcerative colitis			
subjects affected / exposed occurrences (all)	8 / 37 (21.62%) 8		
Diarrhoea			
subjects affected / exposed occurrences (all)	0 / 37 (0.00%) 0		
Nausea			
subjects affected / exposed occurrences (all)	0 / 37 (0.00%) 0		
Flatulence			
subjects affected / exposed occurrences (all)	0 / 37 (0.00%) 0		
Dyspepsia			
subjects affected / exposed occurrences (all)	0 / 37 (0.00%) 0		
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed occurrences (all)	0 / 37 (0.00%) 0		
Alopecia			
subjects affected / exposed occurrences (all)	0 / 37 (0.00%) 0		
Dermatitis atopic			

subjects affected / exposed	0 / 37 (0.00%)		
occurrences (all)	0		
Rash			
subjects affected / exposed	0 / 37 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 37 (2.70%)		
occurrences (all)	1		
Arthritis			
subjects affected / exposed	0 / 37 (0.00%)		
occurrences (all)	0		
Contracture of palmar fascia	Additional description: Dupuytren's contracture		
subjects affected / exposed	0 / 37 (0.00%)		
occurrences (all)	0		
Osteoarthritis			
subjects affected / exposed	0 / 37 (0.00%)		
occurrences (all)	0		
Pain	Additional description: Pain in extremity		
subjects affected / exposed	0 / 37 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	4 / 37 (10.81%)		
occurrences (all)	5		
COVID-19			
subjects affected / exposed	0 / 37 (0.00%)		
occurrences (all)	0		
Conjunctivitis			
subjects affected / exposed	0 / 37 (0.00%)		
occurrences (all)	0		
Herpes zoster			
subjects affected / exposed	0 / 37 (0.00%)		
occurrences (all)	0		
Influenza			

subjects affected / exposed	1 / 37 (2.70%)		
occurrences (all)	1		
Urinary tract infection			
subjects affected / exposed	2 / 37 (5.41%)		
occurrences (all)	2		
Metabolism and nutrition disorders			
Hypermatraemia			
subjects affected / exposed	0 / 37 (0.00%)		
occurrences (all)	0		

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
27 October 2016	<p>In the Schedule of Activities, Section 6 Study Procedures, and Section 7.2.12 Audiogram, added audiogram assessments at regular intervals. In the Schedule of Activities and Section 6 Study Procedures, added Serum Cystatin C (and eGFR) at all time points. In the Schedule of Activities, Section 6.5 Guidelines for Monitoring and Discontinuations, Section 7.2.2 Creatinine and Cystatin C, and Section 8.4.3 Potential Cases of Decreased eGFR, removed statement that a creatinine increase above the ULN will trigger a reflex test for serum cystatin-C in order to facilitate both serum cystatin-C based, and serum creatinine based eGFR calculation. Section 7.2.2 Creatinine and Cystatin C, clarified that creatinine elevations above the ULN will be followed until resolution or baseline. In the Schedule of Activities and Section 6 Study Procedures, added that the screening urinalysis will include a spot urine albumin/creatinine ratio. In the Schedule of Activities, Section 5.3, Subject Compliance, Section 5.5, Administration, and Section 6, Study Procedures, removed reference to subject dosing diary. In the Schedule of Activities, Section 2, Study Objectives and Endpoints, Section 6 Study Procedures, and Section 7.3.5 Ulcerative Colitis Endoscopic Index of Severity, added UCEIS evaluation at same time points as Mayo score. Changes were made in Section 4.1, 4.2 to provide updates in inclusion and exclusion criterion. Section 5.8.1, Oral Corticosteroids, removed requirement for subject to record oral corticosteroids on a daily diary. Section 6.5, Guidelines for Monitoring and Discontinuations, added that treatment with investigational product will be discontinued and subject withdrawn from the study if there is an AST or ALT elevation <math>\geq 3</math> times the upper limit of normal with an INR <math>&gt; 1.5</math>.</p>
14 March 2017	<p>Changes were made in Section 4.1, 4.2 to provide updates in inclusion and exclusion criterion. Section 5.2, Breaking the Blind is revised to state that discussion with a member of the study team in advance of unblinding is not required. Section 5.8.3, Prohibited Medications revised to prohibit any live (attenuated) vaccines from 30 days prior to baseline and through the end of study (Week 36). Section 5.8.4, Vaccinations is added. Section 6.5, Guidelines for Monitoring and Discontinuations revised to state that an absolute neutrophil count <math>&lt; 1.0 \times 10^9/L</math> (<math>&lt; 1000/mm^3</math>) or platelet count <math>&lt; 75 \times 10^9/L</math> (<math>&lt; 75,000/mm^3</math>) or lymphocyte count <math>&lt; 500/mm^3</math> (<math>&lt; 0.5 \times 10^9/L</math>) must be repeated as soon as feasible and within 3 days. Section 6.5, Guidelines for Monitoring and Discontinuations, added criteria to state that subjects who are inadequately responding to investigational product in the opinion of the investigator should be withdrawn from the study. Section 7.2.13, Electrocardiogram revised to include a statement defining QTc prolongations. Section 9.5, Interim Analysis is revised to incorporate futility stopping guidelines and remove reference to re-estimation of sample size.</p>
05 April 2017	<p>Changes were made in Section 1.2.1 to provide clarification for Non-Clinical Pharmacokinetics and Metabolism of PF-06651600. Changes were made in Section 4.1 and 4.2 to provide clarification and update for inclusion and exclusion criterion. Section 5.5, Administration, revised to note that for study visit days (ie, baseline, Weeks 2, 4, 8, 12, 16, 20, and 24), to highlight that on visits where dosing is at the clinic, subjects are to take the dose at the clinic and from their current blister card or bottle. Section 6.1, Screening, Section 6.2.1, Baseline/(Week 0, Day 1), Section 7.3.1, Endoscopy and Schedule of Activities footnote w, revised to clarify that the stool frequency, rectal bleeding and centrally read endoscopy subscores from the screening endoscopy and the PGA obtained at baseline are used to determine eligibility. Section 7.4.6, Stool Samples for Microbiome Analysis revised to indicate sequencing of DNA present in the stool will be performed to better understand disease activity and response to therapy. During this process some human DNA may be inadvertently sequenced, but will not be used for the final microbiome analysis. Appendix 8, France Appendix added to capture operational items not included in the mandatory contract format for France (ie, French "Contrat Unique"). Administrative changes and sentence revisions made throughout the document.</p>

06 March 2018	Changes were made in Section 4.2 Exclusion Criterion to provide clarification, consistency within protocol and remove redundancy. Section 7.2.12 Audiogram Testing: Clarification was provided that results of the audiogram test must be available by the time of the following clinic visit. Gene expression analysis was moved from Section 7.6.1 to Section 7.4.7 of the protocol. Several additional minor editorial changes were made to protocol language for the purposes of improving clarity and readability and for maintaining consistency throughout the document.
16 August 2018	Changes were made in Background and rationale to align with Investigator Brochure. In Protocol Summary, Schedule of Activities (SoA), Section 1 Introduction, Section 2 Study Objectives and Endpoints, Section 3 Study Design, Section 6 Study Procedures, and Section 9 Data Analysis/Statistical Methods, placebo treatment has been removed from the chronic dosing period. Various changes were made to SoA footnote to provide clarification of specific examinations.
17 September 2020	Changes were made in protocol summary, Schedule of Activities, Section 6.1, Section 7 and Section 7.3.6 To provide guidance on study conduct during public emergencies including COVID-19. Schedule of Activities Footnote "d" and Section 7.2.11 updated to clarify that breast and external genitalia examination as a part of physical exam is optional, but skin examination should include a visual examination of the breast and external genitalia to assess rashes. Changes were made in Section 1.3, 1.4, 4.3.1 to align with Investigator Brochure. Section 2: Objectives and Endpoints listed separately for the Induction and Chronic dosing periods. Safety Endpoints for Induction and Chronic dosing periods updated to include laboratory abnormalities, vital signs and 12-lead ECG. Section 4.1 Inclusion criteria #6, Section 5.8.2 and Appendix 1: Updated to reference Steroid conversion table in Appendix 9. Section 4.2: Exclusion criterion #14 updated to exclude re-testing of a positive IGRA test even though protocol states that all screening labs with abnormal results may be repeated within the screening window to confirm abnormal results. Section 5.4.2: Updated to include reference to Appendix 10 on alternative measures during public emergencies. Section 6.5 (Guidelines for Monitoring and Discontinuations): Added Lymphocytes <800/mm <sup>3</sup> ; <0.8 x 10 <sup>9</sup> /L and CK >3x ULN as additional labs to monitor. Section 7.2.6 updated to allow central lab to replace QuantiFERON®-TB Gold test (QFT-G), QuantiFERON®-TB Gold In-Tube test (QFT-GIT) and T-SPOT® TB test with other acceptable QFT tests. Section 7.2.12 updated to indicate that audiogram results may be reviewed by an external audiologist. Section 7.3.1: updated to indicate that a Colonoscopy should not be performed at the Early Termination (ET) visit if the previous colonoscopy was less than 8 weeks prior to this.
18 November 2020	Changes were made in protocol summary, Sections 1.3.2, 1.4.1, 1.4.2, 2.1- 2.2, 3.1, 4.2, 6.5, 7.3.3, 7.3.4, 9.1, 9.2.1 and 9.2.3 with the rationale of clarity and to correct grammatical errors and typographical errors, to align with the updated Investigator Brochure, and regulatory request.

Notes:

## Interruptions (globally)

Were there any global interruptions to the trial? No

## Limitations and caveats

None reported