



Clinical trial results:

A Phase 2, Randomized, Double Blind, Placebo-Controlled, Study to Evaluate the Safety and Efficacy of PF-06826647 in Participants With Moderate to Severe Plaque Psoriasis

Summary

EudraCT number	2018-004669-16
Trial protocol	PL
Global end of trial date	26 November 2020

Results information

Result version number	v1 (current)
This version publication date	22 May 2021
First version publication date	22 May 2021

Trial information

Trial identification

Sponsor protocol code	C2501004
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03895372
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	16 April 2021
Is this the analysis of the primary	No

completion data?	
Global end of trial reached?	Yes
Global end of trial date	26 November 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

This study was conducted to provide data on efficacy, safety, tolerability, and pharmacokinetics of PF-06826647 in the oral treatment of moderate to severe plaque psoriasis.

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	27 June 2019
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	Canada: 19
Country: Number of subjects enrolled	Japan: 13
Country: Number of subjects enrolled	United States: 47
Country: Number of subjects enrolled	Poland: 99
Worldwide total number of subjects	178
EEA total number of subjects	99

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	166
From 65 to 84 years	12
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

This study included 2 treatment periods (16-week investigational treatment period and 24-week extension treatment period) followed by a 4-week follow-up. A total of 179 subjects were enrolled and 178 subjects were treated in investigational treatment period and 153 subjects completed this period and entered the extension treatment period.

Pre-assignment

Screening details:

This was a Phase 2b, randomized, double blind, placebo-controlled, parallel group, and multicenter study in subjects with moderate to severe plaque psoriasis.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo QD->PF-06826647 200 mg QD Group

Arm description:

This study included 2 treatment periods: 16-week investigational treatment period and 24-week extension treatment period. The enrolled subjects entered the investigational treatment period first and then the subjects who completed the investigational treatment period entered the extension treatment period. The subjects in this group received matching placebo (2*25 mg size placebo and 4*100 mg size placebo) once a day (QD) in the investigational treatment period (16 weeks) and PF-06826647 200 mg QD in the extension treatment period (24 weeks). The maximum duration of treatment was 116 days in investigational treatment period and 187 days in extension treatment period.

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

Dosage and administration details:

6 tablets (2 × 25 mg size placebo and 4 × 100 mg size placebo) per day.

Arm title	Placebo QD->PF-06826647 400 mg QD Group
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Arm description:

This study included 2 treatment periods: 16-week investigational treatment period and 24-week extension treatment period. The enrolled subjects entered the investigational treatment period first and then the subjects who completed the investigational treatment period entered the extension treatment period. The subjects in this group received matching placebo (2*25 mg size placebo and 4*100 mg size placebo) once a day (QD) in the investigational treatment period (16 weeks) and PF-06826647 400 mg QD in the extension treatment period (24 weeks). The maximum duration of treatment was 116 days in investigational treatment period and 176 days in extension treatment period.

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

Dosage and administration details:

6 tablets (2 × 25 mg size placebo and 4 × 100 mg size placebo) per day.

Arm title	PF-06826647 50 mg QD->PF-06826647 200 mg QD Group
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Arm description:

This study included 2 treatment periods: 16-week investigational treatment period and 24-week extension treatment period. The enrolled subjects entered the investigational treatment period first and then the subjects who completed the investigational treatment period entered the extension treatment period. The subjects in this group received PF-06826647 50 mg once a day (QD) in the investigational treatment period (16 weeks) and PF-06826647 200 mg QD in the extension treatment period (24 weeks). The maximum duration of treatment was 119 days in investigational treatment period and 182 days in extension treatment period.

Arm type	Experimental
Investigational medicinal product name	PF-06826647
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

2 tablets (2 × 25 mg PF-06826647) per day.

Investigational medicinal product name	Placebo oval tablet
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

4 tablets (4 × 100 mg size placebo) per day.

Arm title	PF-06826647 50 mg QD->PF-06826647 400 mg QD Group
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Arm description:

This study includes 2 treatment periods: 16-week investigational treatment period and 24-week extension treatment period. The enrolled subjects entered the investigational treatment period first and then the subjects who completed the investigational treatment period entered the extension treatment period. The subjects in this group received PF-06826647 50 mg once a day (QD) in the investigational treatment period (16 weeks) and PF-06826647 400 mg QD in the extension treatment period (24 weeks). The maximum duration of treatment was 119 days in investigational treatment period and 183 days in extension treatment period.

Arm type	Experimental
Investigational medicinal product name	PF-06826647
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

2 tablets (2 × 25 mg PF-06826647) per day.

Investigational medicinal product name	Placebo oval tablet
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

4 tablets (4 × 100 mg size placebo) per day.

Arm title	PF-06826647 100 mg QD->PF-06826647 200 mg QD Group
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Arm description:

This study included 2 treatment periods: 16-week investigational treatment period and 24-week extension treatment period. The enrolled subjects entered the investigational treatment period first and then the subjects who completed the investigational treatment period entered the extension treatment period. The subjects in this group received PF-06826647 100 mg once a day (QD) in the investigational treatment period (16 weeks) and PF-06826647 200 mg QD in the extension treatment period (24 weeks). The maximum duration of treatment was 115 days in investigational treatment period and 171 days in extension treatment period.

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

Dosage and administration details:

5 tablets (2 × 25 mg size placebo and 3 × 100 mg size placebo) per day.

Investigational medicinal product name	PF-06826647
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

1 tablet (1 × 100 mg PF-06826647) per day.

Arm title	PF-06826647 100 mg QD->PF-06826647 400 mg QD Group
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Arm description:

This study included 2 treatment periods: 16-week investigational treatment period and 24-week extension treatment period. The enrolled subjects entered the investigational treatment period first and then the subjects who completed the investigational treatment period entered the extension treatment period. The subjects in this group received PF-06826647 100 mg once a day (QD) in the investigational treatment period (16 weeks) and PF-06826647 400 mg QD in the extension treatment period (24 weeks). The maximum duration of treatment was 115 days in investigational treatment period and 174 days in extension treatment period.

Arm type	Experimental
Investigational medicinal product name	PF-06826647
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

1 tablet (1 × 100 mg PF-06826647) per day.

Investigational medicinal product name	Placebo oval tablet
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

5 tablets (2 × 25 mg size placebo and 3 × 100 mg size placebo) per day.

Arm title	PF-06826647 200 mg QD->PF-06826647 200 mg QD Group
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Arm description:

This study included 2 treatment periods: 16-week investigational treatment period and 24-week extension treatment period. The enrolled subjects entered the investigational treatment period first and then the subjects who completed the investigational treatment period entered the extension treatment period. The subjects in this group received PF-06826647 200 mg once a day (QD) in the investigational treatment period (16 weeks) and PF-06826647 200 mg QD in the extension treatment period (24 weeks). The maximum duration of treatment was 120 days in investigational treatment period and 186 days in extension treatment period.

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

Dosage and administration details:

4 tablets (2 × 25 mg size placebo and 2 × 100 mg size placebo) per day.

Investigational medicinal product name	PF-06826647
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

2 tablet (2 × 100 mg PF-06826647) per day.

Arm title	PF-06826647 400 mg QD->PF-06826647 400 mg QD Group
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Arm description:

This study included 2 treatment periods: 16-week investigational treatment period and 24-week extension treatment period. The enrolled subjects entered the investigational treatment period first and then the subjects who completed the investigational treatment period entered the extension treatment period. The subjects in this group received PF-06826647 400 mg once a day (QD) in the investigational treatment period (16 weeks) and PF-06826647 400 mg QD in the extension treatment period (24 weeks). The maximum duration of treatment was 119 days in investigational treatment period and 180 days in extension treatment period.

Arm type	Experimental
Investigational medicinal product name	PF-06826647
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

4 tablet (4 × 100 mg PF-06826647) per day.

Investigational medicinal product name	Placebo oval tablet
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

2 tablets (2 × 25 mg size placebo) per day.

Number of subjects in period 1	Placebo QD->PF-06826647 200 mg QD Group	Placebo QD->PF-06826647 400 mg QD Group	PF-06826647 50 mg QD->PF-06826647 200 mg QD Group
Started	23	22	11
Completed	19	19	10
Not completed	4	3	1
Protocol deviation	-	-	-
Lack of efficacy	1	-	-
Adverse event, non-fatal	1	-	-

Unspecified	-	-	-
Consent withdrawn by subject	2	3	1
Lost to follow-up	-	-	-

Number of subjects in period 1	PF-06826647 50 mg QD->PF-06826647 400 mg QD Group	PF-06826647 100 mg QD->PF-06826647 200 mg QD Group	PF-06826647 100 mg QD->PF-06826647 400 mg QD Group
Started	11	12	11
Completed	9	12	9
Not completed	2	0	2
Protocol deviation	1	-	-
Lack of efficacy	-	-	-
Adverse event, non-fatal	-	-	-
Unspecified	-	-	1
Consent withdrawn by subject	1	-	1
Lost to follow-up	-	-	-

Number of subjects in period 1	PF-06826647 200 mg QD->PF-06826647 200 mg QD Group	PF-06826647 400 mg QD->PF-06826647 400 mg QD Group
Started	45	43
Completed	37	38
Not completed	8	5
Protocol deviation	-	-
Lack of efficacy	-	-
Adverse event, non-fatal	4	3
Unspecified	-	2
Consent withdrawn by subject	3	-
Lost to follow-up	1	-

Period 2

Period 2 title	Extension Treatment Period
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
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Arm title	Placebo QD->PF-06826647 200 mg QD Group
Arm description:	
This study included 2 treatment periods: 16-week investigational treatment period and 24-week extension treatment period. The enrolled subjects entered the investigational treatment period first and then the subjects who completed the investigational treatment period entered the extension treatment period. The subjects in this group received matching placebo (2*25 mg size placebo and 4*100 mg size placebo) once a day (QD) in the investigational treatment period (16 weeks) and PF-06826647 200 mg QD in the extension treatment period (24 weeks). The maximum duration of treatment was 116 days in investigational treatment period and 187 days in extension treatment period.	
Arm type	Experimental
Investigational medicinal product name	PF-06826647
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
2 tablets (2 × 100 mg PF-06826647) per day.	
Investigational medicinal product name	Placebo oval tablet
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
2 tablets (2 × 100 mg size placebo) per day.	
Arm title	Placebo QD->PF-06826647 400 mg QD Group
Arm description:	
This study included 2 treatment periods: 16-week investigational treatment period and 24-week extension treatment period. The enrolled subjects entered the investigational treatment period first and then the subjects who completed the investigational treatment period entered the extension treatment period. The subjects in this group received matching placebo (2*25 mg size placebo and 4*100 mg size placebo) once a day (QD) in the investigational treatment period (16 weeks) and PF-06826647 400 mg QD in the extension treatment period (24 weeks). The maximum duration of treatment was 116 days in investigational treatment period and 176 days in extension treatment period.	
Arm type	Experimental
Investigational medicinal product name	PF-06826647
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
4 tablets (4 × 100 mg PF-06826647) per day.	
Arm title	PF-06826647 50 mg QD->PF-06826647 200 mg QD Group
Arm description:	
This study included 2 treatment periods: 16-week investigational treatment period and 24-week extension treatment period. The enrolled subjects entered the investigational treatment period first and then the subjects who completed the investigational treatment period entered the extension treatment period. The subjects in this group received PF-06826647 50 mg once a day (QD) in the investigational treatment period (16 weeks) and PF-06826647 200 mg QD in the extension treatment period (24 weeks). The maximum duration of treatment was 119 days in investigational treatment period and 182 days in extension treatment period.	
Arm type	Experimental

Investigational medicinal product name	Placebo oval tablet
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: 2 tablets (2 × 100 mg size placebo) per day.	
Investigational medicinal product name	PF-06826647
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: 2 tablets (2 × 100 mg PF-06826647) per day.	
Arm title	PF-06826647 50 mg QD->PF-06826647 400 mg QD Group
Arm description: This study includes 2 treatment periods: 16-week investigational treatment period and 24-week extension treatment period. The enrolled subjects entered the investigational treatment period first and then the subjects who completed the investigational treatment period entered the extension treatment period. The subjects in this group received PF-06826647 50 mg once a day (QD) in the investigational treatment period (16 weeks) and PF-06826647 400 mg QD in the extension treatment period (24 weeks). The maximum duration of treatment was 119 days in investigational treatment period and 183 days in extension treatment period.	
Arm type	Experimental
Investigational medicinal product name	PF-06826647
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: 4 tablets (4 × 100 mg PF-06826647) per day.	
Arm title	PF-06826647 100 mg QD->PF-06826647 200 mg QD Group
Arm description: This study included 2 treatment periods: 16-week investigational treatment period and 24-week extension treatment period. The enrolled subjects entered the investigational treatment period first and then the subjects who completed the investigational treatment period entered the extension treatment period. The subjects in this group received PF-06826647 100 mg once a day (QD) in the investigational treatment period (16 weeks) and PF-06826647 200 mg QD in the extension treatment period (24 weeks). The maximum duration of treatment was 115 days in investigational treatment period and 171 days in extension treatment period.	
Arm type	Experimental
Investigational medicinal product name	PF-06826647
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: 2 tablets (2 × 100 mg PF-06826647) per day.	
Investigational medicinal product name	Placebo oval tablet
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	

2 tablets (2 × 100 mg size placebo) per day.

Arm title	PF-06826647 100 mg QD->PF-06826647 400 mg QD Group
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Arm description:

This study included 2 treatment periods: 16-week investigational treatment period and 24-week extension treatment period. The enrolled subjects entered the investigational treatment period first and then the subjects who completed the investigational treatment period entered the extension treatment period. The subjects in this group received PF-06826647 100 mg once a day (QD) in the investigational treatment period (16 weeks) and PF-06826647 400 mg QD in the extension treatment period (24 weeks). The maximum duration of treatment was 115 days in investigational treatment period and 174 days in extension treatment period.

Arm type	Experimental
Investigational medicinal product name	PF-06826647
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

4 tablets (4 × 100 mg PF-06826647) per day.

Arm title	PF-06826647 200 mg QD->PF-06826647 200 mg QD Group
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Arm description:

This study included 2 treatment periods: 16-week investigational treatment period and 24-week extension treatment period. The enrolled subjects entered the investigational treatment period first and then the subjects who completed the investigational treatment period entered the extension treatment period. The subjects in this group received PF-06826647 200 mg once a day (QD) in the investigational treatment period (16 weeks) and PF-06826647 200 mg QD in the extension treatment period (24 weeks). The maximum duration of treatment was 120 days in investigational treatment period and 186 days in extension treatment period.

Arm type	Experimental
Investigational medicinal product name	PF-06826647
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

2 tablets (2 × 100 mg PF-06826647) per day.

Investigational medicinal product name	Placebo oval tablet
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

2 tablets (2 × 100 mg size placebo) per day.

Arm title	PF-06826647 400 mg QD->PF-06826647 400 mg QD Group
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Arm description:

This study included 2 treatment periods: 16-week investigational treatment period and 24-week extension treatment period. The enrolled subjects entered the investigational treatment period first and then the subjects who completed the investigational treatment period entered the extension treatment period. The subjects in this group received PF-06826647 400 mg once a day (QD) in the investigational treatment period (16 weeks) and PF-06826647 400 mg QD in the extension treatment period (24 weeks). The maximum duration of treatment was 119 days in investigational treatment period and 180 days in extension treatment period.

Arm type	Experimental
Investigational medicinal product name	PF-06826647
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

4 tablets (4 × 100 mg PF-06826647) per day.

Number of subjects in period 2	Placebo QD->PF-06826647 200 mg QD Group	Placebo QD->PF-06826647 400 mg QD Group	PF-06826647 50 mg QD->PF-06826647 200 mg QD Group
Started	19	19	10
Completed	16	14	10
Not completed	3	5	0
Pregnancy	-	-	-
Adverse event, non-fatal	-	1	-
Consent withdrawn by subject	2	1	-
Unspecified	1	3	-

Number of subjects in period 2	PF-06826647 50 mg QD->PF-06826647 400 mg QD Group	PF-06826647 100 mg QD->PF-06826647 200 mg QD Group	PF-06826647 100 mg QD->PF-06826647 400 mg QD Group
Started	9	12	9
Completed	8	9	8
Not completed	1	3	1
Pregnancy	-	1	-
Adverse event, non-fatal	1	-	-
Consent withdrawn by subject	-	1	1
Unspecified	-	1	-

Number of subjects in period 2	PF-06826647 200 mg QD->PF-06826647 200 mg QD Group	PF-06826647 400 mg QD->PF-06826647 400 mg QD Group
Started	37	38
Completed	33	32
Not completed	4	6
Pregnancy	-	-
Adverse event, non-fatal	3	3
Consent withdrawn by subject	1	1
Unspecified	-	2

Baseline characteristics

Reporting groups

Reporting group title	Placebo QD->PF-06826647 200 mg QD Group
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Reporting group description:

This study included 2 treatment periods: 16-week investigational treatment period and 24-week extension treatment period. The enrolled subjects entered the investigational treatment period first and then the subjects who completed the investigational treatment period entered the extension treatment period. The subjects in this group received matching placebo (2*25 mg size placebo and 4*100 mg size placebo) once a day (QD) in the investigational treatment period (16 weeks) and PF-06826647 200 mg QD in the extension treatment period (24 weeks). The maximum duration of treatment was 116 days in investigational treatment period and 187 days in extension treatment period.

Reporting group title	Placebo QD->PF-06826647 400 mg QD Group
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Reporting group description:

This study included 2 treatment periods: 16-week investigational treatment period and 24-week extension treatment period. The enrolled subjects entered the investigational treatment period first and then the subjects who completed the investigational treatment period entered the extension treatment period. The subjects in this group received matching placebo (2*25 mg size placebo and 4*100 mg size placebo) once a day (QD) in the investigational treatment period (16 weeks) and PF-06826647 400 mg QD in the extension treatment period (24 weeks). The maximum duration of treatment was 116 days in investigational treatment period and 176 days in extension treatment period.

Reporting group title	PF-06826647 50 mg QD->PF-06826647 200 mg QD Group
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Reporting group description:

This study included 2 treatment periods: 16-week investigational treatment period and 24-week extension treatment period. The enrolled subjects entered the investigational treatment period first and then the subjects who completed the investigational treatment period entered the extension treatment period. The subjects in this group received PF-06826647 50 mg once a day (QD) in the investigational treatment period (16 weeks) and PF-06826647 200 mg QD in the extension treatment period (24 weeks). The maximum duration of treatment was 119 days in investigational treatment period and 182 days in extension treatment period.

Reporting group title	PF-06826647 50 mg QD->PF-06826647 400 mg QD Group
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Reporting group description:

This study includes 2 treatment periods: 16-week investigational treatment period and 24-week extension treatment period. The enrolled subjects entered the investigational treatment period first and then the subjects who completed the investigational treatment period entered the extension treatment period. The subjects in this group received PF-06826647 50 mg once a day (QD) in the investigational treatment period (16 weeks) and PF-06826647 400 mg QD in the extension treatment period (24 weeks). The maximum duration of treatment was 119 days in investigational treatment period and 183 days in extension treatment period.

Reporting group title	PF-06826647 100 mg QD->PF-06826647 200 mg QD Group
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Reporting group description:

This study included 2 treatment periods: 16-week investigational treatment period and 24-week extension treatment period. The enrolled subjects entered the investigational treatment period first and then the subjects who completed the investigational treatment period entered the extension treatment period. The subjects in this group received PF-06826647 100 mg once a day (QD) in the investigational treatment period (16 weeks) and PF-06826647 200 mg QD in the extension treatment period (24 weeks). The maximum duration of treatment was 115 days in investigational treatment period and 171 days in extension treatment period.

Reporting group title	PF-06826647 100 mg QD->PF-06826647 400 mg QD Group
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Reporting group description:

This study included 2 treatment periods: 16-week investigational treatment period and 24-week extension treatment period. The enrolled subjects entered the investigational treatment period first and then the subjects who completed the investigational treatment period entered the extension treatment period. The subjects in this group received PF-06826647 100 mg once a day (QD) in the investigational treatment period (16 weeks) and PF-06826647 400 mg QD in the extension treatment period (24 weeks). The maximum duration of treatment was 115 days in investigational treatment period and 174 days in extension treatment period.

Reporting group title	PF-06826647 200 mg QD->PF-06826647 200 mg QD Group
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Reporting group description:

This study included 2 treatment periods: 16-week investigational treatment period and 24-week extension treatment period. The enrolled subjects entered the investigational treatment period first and

then the subjects who completed the investigational treatment period entered the extension treatment period. The subjects in this group received PF-06826647 200 mg once a day (QD) in the investigational treatment period (16 weeks) and PF-06826647 200 mg QD in the extension treatment period (24 weeks). The maximum duration of treatment was 120 days in investigational treatment period and 186 days in extension treatment period.

Reporting group title	PF-06826647 400 mg QD->PF-06826647 400 mg QD Group
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Reporting group description:

This study included 2 treatment periods: 16-week investigational treatment period and 24-week extension treatment period. The enrolled subjects entered the investigational treatment period first and then the subjects who completed the investigational treatment period entered the extension treatment period. The subjects in this group received PF-06826647 400 mg once a day (QD) in the investigational treatment period (16 weeks) and PF-06826647 400 mg QD in the extension treatment period (24 weeks). The maximum duration of treatment was 119 days in investigational treatment period and 180 days in extension treatment period.

Reporting group values	Placebo QD->PF-06826647 200 mg QD Group	Placebo QD->PF-06826647 400 mg QD Group	PF-06826647 50 mg QD->PF-06826647 200 mg QD Group
Number of subjects	23	22	11
Age Categorical Units: Subjects			
In utero	0	0	0
Gestational age <37 weeks	0	0	0
0-27 days	0	0	0
28 days - 23 months	0	0	0
2-11 years	0	0	0
12-17 years	0	0	0
18-64 years	21	20	11
65-84 years	2	2	0
85 years and over	0	0	0
Age Continuous Units: Years			
median	46.0	45.5	43.0
full range (min-max)	18 to 72	22 to 71	19 to 57
Sex: Female, Male Units: Subjects			
Female	7	8	2
Male	16	14	9
Race/Ethnicity, Customized Units: Subjects			
White	20	19	10
Black or African American	0	1	0
Asian	3	2	1
Native Hawaiian or Other Pacific Islander	0	0	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	1	1	1
Not Hispanic or Latino	22	21	10

Reporting group values	PF-06826647 50 mg QD->PF-06826647 400 mg QD Group	PF-06826647 100 mg QD->PF-06826647 200 mg QD Group	PF-06826647 100 mg QD->PF-06826647 400 mg QD Group
Number of subjects	11	12	11

Age Categorical Units: Subjects			
In utero	0	0	0
Gestational age <37 weeks	0	0	0
0-27 days	0	0	0
28 days - 23 months	0	0	0
2-11 years	0	0	0
12-17 years	0	0	0
18-64 years	9	12	10
65-84 years	2	0	1
85 years and over	0	0	0
Age Continuous Units: Years			
median	49.0	43.5	42.0
full range (min-max)	23 to 68	23 to 57	23 to 65
Sex: Female, Male Units: Subjects			
Female	5	3	4
Male	6	9	7
Race/Ethnicity, Customized Units: Subjects			
White	11	10	11
Black or African American	0	0	0
Asian	0	2	0
Native Hawaiian or Other Pacific Islander	0	0	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	1	0
Not Hispanic or Latino	11	11	11

Reporting group values	PF-06826647 200 mg QD->PF-06826647 200 mg QD Group	PF-06826647 400 mg QD->PF-06826647 400 mg QD Group	Total
Number of subjects	45	43	178
Age Categorical Units: Subjects			
In utero	0	0	0
Gestational age <37 weeks	0	0	0
0-27 days	0	0	0
28 days - 23 months	0	0	0
2-11 years	0	0	0
12-17 years	0	0	0
18-64 years	43	40	166
65-84 years	2	3	12
85 years and over	0	0	0
Age Continuous Units: Years			
median	44.0	45.0	-
full range (min-max)	18 to 67	20 to 70	-

Sex: Female, Male			
Units: Subjects			
Female	19	8	56
Male	26	35	122
Race/Ethnicity, Customized			
Units: Subjects			
White	37	40	158
Black or African American	1	1	3
Asian	6	2	16
Native Hawaiian or Other Pacific Islander	1	0	1
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	1	4	9
Not Hispanic or Latino	44	39	169

End points

End points reporting groups

Reporting group title	Placebo QD->PF-06826647 200 mg QD Group
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Reporting group description:

This study included 2 treatment periods: 16-week investigational treatment period and 24-week extension treatment period. The enrolled subjects entered the investigational treatment period first and then the subjects who completed the investigational treatment period entered the extension treatment period. The subjects in this group received matching placebo (2*25 mg size placebo and 4*100 mg size placebo) once a day (QD) in the investigational treatment period (16 weeks) and PF-06826647 200 mg QD in the extension treatment period (24 weeks). The maximum duration of treatment was 116 days in investigational treatment period and 187 days in extension treatment period.

Reporting group title	Placebo QD->PF-06826647 400 mg QD Group
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Reporting group description:

This study included 2 treatment periods: 16-week investigational treatment period and 24-week extension treatment period. The enrolled subjects entered the investigational treatment period first and then the subjects who completed the investigational treatment period entered the extension treatment period. The subjects in this group received matching placebo (2*25 mg size placebo and 4*100 mg size placebo) once a day (QD) in the investigational treatment period (16 weeks) and PF-06826647 400 mg QD in the extension treatment period (24 weeks). The maximum duration of treatment was 116 days in investigational treatment period and 176 days in extension treatment period.

Reporting group title	PF-06826647 50 mg QD->PF-06826647 200 mg QD Group
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Reporting group description:

This study included 2 treatment periods: 16-week investigational treatment period and 24-week extension treatment period. The enrolled subjects entered the investigational treatment period first and then the subjects who completed the investigational treatment period entered the extension treatment period. The subjects in this group received PF-06826647 50 mg once a day (QD) in the investigational treatment period (16 weeks) and PF-06826647 200 mg QD in the extension treatment period (24 weeks). The maximum duration of treatment was 119 days in investigational treatment period and 182 days in extension treatment period.

Reporting group title	PF-06826647 50 mg QD->PF-06826647 400 mg QD Group
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Reporting group description:

This study includes 2 treatment periods: 16-week investigational treatment period and 24-week extension treatment period. The enrolled subjects entered the investigational treatment period first and then the subjects who completed the investigational treatment period entered the extension treatment period. The subjects in this group received PF-06826647 50 mg once a day (QD) in the investigational treatment period (16 weeks) and PF-06826647 400 mg QD in the extension treatment period (24 weeks). The maximum duration of treatment was 119 days in investigational treatment period and 183 days in extension treatment period.

Reporting group title	PF-06826647 100 mg QD->PF-06826647 200 mg QD Group
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Reporting group description:

This study included 2 treatment periods: 16-week investigational treatment period and 24-week extension treatment period. The enrolled subjects entered the investigational treatment period first and then the subjects who completed the investigational treatment period entered the extension treatment period. The subjects in this group received PF-06826647 100 mg once a day (QD) in the investigational treatment period (16 weeks) and PF-06826647 200 mg QD in the extension treatment period (24 weeks). The maximum duration of treatment was 115 days in investigational treatment period and 171 days in extension treatment period.

Reporting group title	PF-06826647 100 mg QD->PF-06826647 400 mg QD Group
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Reporting group description:

This study included 2 treatment periods: 16-week investigational treatment period and 24-week extension treatment period. The enrolled subjects entered the investigational treatment period first and then the subjects who completed the investigational treatment period entered the extension treatment period. The subjects in this group received PF-06826647 100 mg once a day (QD) in the investigational treatment period (16 weeks) and PF-06826647 400 mg QD in the extension treatment period (24 weeks). The maximum duration of treatment was 115 days in investigational treatment period and 174 days in extension treatment period.

Reporting group title	PF-06826647 200 mg QD->PF-06826647 200 mg QD Group
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Reporting group description:

This study included 2 treatment periods: 16-week investigational treatment period and 24-week extension treatment period. The enrolled subjects entered the investigational treatment period first and

then the subjects who completed the investigational treatment period entered the extension treatment period. The subjects in this group received PF-06826647 200 mg once a day (QD) in the investigational treatment period (16 weeks) and PF-06826647 200 mg QD in the extension treatment period (24 weeks). The maximum duration of treatment was 120 days in investigational treatment period and 186 days in extension treatment period.

Reporting group title	PF-06826647 400 mg QD->PF-06826647 400 mg QD Group
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Reporting group description:

This study included 2 treatment periods: 16-week investigational treatment period and 24-week extension treatment period. The enrolled subjects entered the investigational treatment period first and then the subjects who completed the investigational treatment period entered the extension treatment period. The subjects in this group received PF-06826647 400 mg once a day (QD) in the investigational treatment period (16 weeks) and PF-06826647 400 mg QD in the extension treatment period (24 weeks). The maximum duration of treatment was 119 days in investigational treatment period and 180 days in extension treatment period.

Reporting group title	Placebo QD->PF-06826647 200 mg QD Group
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Reporting group description:

This study included 2 treatment periods: 16-week investigational treatment period and 24-week extension treatment period. The enrolled subjects entered the investigational treatment period first and then the subjects who completed the investigational treatment period entered the extension treatment period. The subjects in this group received matching placebo (2*25 mg size placebo and 4*100 mg size placebo) once a day (QD) in the investigational treatment period (16 weeks) and PF-06826647 200 mg QD in the extension treatment period (24 weeks). The maximum duration of treatment was 116 days in investigational treatment period and 187 days in extension treatment period.

Reporting group title	Placebo QD->PF-06826647 400 mg QD Group
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Reporting group description:

This study included 2 treatment periods: 16-week investigational treatment period and 24-week extension treatment period. The enrolled subjects entered the investigational treatment period first and then the subjects who completed the investigational treatment period entered the extension treatment period. The subjects in this group received matching placebo (2*25 mg size placebo and 4*100 mg size placebo) once a day (QD) in the investigational treatment period (16 weeks) and PF-06826647 400 mg QD in the extension treatment period (24 weeks). The maximum duration of treatment was 116 days in investigational treatment period and 176 days in extension treatment period.

Reporting group title	PF-06826647 50 mg QD->PF-06826647 200 mg QD Group
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Reporting group description:

This study included 2 treatment periods: 16-week investigational treatment period and 24-week extension treatment period. The enrolled subjects entered the investigational treatment period first and then the subjects who completed the investigational treatment period entered the extension treatment period. The subjects in this group received PF-06826647 50 mg once a day (QD) in the investigational treatment period (16 weeks) and PF-06826647 200 mg QD in the extension treatment period (24 weeks). The maximum duration of treatment was 119 days in investigational treatment period and 182 days in extension treatment period.

Reporting group title	PF-06826647 50 mg QD->PF-06826647 400 mg QD Group
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Reporting group description:

This study includes 2 treatment periods: 16-week investigational treatment period and 24-week extension treatment period. The enrolled subjects entered the investigational treatment period first and then the subjects who completed the investigational treatment period entered the extension treatment period. The subjects in this group received PF-06826647 50 mg once a day (QD) in the investigational treatment period (16 weeks) and PF-06826647 400 mg QD in the extension treatment period (24 weeks). The maximum duration of treatment was 119 days in investigational treatment period and 183 days in extension treatment period.

Reporting group title	PF-06826647 100 mg QD->PF-06826647 200 mg QD Group
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Reporting group description:

This study included 2 treatment periods: 16-week investigational treatment period and 24-week extension treatment period. The enrolled subjects entered the investigational treatment period first and then the subjects who completed the investigational treatment period entered the extension treatment period. The subjects in this group received PF-06826647 100 mg once a day (QD) in the investigational treatment period (16 weeks) and PF-06826647 200 mg QD in the extension treatment period (24 weeks). The maximum duration of treatment was 115 days in investigational treatment period and 171 days in extension treatment period.

Reporting group title	PF-06826647 100 mg QD->PF-06826647 400 mg QD Group
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Reporting group description:

This study included 2 treatment periods: 16-week investigational treatment period and 24-week extension treatment period. The enrolled subjects entered the investigational treatment period first and

then the subjects who completed the investigational treatment period entered the extension treatment period. The subjects in this group received PF-06826647 100 mg once a day (QD) in the investigational treatment period (16 weeks) and PF-06826647 400 mg QD in the extension treatment period (24 weeks). The maximum duration of treatment was 115 days in investigational treatment period and 174 days in extension treatment period.

Reporting group title	PF-06826647 200 mg QD->PF-06826647 200 mg QD Group
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Reporting group description:

This study included 2 treatment periods: 16-week investigational treatment period and 24-week extension treatment period. The enrolled subjects entered the investigational treatment period first and then the subjects who completed the investigational treatment period entered the extension treatment period. The subjects in this group received PF-06826647 200 mg once a day (QD) in the investigational treatment period (16 weeks) and PF-06826647 200 mg QD in the extension treatment period (24 weeks). The maximum duration of treatment was 120 days in investigational treatment period and 186 days in extension treatment period.

Reporting group title	PF-06826647 400 mg QD->PF-06826647 400 mg QD Group
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Reporting group description:

This study included 2 treatment periods: 16-week investigational treatment period and 24-week extension treatment period. The enrolled subjects entered the investigational treatment period first and then the subjects who completed the investigational treatment period entered the extension treatment period. The subjects in this group received PF-06826647 400 mg once a day (QD) in the investigational treatment period (16 weeks) and PF-06826647 400 mg QD in the extension treatment period (24 weeks). The maximum duration of treatment was 119 days in investigational treatment period and 180 days in extension treatment period.

Subject analysis set title	Placebo QD Group
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Subject analysis set type	Per protocol
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Subject analysis set description:

This study included 2 treatment periods: 16-week investigational treatment period and 24-week extension treatment period. The enrolled subjects entered the investigational treatment period first and then the subjects who completed the investigational treatment period entered the extension treatment period. The subjects in this group received matching placebo (2*25 mg size placebo and 4*100 mg size placebo) once a day (QD) in the investigational treatment period (16 weeks). The maximum duration of treatment was 116 days in investigational treatment period.

Subject analysis set title	PF-06826647 50 mg QD Group
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Subject analysis set type	Per protocol
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Subject analysis set description:

This study included 2 treatment periods: 16-week investigational treatment period and 24-week extension treatment period. The enrolled subjects entered the investigational treatment period first and then the subjects who completed the investigational treatment period entered the extension treatment period. The subjects in this group received PF-06826647 50 mg once a day (QD) in the investigational treatment period (16 weeks). The maximum duration of treatment was 119 days in investigational treatment period.

Subject analysis set title	PF-06826647 100 mg QD Group
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Subject analysis set type	Per protocol
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Subject analysis set description:

This study included 2 treatment periods: 16-week investigational treatment period and 24-week extension treatment period. The enrolled subjects entered the investigational treatment period first and then the subjects who completed the investigational treatment period entered the extension treatment period. The subjects in this group received PF-06826647 100 mg once a day (QD) in the investigational treatment period (16 weeks). The maximum duration of treatment was 115 days in investigational treatment period.

Subject analysis set title	PF-06826647 200 mg QD Group
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Subject analysis set type	Per protocol
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Subject analysis set description:

This study included 2 treatment periods: 16-week investigational treatment period and 24-week extension treatment period. The enrolled subjects entered the investigational treatment period first and then the subjects who completed the investigational treatment period entered the extension treatment period. The subjects in this group received PF-06826647 200 mg once a day (QD) in the investigational treatment period (16 weeks). The maximum duration of treatment was 120 days in investigational treatment period.

Subject analysis set title	PF-06826647 400 mg QD Group
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Subject analysis set type	Per protocol
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Subject analysis set description:

This study included 2 treatment periods: 16-week investigational treatment period and 24-week extension treatment period. The enrolled subjects entered the investigational treatment period first and then the subjects who completed the investigational treatment period entered the extension treatment period. The subjects in this group received PF-06826647 400 mg once a day (QD) in the investigational treatment period (16 weeks). The maximum duration of treatment was 119 days in investigational treatment period.

Primary: Percentage of Subjects With a Psoriasis Area and Severity Index 90 (PASI 90) Response Up to Week 16 - Investigational Treatment Period

End point title	Percentage of Subjects With a Psoriasis Area and Severity Index 90 (PASI 90) Response Up to Week 16 - Investigational Treatment Period
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End point description:

The PASI quantifies the severity of a subject's psoriasis based on both lesion severity and the percentage of body surface area (BSA) affected. PASI is a composite scoring by the investigator of degree of erythema, induration, and scaling (each scored separately) for each of 4 body regions (head and neck, upper limbs, trunk [including axillae and groin], and lower limbs [including buttocks]), with adjustment for the percent of BSA involved for each body region and for the proportion of the body region to the whole body. The PASI score can vary in increments of 0.1 and range from 0.0 to 72.0, with higher scores representing greater severity of psoriasis. PASI 90 response was defined as at least a 90% reduction in PASI relative to baseline. The analysis population included all randomized subjects who received at least 1 dose of study drug (PF-06826647 or placebo) after non-responder imputation applied (the subjects discontinued due to coronavirus disease 2019 were removed).

End point type	Primary
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End point timeframe:

Baseline up to Week 16

End point values	Placebo QD Group	PF-06826647 50 mg QD Group	PF-06826647 100 mg QD Group	PF-06826647 200 mg QD Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	42	22	21	45
Units: Percentage of subjects				
number (confidence interval 90%)				
Week 1	0 (0.00 to 6.41)	0 (0.00 to 12.60)	0 (0.00 to 12.33)	0 (0.00 to 5.97)
Week 2	0 (0.00 to 6.41)	0 (0.00 to 12.60)	0 (0.00 to 12.33)	2.2 (0.23 to 9.17)
Week 4	0 (0.00 to 6.41)	0 (0.00 to 12.60)	0 (0.00 to 12.33)	11.1 (5.50 to 21.80)
Week 6	0 (0.00 to 6.41)	4.5 (0.48 to 19.56)	4.8 (0.50 to 20.57)	20.0 (11.72 to 31.73)
Week 8	2.4 (0.25 to 9.85)	4.5 (0.48 to 19.56)	4.8 (0.50 to 20.57)	24.4 (15.47 to 35.88)
Week 12	2.4 (0.25 to 9.85)	13.6 (5.12 to 31.13)	9.5 (2.56 to 24.50)	37.8 (25.96 to 50.95)
Week 16	4.8 (1.27 to 13.53)	13.6 (5.12 to 31.13)	9.5 (2.56 to 24.50)	37.8 (25.96 to 50.95)

End point values	PF-06826647 400 mg QD Group			
Subject group type	Subject analysis set			
Number of subjects analysed	41			

Units: Percentage of subjects				
number (confidence interval 90%)				
Week 1	0 (0.00 to 6.57)			
Week 2	0 (0.00 to 6.57)			
Week 4	7.3 (2.72 to 17.32)			
Week 6	26.8 (17.12 to 39.77)			
Week 8	34.1 (23.04 to 46.94)			
Week 12	48.8 (35.14 to 62.56)			
Week 16	51.2 (37.44 to 64.86)			

Statistical analyses

Statistical analysis title	Difference from Placebo QD at Week 16
Comparison groups	Placebo QD Group v PF-06826647 50 mg QD Group
Number of subjects included in analysis	64
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2621 ^[1]
Method	Chan and Zhang method
Parameter estimate	Risk difference (RD)
Point estimate	8.87
Confidence interval	
level	90 %
sides	2-sided
lower limit	-4.5
upper limit	26.26

Notes:

[1] - One-sided Hochberg p-value, significant level is 0.05.

Statistical analysis title	Difference from Placebo QD at Week 16
Comparison groups	Placebo QD Group v PF-06826647 100 mg QD Group
Number of subjects included in analysis	63
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2621 ^[2]
Method	Chan and Zhang method
Parameter estimate	Risk difference (RD)
Point estimate	4.76
Confidence interval	
level	90 %
sides	2-sided
lower limit	-7.07
upper limit	21.48

Notes:

[2] - One-sided Hochberg p-value, significant level is 0.05.

Statistical analysis title	Difference from Placebo QD at Week 16
Comparison groups	Placebo QD Group v PF-06826647 200 mg QD Group
Number of subjects included in analysis	87
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0004 ^[3]
Method	Chan and Zhang method
Parameter estimate	Risk difference (RD)
Point estimate	33.02
Confidence interval	
level	90 %
sides	2-sided
lower limit	18.01
upper limit	47.11

Notes:

[3] - One-sided Hochberg p-value, significant level is 0.05.

Statistical analysis title	Difference from Placebo QD at Week 16
Comparison groups	Placebo QD Group v PF-06826647 400 mg QD Group
Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 ^[4]
Method	Chan and Zhang method
Parameter estimate	Risk difference (RD)
Point estimate	46.46
Confidence interval	
level	90 %
sides	2-sided
lower limit	30.62
upper limit	60.56

Notes:

[4] - One-sided Hochberg p-value, significant level is 0.05.

Primary: Number of Subjects With Treatment-Emergent Adverse Events (All-Causality), Week 16 to Week 40 - Extension Treatment Period

End point title	Number of Subjects With Treatment-Emergent Adverse Events (All-Causality), Week 16 to Week 40 - Extension Treatment Period ^[5]
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End point description:

An adverse event (AE) was any untoward medical occurrence in a subject who received study drug without regard to possibility of causal relationship. A serious AE (SAE) was an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial or prolonged inpatient hospitalization; life-threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly. An AE was considered treatment-emergent if the event started on or after the first dosing day and time/start time but before the last dose plus the lag time. IP=investigational product; TD=temporary discontinuation. The analysis population included all subjects who received at least 1 dose of study drug (PF-06826647 or placebo) and who entered the extension treatment period.

End point type	Primary
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End point timeframe:

From Week 16 to Week 40

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	Placebo QD- >PF-06826647 200 mg QD Group	Placebo QD- >PF-06826647 400 mg QD Group	PF-06826647 50 mg QD- >PF-06826647 200 mg QD Group	PF-06826647 50 mg QD- >PF-06826647 400 mg QD Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	18	10	9
Units: Subjects				
Subjects with AEs	11	8	7	6
Subjects with SAEs	0	1	0	0
Subjects with severe AEs	2	0	0	0
Subjects discontinued from study due to AEs	0	1	0	1
IP discontinued due to AE, subjects continue	0	0	0	0
Subjects dose reduced or TD due to AEs	0	0	1	0

End point values	PF-06826647 100 mg QD- >PF-06826647 200 mg QD Group	PF-06826647 100 mg QD- >PF-06826647 400 mg QD Group	PF-06826647 200 mg QD- >PF-06826647 200 mg QD Group	PF-06826647 400 mg QD- >PF-06826647 400 mg QD Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	9	37	38
Units: Subjects				
Subjects with AEs	7	7	24	26
Subjects with SAEs	0	1	2	0
Subjects with severe AEs	1	2	2	3
Subjects discontinued from study due to AEs	1	0	3	3
IP discontinued due to AE, subjects continue	1	0	1	0
Subjects dose reduced or TD due to AEs	0	1	4	1

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Treatment-Emergent Adverse Events (Treatment Related), Week 16 to Week 40 - Extension Treatment Period

End point title	Number of Subjects With Treatment-Emergent Adverse Events (Treatment Related), Week 16 to Week 40 - Extension Treatment Period ^[6]
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End point description:

Treatment-related adverse event (AE) was any untoward medical occurrence attributed to study drug in a subject who received study drug. Serious adverse event (SAE) was an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial or prolonged inpatient hospitalization; life-threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly. An AE was considered treatment-emergent if the event started on or after the first dosing day and time/start time but before the last dose plus the lag time. Relatedness to study drug was assessed by the investigator (Yes/No). Subjects with multiple occurrences of an AE within a category were counted once within the category. IP=investigational product; TD=temporary discontinuation. The analysis population included all subjects who received at least 1 dose of study drug (PF-06826647 or placebo) and who entered the extension treatment period.

End point type	Primary
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End point timeframe:

From Week 16 to Week 40

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.

End point values	Placebo QD- >PF-06826647 200 mg QD Group	Placebo QD- >PF-06826647 400 mg QD Group	PF-06826647 50 mg QD- >PF-06826647 200 mg QD Group	PF-06826647 50 mg QD- >PF-06826647 400 mg QD Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	18	10	9
Units: Subjects				
Subjects with AEs	4	3	2	3
Subjects with SAEs	0	0	0	0
Subjects with severe AEs	0	0	0	0
Subjects discontinued from study due to AEs	0	1	0	1
IP discontinued due to AE, subjects continue	0	0	0	0
Subjects dose reduced or TD due to AEs	0	0	1	0

End point values	PF-06826647 100 mg QD- >PF-06826647 200 mg QD Group	PF-06826647 100 mg QD- >PF-06826647 400 mg QD Group	PF-06826647 200 mg QD- >PF-06826647 200 mg QD Group	PF-06826647 400 mg QD- >PF-06826647 400 mg QD Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	9	37	38
Units: Subjects				
Subjects with AEs	0	1	10	5
Subjects with SAEs	0	0	2	0
Subjects with severe AEs	0	0	1	1
Subjects discontinued from study due to AEs	0	0	2	2
IP discontinued due to AE, subjects continue	0	0	0	0
Subjects dose reduced or TD due to AEs	0	0	3	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Laboratory Test Abnormality - Hematology (Normal Baseline), Week 16 to Week 40 - Extension Treatment Period

End point title	Number of Subjects With Laboratory Test Abnormality - Hematology (Normal Baseline), Week 16 to Week 40 - Extension Treatment Period ^[7]
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End point description:

Following hematology parameters were analyzed for laboratory examination: hemoglobin, hematocrit, erythrocytes (Ery.), reticulocytes, Ery. mean corpuscular volume, Ery. mean corpuscular hemoglobin (MCH), Ery. mean corpuscular hemoglobin concentration (MCHC), platelets, reticulocytes/erythrocytes, leukocytes, lymphocytes/leukocytes, neutrophils/leukocytes, basophils, basophils/leukocytes, eosinophils, eosinophils/leukocytes, monocytes, monocytes/leukocytes, activated partial thromboplastin time (aPTT), prothrombin time, prothrombin international (Intl.) normalized ratio, neutrophils total count, and lymphocytes total count. The analysis population included all subjects who received at least 1 dose of study drug (PF-06826647 or placebo) and had at least 1 laboratory assessment and who entered the extension treatment period. LLN=lower limit of normal; ULN=upper limit of normal.

End point type	Primary
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End point timeframe:

From Week 16 to Week 40

Notes:

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

Justification: No statistical analysis was planned for this endpoint.

End point values	Placebo QD- >PF-06826647 200 mg QD Group	Placebo QD- >PF-06826647 400 mg QD Group	PF-06826647 50 mg QD- >PF-06826647 200 mg QD Group	PF-06826647 50 mg QD- >PF-06826647 400 mg QD Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	18	10	9
Units: Subjects				
Hemoglobin (g/dL) <0.8*LLN	0	1	0	0
Hematocrit (%) <0.8*LLN	0	1	0	0
Erythrocytes (10 ⁶ /mm ³) <0.8*LLN	2	2	0	2
Reticulocytes (10 ³ /mm ³) <0.5*LLN	0	1	0	1
Reticulocytes (10 ³ /mm ³) >1.5*ULN	0	1	0	0
Ery. Mean Corpuscular Volume (um ³) <0.9*LLN	0	0	0	0
Ery. Mean Corpuscular Volume (um ³) <1.1*ULN	1	0	1	0
Ery. MCH (pg/cell) <0.9*LLN	0	0	0	0
Ery. MCH (pg/cell) >1.1*ULN	0	0	0	0
Ery. MCHC (g/dL) <0.9*LLN	0	0	0	0
Ery. MCHC (g/dL) >1.1*ULN	0	0	0	0
Platelets (10 ³ /mm ³) <0.5*LLN	0	1	0	0
Platelets (10 ³ /mm ³) >1.75*ULN	0	0	0	0
Reticulocytes/Erythrocytes (%) <0.5*LLN	0	1	0	0
Reticulocytes/Erythrocytes (%) >1.5*ULN	0	2	0	1
Leukocytes(10 ³ /mm ³) <0.6*LLN	0	0	0	0
Leukocytes(10 ³ /mm ³) >1.5*ULN	0	0	0	0
Lymphocytes/Leukocytes (%) <0.8*LLN	0	1	0	0
Lymphocytes/Leukocytes (%) >1.2*ULN	0	5	0	0

Neutrophils/Leukocytes (%) <0.8*LLN	1	3	0	0
Neutrophils/Leukocytes (%) >1.2*ULN	0	0	0	0
Basophils (10 ³ /mm ³) >1.2*ULN	0	0	0	0
Basophils/Leukocytes (%) >1.2*ULN	0	0	0	0
Eosinophils (10 ³ /mm ³) >1.2*ULN	0	0	0	0
Eosinophils/Leukocytes (%) >1.2*ULN	0	1	0	0
Monocytes (10 ³ /mm ³) >1.2*ULN	0	0	0	1
Monocytes/Leukocytes (%) >1.2*ULN	2	1	1	0
aPTT (sec) >1.1*ULN	1	0	0	1
Prothrombin Time (sec) >1.1*ULN	3	0	0	1
Prothrombin Intl. Normalized Ratio >1.1*ULN	0	0	0	0
Neutrophils total count (10 ³ /mm ³) <0.8*LLN	1	3	1	2
Neutrophils total count (10 ³ /mm ³) >1.2*ULN	0	0	0	0
Lymphocytes total count (10 ³ /mm ³) <0.8*LLN	0	2	0	0
Lymphocytes total count (10 ³ /mm ³) >1.2*ULN	0	0	0	0

End point values	PF-06826647 100 mg QD- >PF-06826647 200 mg QD Group	PF-06826647 100 mg QD- >PF-06826647 400 mg QD Group	PF-06826647 200 mg QD- >PF-06826647 200 mg QD Group	PF-06826647 400 mg QD- >PF-06826647 400 mg QD Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	9	37	38
Units: Subjects				
Hemoglobin (g/dL) <0.8*LLN	0	0	1	0
Hematocrit (%) <0.8*LLN	0	0	1	0
Erythrocytes (10 ⁶ /mm ³) <0.8*LLN	1	0	1	0
Reticulocytes (10 ³ /mm ³) <0.5*LLN	0	0	0	0
Reticulocytes (10 ³ /mm ³) >1.5*ULN	0	0	0	1
Ery. Mean Corpuscular Volume (um ³) <0.9*LLN	0	0	0	0
Ery. Mean Corpuscular Volume (um ³) <1.1*ULN	0	0	1	0
Ery. MCH (pg/cell) <0.9*LLN	0	0	0	0
Ery. MCH (pg/cell) >1.1*ULN	0	0	0	0
Ery. MCHC (g/dL) <0.9*LLN	0	0	0	0
Ery. MCHC (g/dL) >1.1*ULN	0	0	0	0
Platelets (10 ³ /mm ³) <0.5*LLN	0	0	0	0
Platelets (10 ³ /mm ³) >1.75*ULN	0	0	0	0
Reticulocytes/Erythrocytes (%) <0.5*LLN	0	0	0	0
Reticulocytes/Erythrocytes (%) >1.5*ULN	0	0	1	2
Leukocytes(10 ³ /mm ³) <0.6*LLN	0	0	0	0
Leukocytes(10 ³ /mm ³) >1.5*ULN	0	0	0	0
Lymphocytes/Leukocytes (%) <0.8*LLN	0	0	0	1
Lymphocytes/Leukocytes (%) >1.2*ULN	0	0	2	5
Neutrophils/Leukocytes (%) <0.8*LLN	0	0	1	3

Neutrophils/Leukocytes (%) >1.2*ULN	0	0	0	0
Basophils (10 ³ /mm ³) >1.2*ULN	0	0	0	0
Basophils/Leukocytes (%) >1.2*ULN	0	0	0	0
Eosinophils (10 ³ /mm ³) >1.2*ULN	0	0	0	1
Eosinophils/Leukocytes (%) >1.2*ULN	0	0	0	0
Monocytes (10 ³ /mm ³) >1.2*ULN	0	0	0	1
Monocytes/Leukocytes (%) >1.2*ULN	0	0	0	3
aPTT (sec) >1.1*ULN	1	0	0	0
Prothrombin Time (sec) >1.1*ULN	0	0	0	0
Prothrombin Intl. Normalized Ratio >1.1*ULN	0	0	0	0
Neutrophils total count (10 ³ /mm ³) <0.8*LLN	2	1	7	4
Neutrophils total count (10 ³ /mm ³) >1.2*ULN	0	0	1	1
Lymphocytes total count (10 ³ /mm ³) <0.8*LLN	0	0	1	0
Lymphocytes total count (10 ³ /mm ³) >1.2*ULN	0	1	1	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Laboratory Test Abnormality - Chemistry (Normal Baseline), Week 16 to Week 40 - Extension Treatment Period

End point title	Number of Subjects With Laboratory Test Abnormality - Chemistry (Normal Baseline), Week 16 to Week 40 - Extension Treatment Period ^[8]
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End point description:

Following clinical chemistry parameters were analyzed for laboratory examination: bilirubin, direct bilirubin, indirect bilirubin, aspartate aminotransferase, alanine aminotransferase, gamma glutamyl transferase, alkaline phosphatase, protein, albumin, blood urea nitrogen, urea, creatinine, urate, HDL cholesterol, LDL cholesterol, triglycerides, sodium, potassium, chloride, calcium, bicarbonate, glucose, creatine kinase, and cholesterol. The analysis population included all subjects who received at least 1 dose of study drug (PF-06826647 or placebo) and had at least 1 laboratory assessment and who entered the extension treatment period. LLN=lower limit of normal; ULN=upper limit of normal.

End point type	Primary
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End point timeframe:

From Week 16 to Week 40

Notes:

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

Justification: No statistical analysis was planned for this endpoint.

End point values	Placebo QD- >PF-06826647 200 mg QD Group	Placebo QD- >PF-06826647 400 mg QD Group	PF-06826647 50 mg QD- >PF-06826647 200 mg QD Group	PF-06826647 50 mg QD- >PF-06826647 400 mg QD Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	18	10	9
Units: Subjects				
Bilirubin (mg/dL) >1.5*ULN	0	0	0	0
Direct Bilirubin (mg/dL) >1.5*ULN	0	0	0	0

Indirect Bilirubin (mg/dL) >1.5*ULN	0	0	0	0
Aspartate Aminotransferase (U/L) > 3.0*ULN	0	1	0	0
Alanine Aminotransferase (U/L) > 3.0*ULN	0	0	0	0
Gamma Glutamyl Transferase (U/L) > 3.0*ULN	0	0	0	0
Alkaline Phosphatase (U/L) > 3.0*ULN	0	0	0	0
Protein (g/dL) <0.8*LLN	0	0	0	0
Protein (g/dL) >1.2*ULN	0	0	0	0
Albumin (g/dL) <0.8*LLN	0	0	0	0
Albumin (g/dL) >1.2*ULN	0	0	0	0
Blood Urea Nitrogen (mg/dL) >1.3*ULN	1	0	0	0
Urea (mg/dL) >1.3*ULN	0	0	0	0
Creatinine (mg/dL) >1.3*ULN	0	1	0	0
Urate (mg/dL) >1.2*ULN	0	0	0	0
HDL Cholesterol (mg/dL) <0.8*LLN	0	0	0	0
LDL Cholesterol (mg/dL) >1.2*ULN	0	0	0	0
Triglycerides (mg/dL) >1.3*ULN	0	0	0	0
Sodium (Meq/L) <0.95*LLN	0	0	0	0
Sodium (Meq/L) >1.05*ULN	0	0	0	0
Potassium (Meq/L) <0.9*LLN	0	0	0	0
Potassium (Meq/L) >1.1*ULN	1	0	0	0
Chloride (Meq/L) <0.9*LLN	0	0	0	0
Chloride (Meq/L) >1.1*ULN	0	0	0	0
Calcium (mg/dL) <0.9*LLN	0	0	0	0
Calcium (mg/dL) >1.1*ULN	0	0	0	0
Bicarbonate (Meq/L) <0.9*LLN	0	0	0	0
Bicarbonate (Meq/L) >1.1*ULN	0	0	0	0
Glucose (mg/dL) <0.6*LLN	0	0	0	0
Glucose (mg/dL) >1.5*ULN	1	0	0	0
Creatine Kinase (U/L) >2.0*ULN	2	6	2	5
Cholesterol (mg/dL) >1.3*ULN	0	0	0	0

End point values	PF-06826647 100 mg QD- >PF-06826647 200 mg QD Group	PF-06826647 100 mg QD- >PF-06826647 400 mg QD Group	PF-06826647 200 mg QD- >PF-06826647 200 mg QD Group	PF-06826647 400 mg QD- >PF-06826647 400 mg QD Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	9	37	38
Units: Subjects				
Bilirubin (mg/dL) >1.5*ULN	0	0	1	0
Direct Bilirubin (mg/dL) >1.5*ULN	0	0	0	0
Indirect Bilirubin (mg/dL) >1.5*ULN	0	0	0	0
Aspartate Aminotransferase (U/L) > 3.0*ULN	0	1	1	2
Alanine Aminotransferase (U/L) > 3.0*ULN	0	0	2	0
Gamma Glutamyl Transferase (U/L) > 3.0*ULN	0	0	2	0
Alkaline Phosphatase (U/L) > 3.0*ULN	0	0	0	0

Protein (g/dL) <0.8*LLN	0	0	0	0
Protein (g/dL) >1.2*ULN	0	0	0	0
Albumin (g/dL) <0.8*LLN	0	0	0	0
Albumin (g/dL) >1.2*ULN	0	0	0	0
Blood Urea Nitrogen (mg/dL) >1.3*ULN	0	0	0	0
Urea (mg/dL) >1.3*ULN	0	0	0	0
Creatinine (mg/dL) >1.3*ULN	0	0	0	1
Urate (mg/dL) >1.2*ULN	0	0	0	1
HDL Cholesterol (mg/dL) <0.8*LLN	0	0	0	0
LDL Cholesterol (mg/dL) >1.2*ULN	0	0	0	0
Triglycerides (mg/dL) >1.3*ULN	0	1	0	1
Sodium (Meq/L) <0.95*LLN	0	0	0	0
Sodium (Meq/L) >1.05*ULN	0	0	0	0
Potassium (Meq/L) <0.9*LLN	0	0	0	0
Potassium (Meq/L) >1.1*ULN	0	0	0	1
Chloride (Meq/L) <0.9*LLN	0	0	0	0
Chloride (Meq/L) >1.1*ULN	0	0	0	0
Calcium (mg/dL) <0.9*LLN	0	0	0	0
Calcium (mg/dL) >1.1*ULN	0	0	0	0
Bicarbonate (Meq/L) <0.9*LLN	0	0	0	0
Bicarbonate (Meq/L) >1.1*ULN	0	0	0	0
Glucose (mg/dL) <0.6*LLN	0	0	0	0
Glucose (mg/dL) >1.5*ULN	0	0	3	2
Creatine Kinase (U/L) >2.0*ULN	2	3	5	12
Cholesterol (mg/dL) >1.3*ULN	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Laboratory Test Abnormality - Urinalysis (Normal Baseline), Week 16 to Week 40 - Extension Treatment Period

End point title	Number of Subjects With Laboratory Test Abnormality - Urinalysis (Normal Baseline), Week 16 to Week 40 - Extension Treatment Period ^[9]
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End point description:

Following urinalysis parameters were analyzed for laboratory examination: urine pH, urine glucose, urine ketones, urine protein, urine hemoglobin, urine urobilinogen, urine bilirubin, urine nitrite, urine leukocyte esterase, urine erythrocytes, urine leukocytes, urine hyaline, and urine bacteria. The analysis population included all subjects who received at least 1 dose of study drug (PF-06826647 or placebo) and had at least 1 laboratory assessment and who entered the extension treatment period. LLN=lower limit of normal; ULN=upper limit of normal.

End point type	Primary
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End point timeframe:

From Week 16 to Week 40

Notes:

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

Justification: No statistical analysis was planned for this endpoint.

End point values	Placebo QD- >PF-06826647 200 mg QD Group	Placebo QD- >PF-06826647 400 mg QD Group	PF-06826647 50 mg QD- >PF-06826647 200 mg QD Group	PF-06826647 50 mg QD- >PF-06826647 400 mg QD Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	18	10	9
Units: Subjects				
Urine pH (Scalar) <4.5	0	0	0	0
Urine pH (Scalar) >8	0	0	0	0
Urine Glucose >=1	0	0	0	0
Urine Ketones (Scalar) >=1	0	0	0	0
Urine Protein >=1	1	0	0	0
Urine Hemoglobin (Scalar) >=1	0	1	1	0
Urine Urobilinogen (EU/dL) >=1	0	0	0	0
Urine Bilirubin (Scalar) >=1	0	0	0	0
Urine Nitrite (Scalar) >=1	2	0	0	0
Urine Leukocyte Esterase (Scalar) >=1	2	1	0	1
Urine Erythrocytes (Scalar) >=20	0	0	0	0
Urine Leukocytes (/HPF) >=20	1	0	0	0
Urine Hyaline Casts (/LPF) >1	0	0	0	0
Urine Bacteria (/LPF) >20	0	0	0	0

End point values	PF-06826647 100 mg QD- >PF-06826647 200 mg QD Group	PF-06826647 100 mg QD- >PF-06826647 400 mg QD Group	PF-06826647 200 mg QD- >PF-06826647 200 mg QD Group	PF-06826647 400 mg QD- >PF-06826647 400 mg QD Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	9	37	38
Units: Subjects				
Urine pH (Scalar) <4.5	0	0	0	0
Urine pH (Scalar) >8	0	0	0	0
Urine Glucose >=1	0	0	0	1
Urine Ketones (Scalar) >=1	0	0	0	0
Urine Protein >=1	0	0	1	0
Urine Hemoglobin (Scalar) >=1	0	0	0	2
Urine Urobilinogen (EU/dL) >=1	0	0	2	0
Urine Bilirubin (Scalar) >=1	0	0	0	0
Urine Nitrite (Scalar) >=1	0	0	0	0
Urine Leukocyte Esterase (Scalar) >=1	0	1	2	0
Urine Erythrocytes (Scalar) >=20	0	0	0	0
Urine Leukocytes (/HPF) >=20	0	1	0	0
Urine Hyaline Casts (/LPF) >1	0	0	0	0
Urine Bacteria (/LPF) >20	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Electrocardiogram (ECG) Data Meeting Pre-defined Criteria, Week 16 to Week 40 - Extension Treatment Period

End point title	Number of Subjects With Electrocardiogram (ECG) Data Meeting Pre-defined Criteria, Week 16 to Week 40 - Extension Treatment Period ^[10]
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End point description:

Criteria for ECG abnormalities: maximum increase PR interval increase from baseline (IFB): percent change (Pctchg) ≥ 25 percent (%) for baseline value of >200 milliseconds (msec) and Pctchg $\geq 50\%$ for baseline value of ≤ 200 msec for PR interval, a maximum IFB: Pctchg $\geq 50\%$, maximum QTcF interval (Fridericia's Correction) of 450 msec to ≤ 480 msec, 480 msec to ≤ 500 msec and a maximum change of <30 change ≤ 60 or >60 msec from baseline. The analysis population included all subjects who received at least 1 dose of study drug (PF-06826647 or placebo) and who had at least 1 ECG assessment and who entered the extension treatment period.

End point type	Primary
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End point timeframe:

From Week 16 to Week 40

Notes:

[10] - 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	Placebo QD- >PF-06826647 200 mg QD Group	Placebo QD- >PF-06826647 400 mg QD Group	PF-06826647 50 mg QD- >PF-06826647 200 mg QD Group	PF-06826647 50 mg QD- >PF-06826647 400 mg QD Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	17	10	9
Units: Subjects				
PR interval, single beat (msec) Pctchg $\geq 25/50\%$	0	0	0	0
QRS duration, single beat (msec) Pctchg $\geq 50\%$	0	0	0	0
QT interval, single beat (msec) >500	0	0	1	0
450 < QTcF (msec) ≤ 480	0	0	1	0
480 < QTcF (msec) ≤ 500	0	0	0	0
30 < QTcF (msec) change ≤ 60	1	0	0	0
QTcF (msec) change >60	0	0	0	0

End point values	PF-06826647 100 mg QD- >PF-06826647 200 mg QD Group	PF-06826647 100 mg QD- >PF-06826647 400 mg QD Group	PF-06826647 200 mg QD- >PF-06826647 200 mg QD Group	PF-06826647 400 mg QD- >PF-06826647 400 mg QD Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	8	37	36
Units: Subjects				
PR interval, single beat (msec) Pctchg $\geq 25/50\%$	1	0	0	0
QRS duration, single beat (msec) Pctchg $\geq 50\%$	1	0	0	0
QT interval, single beat (msec) >500	0	0	0	0
450 < QTcF (msec) ≤ 480	1	0	1	0
480 < QTcF (msec) ≤ 500	1	0	0	0
30 < QTcF (msec) change ≤ 60	2	0	3	1

QTcF (msec) change >60	1	0	0	0
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Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Vital Sign Data Meeting Pre-defined Criteria, Week 16 to Week 40 - Extension Treatment Period

End point title	Number of Subjects With Vital Sign Data Meeting Pre-defined Criteria, Week 16 to Week 40 - Extension Treatment Period ^[11]
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End point description:

The vital signs were obtained with subject in the seated position, after having sat calmly for at least 5 minutes. Criteria for vital signs abnormalities: sitting diastolic blood pressure (BP) < 50 millimeter of mercury (mmHg), sitting diastolic BP change \geq 20 mmHg increase, sitting diastolic BP change \geq 20 mmHg decrease, sitting systolic BP < 90 mmHg, sitting systolic BP change \geq 30 mmHg increase, and sitting systolic BP change \geq 30 mmHg decrease. The analysis population included all subjects who received at least 1 dose of investigational product and who entered the extension treatment period.

End point type	Primary
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End point timeframe:

From Week 16 to Week 40

Notes:

[11] - 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	Placebo QD- >PF-06826647 200 mg QD Group	Placebo QD- >PF-06826647 400 mg QD Group	PF-06826647 50 mg QD- >PF-06826647 200 mg QD Group	PF-06826647 50 mg QD- >PF-06826647 400 mg QD Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	18	10	9
Units: Subjects				
Sitting diastolic BP (mmHg) <50	0	1	0	0
Sitting diastolic BP (mmHg) change \geq 20 increase	0	1	1	0
Sitting diastolic BP (mmHg) change \geq 20 decrease	1	1	0	2
Sitting systolic BP (mmHg) <90	0	0	0	0
Sitting systolic BP (mmHg) change \geq 30 increase	0	0	0	1
Sitting systolic BP (mmHg) change \geq 30 decrease	0	2	0	0

End point values	PF-06826647 100 mg QD- >PF-06826647 200 mg QD Group	PF-06826647 100 mg QD- >PF-06826647 400 mg QD Group	PF-06826647 200 mg QD- >PF-06826647 200 mg QD Group	PF-06826647 400 mg QD- >PF-06826647 400 mg QD Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group

Number of subjects analysed	12	9	37	38
Units: Subjects				
Sitting diastolic BP (mmHg) <50	0	0	0	0
Sitting diastolic BP (mmHg) change >= 20 increase	0	0	4	4
Sitting diastolic BP (mmHg) change >= 20 decrease	0	0	3	4
Sitting systolic BP (mmHg) <90	0	0	1	0
Sitting systolic BP (mmHg) change >= 30 increase	0	2	4	5
Sitting systolic BP (mmHg) change >= 30 decrease	0	0	1	1

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With a Psoriasis Area and Severity Index 75 (PASI 75) Response Up to Week 16 - Investigational Treatment Period

End point title	Percentage of Subjects With a Psoriasis Area and Severity Index 75 (PASI 75) Response Up to Week 16 - Investigational Treatment Period
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End point description:

The PASI quantifies the severity of a subject's psoriasis based on both "lesion severity" and the "percent of body surface area (BSA)" affected. PASI is a composite scoring by the investigator of degree of erythema, induration, and scaling (each scored separately) for each of 4 body regions (head and neck, upper limbs, trunk [including axillae and groin], and lower limbs [including buttocks]), with adjustment for the percent of BSA involved for each body region and for the proportion of the body region to the whole body. The PASI score can vary in increments of 0.1 and range from 0.0 to 72.0, with higher scores representing greater severity of psoriasis. PASI 75 response was defined as at least a 75 percent (%) reduction in PASI relative to Baseline. The analysis population included all randomized subjects who received at least 1 dose of study drug (PF-06826647 or placebo) after non-responder imputation applied (the subjects discontinued due to coronavirus disease 2019 were removed).

End point type	Secondary
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End point timeframe:

Baseline up to Week 16

End point values	Placebo QD Group	PF-06826647 50 mg QD Group	PF-06826647 100 mg QD Group	PF-06826647 200 mg QD Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	42	22	21	45
Units: Percentage of subjects				
number (confidence interval 90%)				
Week 1	0 (0.00 to 6.41)	0 (0.00 to 12.60)	0 (0.00 to 12.33)	2.2 (0.23 to 9.17)
Week 2	4.8 (1.27 to 13.53)	0 (0 to 12.60)	0 (0 to 12.33)	8.9 (3.93 to 18.01)
Week 4	7.1 (2.56 to 17.39)	4.5 (0.48 to 19.56)	0 (0 to 12.33)	24.4 (15.47 to 35.88)
Week 6	7.1 (2.56 to 17.39)	13.6 (5.12 to 31.13)	4.8 (0.50 to 20.57)	33.3 (21.80 to 46.08)

Week 8	4.8 (1.27 to 13.53)	13.6 (5.12 to 31.13)	14.3 (5.37 to 32.81)	40.0 (28.66 to 52.89)
Week 12	9.5 (4.22 to 19.38)	13.6 (5.12 to 31.13)	9.5 (2.56 to 24.50)	51.1 (38.26 to 64.12)
Week 16	14.3 (6.41 to 25.56)	18.2 (8.17 to 35.25)	9.5 (2.56 to 24.50)	46.7 (33.79 to 59.13)

End point values	PF-06826647 400 mg QD Group			
Subject group type	Subject analysis set			
Number of subjects analysed	41			
Units: Percentage of subjects				
number (confidence interval 90%)				
Week 1	0 (0.00 to 6.57)			
Week 2	2.4 (0.26 to 10.10)			
Week 4	31.7 (19.88 to 44.52)			
Week 6	43.9 (31.18 to 57.87)			
Week 8	61.0 (46.94 to 73.77)			
Week 12	70.7 (57.87 to 82.16)			
Week 16	73.2 (60.23 to 82.88)			

Statistical analyses

Statistical analysis title	Difference from Placebo QD at Week 16
Comparison groups	Placebo QD Group v PF-06826647 50 mg QD Group
Number of subjects included in analysis	64
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Risk difference (RD)
Point estimate	3.9
Confidence interval	
level	90 %
sides	2-sided
lower limit	-11.82
upper limit	23.42

Statistical analysis title	Difference from Placebo QD at Week 16
Comparison groups	Placebo QD Group v PF-06826647 100 mg QD Group
Number of subjects included in analysis	63
Analysis specification	Pre-specified

Analysis type	superiority
Parameter estimate	Risk difference (RD)
Point estimate	-4.76
Confidence interval	
level	90 %
sides	2-sided
lower limit	-18.61
upper limit	13.29

Statistical analysis title	Difference from Placebo QD at Week 16
Comparison groups	Placebo QD Group v PF-06826647 200 mg QD Group
Number of subjects included in analysis	87
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Risk difference (RD)
Point estimate	32.38
Confidence interval	
level	90 %
sides	2-sided
lower limit	14.32
upper limit	47.52

Statistical analysis title	Difference from Placebo QD at Week 16
Comparison groups	Placebo QD Group v PF-06826647 400 mg QD Group
Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Risk difference (RD)
Point estimate	58.89
Confidence interval	
level	90 %
sides	2-sided
lower limit	41.01
upper limit	72.41

Secondary: Percentage of Subjects With Physician Global Assessment (PGA) of Psoriasis Score of "Clear" or "Almost Clear" and ≥ 2 Points Improvement Up to Week 16 - Investigational Treatment Period

End point title	Percentage of Subjects With Physician Global Assessment (PGA) of Psoriasis Score of "Clear" or "Almost Clear" and ≥ 2 Points Improvement Up to Week 16 - Investigational Treatment Period
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End point description:

The PGA of psoriasis is scored on a 5-point scale, reflecting a global consideration of the erythema, induration, and scaling across all psoriatic lesions. Average erythema, induration, and scaling are scored

separately over the whole body according to a 5-point severity scale (0 [no symptom] to 4 [severe symptom]). The total score was calculated as average of the 3 severity scores and rounded to the nearest whole number score to determine the PGA score and category (0=clear; 1=almost clear; 2=mild; 3=moderate; and 4=severe). The analysis population included all randomized subjects who received at least 1 dose of study drug (PF-06826647 or placebo) after non-responder imputation applied (the subjects discontinued due to coronavirus disease 2019 were removed).

End point type	Secondary
End point timeframe:	
Baseline up to Week 16	

End point values	Placebo QD Group	PF-06826647 50 mg QD Group	PF-06826647 100 mg QD Group	PF-06826647 200 mg QD Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	42	22	21	45
Units: Percentage of subjects				
number (confidence interval 90%)				
Week 1	2.4 (0.25 to 9.85)	0 (0.00 to 12.60)	4.8 (0.50 to 20.57)	4.4 (1.19 to 12.58)
Week 2	2.4 (0.25 to 9.85)	0 (0.00 to 12.60)	4.8 (0.50 to 20.57)	11.1 (5.50 to 21.80)
Week 4	9.5 (4.22 to 19.38)	9.1 (2.44 to 23.60)	4.8 (0.50 to 20.57)	35.6 (23.73 to 48.68)
Week 6	14.3 (6.41 to 25.56)	13.6 (5.12 to 31.13)	14.3 (5.37 to 32.81)	46.7 (33.79 to 59.13)
Week 8	14.3 (6.41 to 25.56)	18.2 (8.17 to 35.25)	14.3 (5.37 to 32.81)	44.4 (31.73 to 56.75)
Week 12	14.3 (6.41 to 25.56)	18.2 (8.17 to 35.25)	19.0 (8.58 to 37.19)	46.7 (33.79 to 59.13)
Week 16	16.7 (9.06 to 27.68)	18.2 (8.17 to 35.25)	14.3 (5.37 to 32.81)	44.4 (31.73 to 56.75)

End point values	PF-06826647 400 mg QD Group			
Subject group type	Subject analysis set			
Number of subjects analysed	41			
Units: Percentage of subjects				
number (confidence interval 90%)				
Week 1	4.9 (1.30 to 13.87)			
Week 2	7.3 (2.72 to 17.32)			
Week 4	36.6 (24.57 to 50.00)			
Week 6	53.7 (39.77 to 66.11)			
Week 8	63.4 (50.00 to 75.43)			
Week 12	78.0 (64.86 to 87.04)			
Week 16	70.7 (57.87 to 82.16)			

Statistical analyses

Statistical analysis title	Difference from Placebo QD at Week 16
Comparison groups	Placebo QD Group v PF-06826647 50 mg QD Group
Number of subjects included in analysis	64
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Risk difference (RD)
Point estimate	1.52
Confidence interval	
level	90 %
sides	2-sided
lower limit	-14.52
upper limit	20.77

Statistical analysis title	Difference from Placebo QD at Week 16
Comparison groups	Placebo QD Group v PF-06826647 100 mg QD Group
Number of subjects included in analysis	63
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Risk difference (RD)
Point estimate	-2.38
Confidence interval	
level	90 %
sides	2-sided
lower limit	-17.67
upper limit	17.01

Statistical analysis title	Difference from Placebo QD at Week 16
Comparison groups	Placebo QD Group v PF-06826647 200 mg QD Group
Number of subjects included in analysis	87
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Risk difference (RD)
Point estimate	27.78
Confidence interval	
level	90 %
sides	2-sided
lower limit	8.86
upper limit	43.26

Statistical analysis title	Difference from Placebo QD at Week 16
Comparison groups	Placebo QD Group v PF-06826647 400 mg QD Group
Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Risk difference (RD)
Point estimate	54.07
Confidence interval	
level	90 %
sides	2-sided
lower limit	36.46
upper limit	68.27

Secondary: Percentage of Subjects With Physician Global Assessment (PGA) of Psoriasis Score of "Clear" or "Almost Clear", Up to Week 16 - Investigational Treatment Period

End point title	Percentage of Subjects With Physician Global Assessment (PGA) of Psoriasis Score of "Clear" or "Almost Clear", Up to Week 16 - Investigational Treatment Period
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End point description:

The PGA of psoriasis is scored on a 5-point scale, reflecting a global consideration of the erythema, induration, and scaling across all psoriatic lesions. Average erythema, induration, and scaling are scored separately over the whole body according to a 5-point severity scale (0 [no symptom] to 4 [severe symptom]). The total score was calculated as average of the 3 severity scores and rounded to the nearest whole number score to determine the PGA score and category (0=clear; 1=almost clear; 2=mild; 3=moderate; and 4=severe). PGA response was defined as 0 (clear) or 1 (almost clear). The analysis population included all randomized subjects who received at least 1 dose of study drug (PF-06826647 or placebo) after non-responder imputation applied (the subjects discontinued due to coronavirus disease 2019 were removed).

End point type	Secondary
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End point timeframe:

Baseline up to Week 16

End point values	Placebo QD Group	PF-06826647 50 mg QD Group	PF-06826647 100 mg QD Group	PF-06826647 200 mg QD Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	42	22	21	45
Units: Percentage of subjects				
number (confidence interval 90%)				
Week 1	2.4 (0.25 to 9.85)	0 (0.00 to 12.60)	4.8 (0.50 to 20.57)	4.4 (1.19 to 12.58)
Week 2	2.4 (0.25 to 9.85)	0 (0.00 to 12.60)	4.8 (0.50 to 20.57)	11.1 (5.50 to 21.80)
Week 4	9.5 (4.22 to 19.38)	9.1 (2.44 to 23.60)	4.8 (0.50 to 20.57)	35.6 (23.73 to 48.68)
Week 6	14.3 (6.41 to 25.56)	13.6 (5.12 to 31.13)	14.3 (5.37 to 32.81)	46.7 (33.79 to 59.13)

Week 8	14.3 (6.41 to 25.56)	18.2 (8.17 to 35.25)	14.3 (5.37 to 32.81)	44.4 (31.73 to 56.75)
Week 12	14.3 (6.41 to 25.56)	18.2 (8.17 to 35.25)	19.0 (8.58 to 37.19)	46.7 (33.79 to 59.13)
Week 16	16.7 (9.06 to 27.68)	18.2 (8.17 to 35.25)	14.3 (5.37 to 32.81)	44.4 (31.73 to 56.75)

End point values	PF-06826647 400 mg QD Group			
Subject group type	Subject analysis set			
Number of subjects analysed	41			
Units: Percentage of subjects				
number (confidence interval 90%)				
Week 1	4.9 (1.30 to 13.87)			
Week 2	7.3 (2.72 to 17.32)			
Week 4	36.6 (24.57 to 50.00)			
Week 6	53.7 (39.77 to 66.11)			
Week 8	63.4 (50.00 to 75.43)			
Week 12	78.0 (64.86 to 87.04)			
Week 16	70.7 (57.87 to 82.16)			

Statistical analyses

Statistical analysis title	Difference from Placebo QD at Week 16
Comparison groups	Placebo QD Group v PF-06826647 50 mg QD Group
Number of subjects included in analysis	64
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Risk difference (RD)
Point estimate	1.52
Confidence interval	
level	90 %
sides	2-sided
lower limit	-14.52
upper limit	20.77

Statistical analysis title	Difference from Placebo QD at Week 16
Comparison groups	Placebo QD Group v PF-06826647 100 mg QD Group
Number of subjects included in analysis	63
Analysis specification	Pre-specified

Analysis type	superiority
Parameter estimate	Risk difference (RD)
Point estimate	-2.38
Confidence interval	
level	90 %
sides	2-sided
lower limit	-17.67
upper limit	17.01

Statistical analysis title	Difference from Placebo QD at Week 16
Comparison groups	Placebo QD Group v PF-06826647 200 mg QD Group
Number of subjects included in analysis	87
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Risk difference (RD)
Point estimate	27.78
Confidence interval	
level	90 %
sides	2-sided
lower limit	8.86
upper limit	43.26

Statistical analysis title	Difference from Placebo QD at Week 16
Comparison groups	Placebo QD Group v PF-06826647 400 mg QD Group
Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Risk difference (RD)
Point estimate	54.07
Confidence interval	
level	90 %
sides	2-sided
lower limit	36.46
upper limit	68.27

Secondary: Percentage of Subjects With a Psoriasis Area and Severity Index 50 (PASI 50) Response Up to Week 16 - Investigational Treatment Period

End point title	Percentage of Subjects With a Psoriasis Area and Severity Index 50 (PASI 50) Response Up to Week 16 - Investigational Treatment Period
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End point description:

The PASI quantifies the severity of a subject's psoriasis based on both, "lesion severity" and "percent of BSA" affected. PASI is a composite scoring by the investigator of degree of erythema, induration, and scaling (each scored separately) for each of 4 body regions (head and neck, upper limbs, trunk [including axillae and groin], and lower limbs [including buttocks]), with adjustment for the percent of BSA involved for each body region and for the proportion of the body region to the whole body. The

PASI score can vary in increments of 0.1 and range from 0.0 to 72.0, with higher scores representing greater severity of psoriasis. PASI 50 response was defined as at least 50% reduction in PASI relative to Baseline. The analysis population included all randomized subjects who received at least 1 dose of study drug (PF-06826647 or placebo) after non-responder imputation applied (the subjects discontinued due to coronavirus disease 2019 were removed).

End point type	Secondary
End point timeframe:	
Baseline up to Week 16	

End point values	Placebo QD Group	PF-06826647 50 mg QD Group	PF-06826647 100 mg QD Group	PF-06826647 200 mg QD Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	36	20	20	38
Units: Percentage of subjects				
number (not applicable)				
Week 1 (n=42, 22, 21, 44, 40)	2.4	0	4.8	11.4
Week 2 (n=42, 22, 21, 45, 41)	7.1	13.6	4.8	28.9
Week 4 (n=40, 21, 21, 44, 40)	22.5	19.0	14.3	50.0
Week 6 (n=38, 21, 20, 44, 39)	28.9	33.3	30.0	59.1
Week 8 (n=37, 20, 20, 41, 40)	32.4	35.0	25.0	70.7
Week 12 (n=36, 20, 21, 41, 40)	38.9	45.0	38.1	73.2
Week 16 (n=36, 20, 20, 38, 39)	41.7	45.0	45.0	68.4

End point values	PF-06826647 400 mg QD Group			
Subject group type	Subject analysis set			
Number of subjects analysed	39			
Units: Percentage of subjects				
number (not applicable)				
Week 1 (n=42, 22, 21, 44, 40)	5.0			
Week 2 (n=42, 22, 21, 45, 41)	22.0			
Week 4 (n=40, 21, 21, 44, 40)	65.0			
Week 6 (n=38, 21, 20, 44, 39)	69.2			
Week 8 (n=37, 20, 20, 41, 40)	75.0			
Week 12 (n=36, 20, 21, 41, 40)	92.5			
Week 16 (n=36, 20, 20, 38, 39)	94.9			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With a Psoriasis Area and Severity Index 100 (PASI 100) Response Up to Week 16 - Investigational Treatment Period

End point title	Percentage of Subjects With a Psoriasis Area and Severity
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End point description:

The PASI quantifies the severity of a subject's psoriasis based on both "lesion severity" and the "percent of body surface area (BSA)" affected. PASI is a composite scoring by the investigator of degree of erythema, induration, and scaling (each scored separately) for each of 4 body regions (head and neck, upper limbs, trunk [including axillae and groin], and lower limbs [including buttocks]), with adjustment for the percent of BSA involved for each body region and for the proportion of the body region to the whole body. The PASI score can vary in increments of 0.1 and range from 0.0 to 72.0, with higher scores representing greater severity of psoriasis. PASI 100 response was defined as at least a 100% reduction in PASI relative to Baseline. The analysis population included all randomized subjects who received at least 1 dose of study drug (PF-06826647 or placebo) after non-responder imputation applied (the subjects discontinued due to coronavirus disease 2019 were removed).

End point type Secondary

End point timeframe:

Baseline up to Week 16

End point values	Placebo QD Group	PF-06826647 50 mg QD Group	PF-06826647 100 mg QD Group	PF-06826647 200 mg QD Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	36	20	20	38
Units: Percentage of subjects				
number (not applicable)				
Week 1 (n=42, 22, 21, 44, 40)	0	0	0	0
Week 2 (n=42, 22, 21, 45, 41)	0	0	0	2.2
Week 4 (n=40, 21, 21, 44, 40)	0	0	0	4.5
Week 6 (n=38, 21, 20, 44, 39)	0	4.8	0	9.1
Week 8 (n=37, 20, 20, 41, 40)	0	5.0	0	17.1
Week 12 (n=36, 20, 21, 41, 40)	0	5.0	4.8	12.2
Week 16 (n=36, 20, 20, 38, 39)	0	15.0	5.0	15.8

End point values	PF-06826647 400 mg QD Group			
Subject group type	Subject analysis set			
Number of subjects analysed	39			
Units: Percentage of subjects				
number (not applicable)				
Week 1 (n=42, 22, 21, 44, 40)	0			
Week 2 (n=42, 22, 21, 45, 41)	0			
Week 4 (n=40, 21, 21, 44, 40)	0			
Week 6 (n=38, 21, 20, 44, 39)	7.7			
Week 8 (n=37, 20, 20, 41, 40)	15.0			
Week 12 (n=36, 20, 21, 41, 40)	22.5			
Week 16 (n=36, 20, 20, 38, 39)	20.5			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Psoriasis Area and Severity Index (PASI) scores, Up to Week 16 - Investigational Treatment Period

End point title	Change From Baseline in Psoriasis Area and Severity Index (PASI) scores, Up to Week 16 - Investigational Treatment Period
End point description:	Combined assessment of lesion severity and area affected into single score. Body was divided into 4 sections: head, arms, trunk, legs. For each section, percent area of skin involved was estimated: 0= 0% to 6= 90–100%. Severity was estimated by clinical signs: erythema, induration, desquamation; scale: 0= none to 4= maximum. Final PASI = sum of severity parameters for each section*area score*weight of section (head: 0.1, arms: 0.2, body: 0.3, legs: 0.4); total possible score range: 0= no disease to 72= maximal disease. The analysis population included all randomized subjects who received at least 1 dose of study drug (PF-06826647 or placebo) after non-responder imputation applied (the subjects discontinued due to coronavirus disease 2019 were removed).
End point type	Secondary
End point timeframe:	Baseline up to Week 16

End point values	Placebo QD Group	PF-06826647 50 mg QD Group	PF-06826647 100 mg QD Group	PF-06826647 200 mg QD Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	36	20	20	38
Units: Units on a scale				
least squares mean (standard error)				
Week 1 (n=42, 22, 21, 44, 40)	-1.18 (± 0.697)	-2.82 (± 0.969)	-1.96 (± 0.984)	-4.32 (± 0.676)
Week 2 (n=42, 22, 21, 45, 41)	-3.44 (± 0.959)	-3.83 (± 1.330)	-3.24 (± 1.356)	-0.804 (± 0.926)
Week 4 (n=40, 21, 21, 44, 40)	-5.08 (± 1.108)	-5.16 (± 1.528)	-4.68 (± 1.553)	-12.25 (± 1.065)
Week 6 (n=38, 21, 20, 44, 39)	-6.02 (± 1.268)	-6.96 (± 1.737)	-7.53 (± 1.769)	-14.45 (± 1.212)
Week 8 (n=37, 20, 20, 41, 40)	-7.43 (± 1.333)	-7.55 (± 1.827)	-9.29 (± 1.847)	-15.74 (± 1.274)
Week 12 (n=36, 20, 21, 41, 40)	-8.09 (± 1.364)	-8.58 (± 1.863)	-10.02 (± 1.861)	-16.79 (± 1.300)
Week 16 (n=36, 20, 20, 38, 39)	-7.88 (± 1.417)	-9.34 (± 1.932)	-11.42 (± 1.928)	-17.68 (± 1.354)

End point values	PF-06826647 400 mg QD Group			
Subject group type	Subject analysis set			
Number of subjects analysed	39			
Units: Units on a scale				
least squares mean (standard error)				
Week 1 (n=42, 22, 21, 44, 40)	-3.00 (± 0.708)			

Week 2 (n=42, 22, 21, 45, 41)	-7.40 (\pm 0.970)			
Week 4 (n=40, 21, 21, 44, 40)	-12.16 (\pm 1.114)			
Week 6 (n=38, 21, 20, 44, 39)	-14.78 (\pm 1.268)			
Week 8 (n=37, 20, 20, 41, 40)	-17.12 (\pm 1.324)			
Week 12 (n=36, 20, 21, 41, 40)	-19.69 (\pm 1.340)			
Week 16 (n=36, 20, 20, 38, 39)	-20.21 (\pm 1.387)			

Statistical analyses

Statistical analysis title	Difference from Placebo QD at Week 16
Comparison groups	Placebo QD Group v PF-06826647 50 mg QD Group
Number of subjects included in analysis	56
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Least Squares Mean Difference
Point estimate	-1.46
Confidence interval	
level	90 %
sides	2-sided
lower limit	-5.42
upper limit	2.51

Statistical analysis title	Difference from Placebo QD at Week 16
Comparison groups	Placebo QD Group v PF-06826647 100 mg QD Group
Number of subjects included in analysis	56
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Least Squares Mean Difference
Point estimate	-3.54
Confidence interval	
level	90 %
sides	2-sided
lower limit	-7.5
upper limit	0.42

Statistical analysis title	Difference from Placebo QD at Week 16
Comparison groups	Placebo QD Group v PF-06826647 200 mg QD Group
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	superiority

Parameter estimate	Least Squares Mean Difference
Point estimate	-9.8
Confidence interval	
level	90 %
sides	2-sided
lower limit	-13.05
upper limit	-6.56

Statistical analysis title	Difference from Placebo QD at Week 16
Comparison groups	Placebo QD Group v PF-06826647 400 mg QD Group
Number of subjects included in analysis	75
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Least Squares Mean Difference
Point estimate	-12.33
Confidence interval	
level	90 %
sides	2-sided
lower limit	-15.61
upper limit	-9.04

Secondary: Percent Change From Baseline in Psoriasis Area and Severity Index (PASI) scores, Up to Week 16 - Investigational Treatment Period

End point title	Percent Change From Baseline in Psoriasis Area and Severity Index (PASI) scores, Up to Week 16 - Investigational Treatment Period
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End point description:

Combined assessment of lesion severity and area affected into single score. Body was divided into 4 sections: head, arms, trunk, legs. For each section, percent area of skin involved was estimated: 0= 0% to 6= 90–100%. Severity was estimated by clinical signs: erythema, induration, desquamation; scale: 0= none to 4= maximum. Final PASI = sum of severity parameters for each section*area score*weight of section (head: 0.1, arms: 0.2, body: 0.3, legs: 0.4); total possible score range: 0= no disease to 72= maximal disease. The analysis population included all randomized subjects who received at least 1 dose of study drug (PF-06826647 or placebo) after non-responder imputation applied (the subjects discontinued due to coronavirus disease 2019 were removed).

End point type	Secondary
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End point timeframe:

Baseline up to Week 16

End point values	Placebo QD Group	PF-06826647 50 mg QD Group	PF-06826647 100 mg QD Group	PF-06826647 200 mg QD Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	36	20	20	38
Units: Percent change				
least squares mean (standard error)				

Week 1 (n=42, 22, 21, 44, 40)	-5.63 (± 2.858)	-9.42 (± 3.975)	-8.93 (± 4.039)	-17.41 (± 2.774)
Week 2 (n=42, 22, 21, 45, 41)	-16.18 (± 3.809)	-14.80 (± 5.283)	-14.37 (± 5.385)	-33.65 (± 3.677)
Week 4 (n=40, 21, 21, 44, 40)	-22.66 (± 4.437)	-20.88 (± 6.107)	-22.70 (± 6.205)	-51.26 (± 4.259)
Week 6 (n=38, 21, 20, 44, 39)	-27.07 (± 4.833)	-30.25 (± 6.619)	-33.79 (± 6.739)	-60.63 (± 4.620)
Week 8 (n=37, 20, 20, 41, 40)	-31.16 (± 4.983)	-33.27 (± 6.831)	-39.81 (± 6.909)	-66.51 (± 4.763)
Week 12 (n=36, 20, 21, 41, 40)	-32.66 (± 5.137)	-37.24 (± 7.010)	-42.25 (± 6.996)	-70.28 (± 4.886)
Week 16 (n=36, 20, 20, 38, 39)	-33.29 (± 5.369)	-41.92 (± 7.304)	-46.31 (± 7.271)	-74.03 (± 5.122)

End point values	PF-06826647 400 mg QD Group			
Subject group type	Subject analysis set			
Number of subjects analysed	39			
Units: Percent change				
least squares mean (standard error)				
Week 1 (n=42, 22, 21, 44, 40)	-12.55 (± 2.908)			
Week 2 (n=42, 22, 21, 45, 41)	-30.58 (± 3.851)			
Week 4 (n=40, 21, 21, 44, 40)	-53.81 (± 4.449)			
Week 6 (n=38, 21, 20, 44, 39)	-64.03 (± 4.828)			
Week 8 (n=37, 20, 20, 41, 40)	-72.81 (± 4.954)			
Week 12 (n=36, 20, 21, 41, 40)	-84.17 (± 5.039)			
Week 16 (n=36, 20, 20, 38, 39)	-86.33 (± 5.236)			

Statistical analyses

Statistical analysis title	Difference from Placebo QD at Week 16
Comparison groups	Placebo QD Group v PF-06826647 50 mg QD Group
Number of subjects included in analysis	56
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Least Squares Mean Difference
Point estimate	-8.63
Confidence interval	
level	90 %
sides	2-sided
lower limit	-23.61
upper limit	6.35

Statistical analysis title	Difference from Placebo QD at Week 16
Comparison groups	Placebo QD Group v PF-06826647 100 mg QD Group
Number of subjects included in analysis	56
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Least Squares Mean Difference
Point estimate	-13.02
Confidence interval	
level	90 %
sides	2-sided
lower limit	-27.98
upper limit	1.94

Statistical analysis title	Difference from Placebo QD at Week 16
Comparison groups	Placebo QD Group v PF-06826647 200 mg QD Group
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Least Squares Mean Difference
Point estimate	-40.74
Confidence interval	
level	90 %
sides	2-sided
lower limit	-53.02
upper limit	-28.46

Statistical analysis title	Difference from Placebo QD at Week 16
Comparison groups	Placebo QD Group v PF-06826647 400 mg QD Group
Number of subjects included in analysis	75
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Least Squares Mean Difference
Point estimate	-53.04
Confidence interval	
level	90 %
sides	2-sided
lower limit	-65.44
upper limit	-40.63

Secondary: Change From Baseline in PeakPruritus Numerical Rating Scale (PP-

NRS) scores, Up to Week 16 - Investigational Treatment Period

End point title	Change From Baseline in PeakPruritus Numerical Rating Scale (PP-NRS) scores, Up to Week 16 - Investigational Treatment Period
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End point description:

The intensity of pruritus was assessed by a PP-NRS, an 11-category numeric rating scale from 0 to 10, which was subject reported. Subjects were asked to assess their itch over the past 24 hours, anchored by the terms "no itch" (0) and "worst itch imaginable" (10) at the ends. The analysis population included all randomized subjects who received at least 1 dose of study drug (PF-06826647 or placebo) after non-responder imputation applied (the subjects discontinued due to coronavirus disease 2019 were removed).

End point type	Secondary
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End point timeframe:

Baseline up to Week 16

End point values	Placebo QD Group	PF-06826647 50 mg QD Group	PF-06826647 100 mg QD Group	PF-06826647 200 mg QD Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	33	17	18	35
Units: Units on a scale				
least squares mean (standard error)				
Study Day 2, Week 1 (n=38, 17, 19, 41, 37)	-0.60 (± 0.238)	0.05 (± 0.355)	-0.64 (± 0.331)	-0.76 (± 0.229)
Study Day 3, Week 1 (n=38, 17, 20, 40, 38)	-0.71 (± 0.239)	-0.65 (± 0.354)	-0.90 (± 0.325)	-0.83 (± 0.230)
Study Day 4, Week 1 (n=38, 17, 19, 41, 37)	-0.76 (± 0.234)	-0.83 (± 0.348)	-0.89 (± 0.323)	-1.24 (± 0.224)
Study Day 5, Week 1 (n=38, 16, 18, 41, 35)	-0.63 (± 0.233)	-0.91 (± 0.348)	-1.12 (± 0.324)	-1.26 (± 0.223)
Study Day 6, Week 1 (n=38, 17, 19, 41, 34)	-0.82 (± 0.246)	-0.94 (± 0.362)	-0.81 (± 0.336)	-1.49 (± 0.235)
Study Day 7, Week 1 (n=37, 17, 18, 38, 37)	-0.72 (± 0.272)	-1.11 (± 0.399)	-0.86 (± 0.372)	-1.75 (± 0.261)
Study Day 8, Week 1 (n=37, 16, 20, 42, 37)	-0.83 (± 0.274)	-1.26 (± 0.403)	-0.92 (± 0.371)	-1.65 (± 0.261)
Study Day 9, Week 1 (n=37, 17, 18, 39, 37)	-0.79 (± 0.289)	-1.32 (± 0.425)	-1.08 (± 0.394)	-1.50 (± 0.278)
Study Day 10, Week 1 (n=37, 16, 20, 40, 36)	-0.85 (± 0.284)	-1.48 (± 0.420)	-1.01 (± 0.384)	-1.63 (± 0.272)
Study Day 11, Week 1 (n=33, 15, 19, 37, 36)	-0.70 (± 0.291)	-1.55 (± 0.429)	-1.11 (± 0.392)	-1.67 (± 0.278)
Study Day 12, Week 2 (n=32, 16, 18, 38, 35)	-0.63 (± 0.289)	-1.67 (± 0.424)	-0.92 (± 0.390)	-1.93 (± 0.275)
Study Day 13, Week 2 (n=34, 16, 19, 41, 33)	-0.78 (± 0.294)	-1.49 (± 0.433)	-1.15 (± 0.397)	-2.18 (± 0.280)
Study Day 14, Week 2 (n=34, 17, 20, 38, 36)	-0.82 (± 0.317)	-1.66 (± 0.464)	-1.21 (± 0.426)	-2.15 (± 0.302)
Study Day 15, Week 2 (n=36, 16, 19, 40, 38)	-0.75 (± 0.308)	-1.48 (± 0.454)	-1.18 (± 0.417)	-2.20 (± 0.294)
Study Day 16, Week 2 (n=34, 16, 18, 37, 37)	-0.73 (± 0.314)	-1.52 (± 0.462)	-1.13 (± 0.426)	-2.29 (± 0.301)
Week 4 (n=36, 17, 20, 41, 37)	-0.54 (± 0.354)	-1.74 (± 0.517)	-1.64 (± 0.477)	-2.90 (± 0.337)
Week 8 (n=34, 17, 20, 37, 38)	-1.24 (± 0.391)	-1.10 (± 0.561)	-1.93 (± 0.517)	-4.10 (± 0.374)

Week 12 (n=34, 17, 20, 38, 37)	-0.84 (± 0.455)	-1.66 (± 0.651)	-2.18 (± 0.599)	-3.92 (± 0.433)
Week 16 (n=33, 17, 18, 35, 36)	-0.93 (± 0.453)	-2.15 (± 0.645)	-2.14 (± 0.604)	-4.40 (± 0.435)

End point values	PF-06826647 400 mg QD Group			
Subject group type	Subject analysis set			
Number of subjects analysed	36			
Units: Units on a scale				
least squares mean (standard error)				
Study Day 2, Week 1 (n=38, 17, 19, 41, 37)	-0.41 (± 0.241)			
Study Day 3, Week 1 (n=38, 17, 20, 40, 38)	-0.88 (± 0.239)			
Study Day 4, Week 1 (n=38, 17, 19, 41, 37)	-1.04 (± 0.236)			
Study Day 5, Week 1 (n=38, 16, 18, 41, 35)	-1.08 (± 0.237)			
Study Day 6, Week 1 (n=38, 17, 19, 41, 34)	-1.34 (± 0.250)			
Study Day 7, Week 1 (n=37, 17, 18, 38, 37)	-1.11 (± 0.273)			
Study Day 8, Week 1 (n=37, 16, 20, 42, 37)	-1.21 (± 0.276)			
Study Day 9, Week 1 (n=37, 17, 18, 39, 37)	-1.43 (± 0.292)			
Study Day 10, Week 1 (n=37, 16, 20, 40, 36)	-1.46 (± 0.286)			
Study Day 11, Week 1 (n=33, 15, 19, 37, 36)	-1.27 (± 0.291)			
Study Day 12, Week 2 (n=32, 16, 18, 38, 35)	-1.39 (± 0.289)			
Study Day 13, Week 2 (n=34, 16, 19, 41, 33)	-1.61 (± 0.296)			
Study Day 14, Week 2 (n=34, 17, 20, 38, 36)	-1.81 (± 0.317)			
Study Day 15, Week 2 (n=36, 16, 19, 40, 38)	-1.83 (± 0.309)			
Study Day 16, Week 2 (n=34, 16, 18, 37, 37)	-1.80 (± 0.314)			
Week 4 (n=36, 17, 20, 41, 37)	-2.57 (± 0.354)			
Week 8 (n=34, 17, 20, 37, 38)	-4.12 (± 0.381)			
Week 12 (n=34, 17, 20, 38, 37)	-4.27 (± 0.442)			
Week 16 (n=33, 17, 18, 35, 36)	-4.59 (± 0.440)			

Statistical analyses

Statistical analysis title	Difference from Placebo QD at Week 16
Comparison groups	Placebo QD Group v PF-06826647 50 mg QD Group
Number of subjects included in analysis	50
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Least Squares Mean Difference
Point estimate	-1.22
Confidence interval	
level	90 %
sides	2-sided
lower limit	-2.52
upper limit	0.09

Statistical analysis title	Difference from Placebo QD at Week 16
Comparison groups	Placebo QD Group v PF-06826647 100 mg QD Group
Number of subjects included in analysis	51
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Least Squares Mean Difference
Point estimate	-1.21
Confidence interval	
level	90 %
sides	2-sided
lower limit	-2.46
upper limit	0.05

Statistical analysis title	Difference from Placebo QD at Week 16
Comparison groups	Placebo QD Group v PF-06826647 200 mg QD Group
Number of subjects included in analysis	68
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Least Squares Mean Difference
Point estimate	-3.47
Confidence interval	
level	90 %
sides	2-sided
lower limit	-4.51
upper limit	-2.43

Statistical analysis title	Difference from Placebo QD at Week 16
Comparison groups	Placebo QD Group v PF-06826647 400 mg QD Group
Number of subjects included in analysis	69
Analysis specification	Pre-specified

Analysis type	superiority
Parameter estimate	Least Squares Mean Difference
Point estimate	-3.66
Confidence interval	
level	90 %
sides	2-sided
lower limit	-4.71
upper limit	-2.61

Secondary: Percentage of Subjects Achieving Psoriasis Symptom Inventory (PSI) Response of "Not at All" or "Mild" on Every Item, at Week 16 - Investigational Treatment Period

End point title	Percentage of Subjects Achieving Psoriasis Symptom Inventory (PSI) Response of "Not at All" or "Mild" on Every Item, at Week 16 - Investigational Treatment Period
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End point description:

The Psoriasis Symptom Inventory (PSI) is a self administered 8-item questionnaire that measures the severity of psoriasis symptoms over the past 24 hours and the past 7 days. The measure includes concepts of itch, pain, burning, stinging, cracking, scaling, flaking, and redness. Subjects were asked to respond to each item using a 5-point Likert response scale: 0: not all severe, 1: mild, 2: moderate, 3: severe and 4: very severe. The analysis population included all randomized subjects who received at least 1 dose of study drug (PF-06826647 or placebo) after non-responder imputation applied (the subjects discontinued due to coronavirus disease 2019 were removed).

End point type	Secondary
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End point timeframe:

Baseline up to Week 16

End point values	Placebo QD Group	PF-06826647 50 mg QD Group	PF-06826647 100 mg QD Group	PF-06826647 200 mg QD Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	42	22	21	45
Units: Percentage of subjects				
number (confidence interval 90%)				
Study Day 2, Week 1	7.1 (2.65 to 17.39)	0 (0.00 to 12.60)	4.8 (0.50 to 20.57)	6.7 (2.47 to 16.17)
Study Day 3, Week 1	7.1 (2.65 to 17.39)	0 (0.00 to 12.60)	19.0 (8.58 to 37.19)	6.7 (2.47 to 16.17)
Study Day 4, Week 1	9.5 (4.22 to 19.38)	4.5 (0.48 to 19.56)	14.3 (5.37 to 32.81)	13.3 (5.97 to 23.73)
Study Day 5, Week 1	7.1 (2.65 to 17.39)	9.1 (2.44 to 23.60)	14.3 (5.37 to 32.81)	15.6 (8.42 to 25.96)
Study Day 6, Week 1	4.8 (1.27 to 13.53)	13.6 (5.12 to 31.13)	19.0 (8.58 to 37.19)	20.0 (11.72 to 31.73)
Study Day 7, Week 1	9.5 (4.22 to 19.38)	9.1 (2.44 to 23.60)	19.0 (8.58 to 37.19)	17.8 (9.17 to 29.70)
Study Day 8, Week 1	11.9 (5.91 to 22.74)	9.1 (2.44 to 23.60)	14.3 (5.37 to 32.81)	20.0 (11.72 to 31.73)
Study Day 9, Week 1	9.5 (4.22 to 19.38)	9.1 (2.44 to 23.60)	9.5 (2.56 to 24.50)	20.0 (11.72 to 31.73)
Study Day 10, Week 1	11.9 (5.91 to 22.74)	4.5 (0.48 to 19.56)	19.0 (8.58 to 37.19)	24.4 (15.47 to 35.88)

Study Day 11, Week 1	9.5 (4.22 to 19.38)	4.5 (0.48 to 19.56)	19.0 (8.58 to 37.19)	20.0 (11.72 to 31.73)
Study Day 12, Week 2	4.8 (1.27 to 13.53)	4.5 (0.48 to 19.56)	19.0 (8.58 to 37.19)	22.2 (12.58 to 33.79)
Study Day 13, Week 2	11.9 (5.91 to 22.74)	18.2 (8.17 to 35.25)	14.3 (5.37 to 32.81)	40.0 (28.66 to 52.89)
Study Day 14, Week 2	11.9 (5.91 to 22.74)	22.7 (11.49 to 39.52)	14.3 (5.37 to 32.81)	33.3 (21.80 to 46.08)
Study Day 15, Week 2	4.8 (1.27 to 13.53)	9.1 (2.44 to 23.60)	14.3 (5.37 to 32.81)	33.3 (21.80 to 46.08)
Study Day 16, Week 2	14.3 (6.41 to 25.56)	13.6 (5.12 to 31.13)	9.5 (2.56 to 24.50)	24.4 (15.47 to 35.88)
Week 4	14.3 (6.41 to 25.56)	13.6 (5.12 to 31.13)	28.6 (13.24 to 46.41)	44.4 (31.73 to 56.75)
Week 8	11.9 (5.91 to 22.74)	22.7 (11.49 to 39.52)	23.8 (12.06 to 41.72)	53.3 (40.87 to 66.21)
Week 12	7.1 (2.65 to 17.39)	31.8 (18.11 to 50.00)	28.6 (13.24 to 46.41)	55.6 (43.25 to 68.27)
Week 16	14.3 (6.41 to 25.56)	27.3 (12.60 to 44.36)	38.1 (20.57 to 58.28)	55.6 (43.25 to 68.27)

End point values	PF-06826647 400 mg QD Group			
Subject group type	Subject analysis set			
Number of subjects analysed	41			
Units: Percentage of subjects				
number (confidence interval 90%)				
Study Day 2, Week 1	12.2 (6.05 to 23.04)			
Study Day 3, Week 1	12.2 (6.05 to 23.04)			
Study Day 4, Week 1	14.6 (6.57 to 26.23)			
Study Day 5, Week 1	19.5 (10.10 to 31.18)			
Study Day 6, Week 1	19.5 (10.10 to 31.18)			
Study Day 7, Week 1	19.5 (10.10 to 31.18)			
Study Day 8, Week 1	19.5 (10.10 to 31.18)			
Study Day 9, Week 1	22.0 (12.96 to 35.14)			
Study Day 10, Week 1	19.5 (10.10 to 31.18)			
Study Day 11, Week 1	26.8 (17.12 to 39.77)			
Study Day 12, Week 2	29.3 (17.84 to 42.13)			
Study Day 13, Week 2	26.8 (17.12 to 39.77)			
Study Day 14, Week 2	34.1 (23.04 to 46.94)			
Study Day 15, Week 2	29.3 (17.84 to 42.13)			
Study Day 16, Week 2	39.0 (26.23 to 53.06)			

Week 4	43.9 (31.18 to 57.87)			
Week 8	63.4 (50.00 to 75.43)			
Week 12	63.4 (50.00 to 75.43)			
Week 16	63.4 (50.00 to 75.43)			

Statistical analyses

Statistical analysis title	Difference from Placebo QD at Week 16
Comparison groups	Placebo QD Group v PF-06826647 50 mg QD Group
Number of subjects included in analysis	64
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Risk difference (RD)
Point estimate	12.99
Confidence interval	
level	90 %
sides	2-sided
lower limit	-4.52
upper limit	32.87

Statistical analysis title	Difference from Placebo QD at Week 16
Comparison groups	Placebo QD Group v PF-06826647 100 mg QD Group
Number of subjects included in analysis	63
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Risk difference (RD)
Point estimate	23.81
Confidence interval	
level	90 %
sides	2-sided
lower limit	2.62
upper limit	44.64

Statistical analysis title	Difference from Placebo QD at Week 16
Comparison groups	Placebo QD Group v PF-06826647 200 mg QD Group
Number of subjects included in analysis	87
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Risk difference (RD)

Point estimate	41.27
Confidence interval	
level	90 %
sides	2-sided
lower limit	23.47
upper limit	56.18

Statistical analysis title	Difference from Placebo QD at Week 16
Comparison groups	Placebo QD Group v PF-06826647 400 mg QD Group
Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Risk difference (RD)
Point estimate	49.13
Confidence interval	
level	90 %
sides	2-sided
lower limit	30.62
upper limit	63.69

Secondary: Change From Baseline in Psoriasis Symptom Inventory (PSI), Up to Week 16 - Investigational Treatment Period

End point title	Change From Baseline in Psoriasis Symptom Inventory (PSI), Up to Week 16 - Investigational Treatment Period
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End point description:

The Psoriasis Symptom Inventory (PSI) is a self administered 8-item questionnaire that measures the severity of psoriasis symptoms over the past 24 hours and the past 7 days. The measure includes concepts of itch, pain, burning, stinging, cracking, scaling, flaking, and redness. Subjects were asked to respond to each item using a 5-point Likert response scale: 0: not all severe, 1: mild, 2: moderate, 3: severe and 4: very severe. The analysis population included all randomized subjects who received at least 1 dose of study drug (PF-06826647 or placebo) after non-responder imputation applied (the subjects discontinued due to coronavirus disease 2019 were removed).

End point type	Secondary
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End point timeframe:

Baseline up to Week 16

End point values	Placebo QD Group	PF-06826647 50 mg QD Group	PF-06826647 100 mg QD Group	PF-06826647 200 mg QD Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	33	17	18	35
Units: Units on a scale				
least squares mean (standard error)				
Study Day 2, Week 1 (n=38, 18, 19, 42, 37)	-1.51 (± 0.636)	-0.89 (± 0.927)	-1.98 (± 0.880)	-2.54 (± 0.605)
Study Day 3, Week 1 (n=38, 18, 21, 41, 38)	-2.70 (± 0.653)	-1.95 (± 0.952)	-3.65 (± 0.879)	-3.45 (± 0.624)

Study Day 4, Week 1 (n=38, 17, 19, 41, 37)	-2.88 (± 0.666)	-3.05 (± 0.985)	-3.95 (± 0.915)	-4.61 (± 0.637)
Study Day 5, Week 1 (n=38, 16, 18, 41, 35)	-2.55 (± 0.692)	-3.18 (± 1.032)	-3.87 (± 0.959)	-5.40 (± 0.661)
Study Day 6, Week 1 (n=38, 17, 19, 41, 35)	-3.01 (± 0.716)	-3.98 (± 1.058)	-3.94 (± 0.981)	-5.43 (± 0.684)
Study Day 7, Week 1 (n=37, 17, 18, 38, 38)	-3.23 (± 0.770)	-4.34 (± 1.134)	-4.08 (± 1.059)	-6.42 (± 0.740)
Study Day 8, Week 1 (n=37, 16, 20, 42, 38)	-3.27 (± 0.768)	-4.38 (± 1.137)	-4.65 (± 1.042)	-6.23 (± 0.731)
Study Day 9, Week 1 (n=37, 17, 18, 39, 38)	-3.11 (± 0.788)	-3.95 (± 1.159)	-4.54 (± 1.078)	-5.71 (± 0.756)
Study Day 10, Week 1 (n=37, 17, 20, 40, 37)	-3.29 (± 0.781)	-4.24 (± 1.150)	-4.15 (± 1.055)	-6.22 (± 0.747)
Study Day 11, Week 1 (n=33, 15, 19, 37, 37)	-2.89 (± 0.825)	-4.72 (± 1.216)	-4.41 (± 1.111)	-7.06 (± 0.787)
Study Day 12, Week 2 (n=32, 16, 19, 38, 36)	-3.04 (± 0.763)	-4.54 (± 1.118)	-4.65 (± 1.027)	-7.10 (± 0.726)
Study Day 13, Week 2 (n=34, 16, 19, 41, 34)	-2.94 (± 0.781)	-5.61 (± 1.149)	-4.79 (± 1.055)	-7.94 (± 0.742)
Study Day 14, Week 2 (n=34, 17, 21, 38, 37)	-3.25 (± 0.793)	-5.84 (± 1.162)	-5.22 (± 1.065)	-8.12 (± 0.757)
Study Day 15, Week 2 (n=36, 16, 20, 40, 39)	-2.71 (± 0.830)	-4.98 (± 1.227)	-5.23 (± 1.123)	-7.84 (± 0.793)
Study Day 16, Week 2 (n=34, 16, 18, 37, 38)	-3.27 (± 0.847)	-5.03 (± 1.250)	-4.83 (± 1.150)	-8.12 (± 0.810)
Week 4 (n=36, 17, 20, 41, 38)	-2.53 (± 0.990)	-4.83 (± 1.449)	-6.58 (± 1.338)	-9.14 (± 0.943)
Week 8 (n=34, 17, 20, 37, 39)	-3.45 (± 1.069)	-4.09 (± 1.536)	-7.30 (± 1.407)	-11.63 (± 1.022)
Week 12 (n=34, 17, 20, 38, 38)	-2.27 (± 1.208)	-5.65 (± 1.722)	-7.35 (± 1.572)	-11.50 (± 1.146)
Week 16 (n=33, 17, 18, 35, 37)	-1.87 (± 1.260)	-6.07 (± 1.782)	-8.31 (± 1.661)	-12.38 (± 1.205)

End point values	PF-06826647 400 mg QD Group			
Subject group type	Subject analysis set			
Number of subjects analysed	37			
Units: Units on a scale				
least squares mean (standard error)				
Study Day 2, Week 1 (n=38, 18, 19, 42, 37)	-1.25 (± 0.639)			
Study Day 3, Week 1 (n=38, 18, 21, 41, 38)	-2.79 (± 0.650)			
Study Day 4, Week 1 (n=38, 17, 19, 41, 37)	-4.28 (± 0.665)			
Study Day 5, Week 1 (n=38, 16, 18, 41, 35)	-3.93 (± 0.696)			
Study Day 6, Week 1 (n=38, 17, 19, 41, 35)	-4.77 (± 0.717)			
Study Day 7, Week 1 (n=37, 17, 18, 38, 38)	-4.90 (± 0.763)			
Study Day 8, Week 1 (n=37, 16, 20, 42, 38)	-5.67 (± 0.762)			
Study Day 9, Week 1 (n=37, 17, 18, 39, 38)	-5.70 (± 0.782)			

Study Day 10, Week 1 (n=37, 17, 20, 40, 37)	-6.02 (± 0.776)			
Study Day 11, Week 1 (n=33, 15, 19, 37, 37)	-6.03 (± 0.812)			
Study Day 12, Week 2 (n=32, 16, 19, 38, 36)	-6.62 (± 0.753)			
Study Day 13, Week 2 (n=34, 16, 19, 41, 34)	-7.16 (± 0.776)			
Study Day 14, Week 2 (n=34, 17, 21, 38, 37)	-7.09 (± 0.784)			
Study Day 15, Week 2 (n=36, 16, 20, 40, 39)	-7.47 (± 0.821)			
Study Day 16, Week 2 (n=34, 16, 18, 37, 38)	-7.45 (± 0.836)			
Week 4 (n=36, 17, 20, 41, 38)	-9.02 (± 0.978)			
Week 8 (n=34, 17, 20, 37, 39)	-12.19 (± 1.026)			
Week 12 (n=34, 17, 20, 38, 38)	-13.42 (± 1.145)			
Week 16 (n=33, 17, 18, 35, 37)	-12.68 (± 1.191)			

Statistical analyses

Statistical analysis title	Difference from Placebo QD at Week 16
Comparison groups	Placebo QD Group v PF-06826647 50 mg QD Group
Number of subjects included in analysis	50
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Least Squares Mean Difference
Point estimate	-4.21
Confidence interval	
level	90 %
sides	2-sided
lower limit	-7.82
upper limit	-0.59

Statistical analysis title	Difference from Placebo QD at Week 16
Comparison groups	Placebo QD Group v PF-06826647 100 mg QD Group
Number of subjects included in analysis	51
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Least Squares Mean Difference
Point estimate	-6.44
Confidence interval	
level	90 %
sides	2-sided
lower limit	-9.89
upper limit	-2.99

Statistical analysis title	Difference from Placebo QD at Week 16
Comparison groups	Placebo QD Group v PF-06826647 200 mg QD Group
Number of subjects included in analysis	68
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Least Squares Mean Difference
Point estimate	-10.51
Confidence interval	
level	90 %
sides	2-sided
lower limit	-13.4
upper limit	-7.62

Statistical analysis title	Difference from Placebo QD at Week 16
Comparison groups	Placebo QD Group v PF-06826647 400 mg QD Group
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Least Squares Mean Difference
Point estimate	-10.81
Confidence interval	
level	90 %
sides	2-sided
lower limit	-13.68
upper limit	-7.94

Secondary: Number of Subjects With Treatment-Emergent Adverse Events (All-Causality), Up to Week 16 - Investigational Treatment Period

End point title	Number of Subjects With Treatment-Emergent Adverse Events (All-Causality), Up to Week 16 - Investigational Treatment Period
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End point description:

An adverse event (AE) was any untoward medical occurrence in a subject who received study drug without regard to possibility of causal relationship. A serious AE (SAE) was an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial or prolonged inpatient hospitalization; life-threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly. An AE was considered treatment-emergent if the event started on or after the first dosing day and time/start time but before the last dose plus the lag time. IP=investigational product; TD=temporary discontinuation. The analysis population included all subjects who received at least 1 dose of study drug (PF-06826647 or placebo).

End point type	Secondary
End point timeframe:	
Baseline up to Week 16	

End point values	Placebo QD Group	PF-06826647 50 mg QD Group	PF-06826647 100 mg QD Group	PF-06826647 200 mg QD Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	22	23	45
Units: Subjects				
Subjects with AEs	23	13	16	28
Subjects with SAEs	0	1	0	1
Subjects with severe AEs	1	0	1	2
Subjects discontinued from study due to AEs	1	0	0	5
IP discontinued due to AE, subjects continue	0	0	0	1
Subjects dose reduced or TD due to AEs	1	1	2	3

End point values	PF-06826647 400 mg QD Group			
Subject group type	Subject analysis set			
Number of subjects analysed	43			
Units: Subjects				
Subjects with AEs	29			
Subjects with SAEs	0			
Subjects with severe AEs	3			
Subjects discontinued from study due to AEs	3			
IP discontinued due to AE, subjects continue	0			
Subjects dose reduced or TD due to AEs	3			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Treatment-Emergent Adverse Events (Treatment Related), Up to Week 16 - Investigational Treatment Period

End point title	Number of Subjects With Treatment-Emergent Adverse Events (Treatment Related), Up to Week 16 - Investigational Treatment Period
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End point description:

Treatment-related adverse event (AE) was any untoward medical occurrence attributed to study drug in a subject who received study drug. Serious adverse event (SAE) was an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial or prolonged inpatient hospitalization; life-threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly. An AE was considered treatment-emergent if the event started on or after the first dosing day and time/start time but before the last dose plus the lag time. Relatedness to investigational product was assessed by the investigator. Subjects with multiple occurrences of an AE within a category were counted once within the category. IP=investigational product; TD=temporary discontinuation. The analysis population included all subjects who received at least 1 dose of study drug (PF-06826647 or placebo).

End point type	Secondary
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End point timeframe:

End point values	Placebo QD Group	PF-06826647 50 mg QD Group	PF-06826647 100 mg QD Group	PF-06826647 200 mg QD Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	22	23	45
Units: Subjects				
Subjects with AEs	4	0	4	11
Subjects with SAEs	0	0	0	1
Subjects with severe AEs	0	0	0	2
Subjects discontinued from study due to AEs	0	0	0	4
IP discontinued due to AE, subjects continue	0	0	0	1
Subjects dose reduced or TD due to AEs	0	0	0	1

End point values	PF-06826647 400 mg QD Group			
Subject group type	Subject analysis set			
Number of subjects analysed	43			
Units: Subjects				
Subjects with AEs	8			
Subjects with SAEs	0			
Subjects with severe AEs	1			
Subjects discontinued from study due to AEs	3			
IP discontinued due to AE, subjects continue	0			
Subjects dose reduced or TD due to AEs	1			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Electrocardiogram (ECG) Data Meeting Pre-defined Criteria, Up to Week 16 - Investigational Treatment Period

End point title	Number of Subjects With Electrocardiogram (ECG) Data Meeting Pre-defined Criteria, Up to Week 16 - Investigational Treatment Period
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End point description:

Criteria for ECG abnormalities: maximum PR interval ≥ 300 milliseconds (msec) and maximum increase PR interval increase from baseline (IFB): percent change (Pctchg) ≥ 25 percent (%) for baseline value of >200 msec and Pctchg $\geq 50\%$ for baseline value of ≤ 200 msec for PR interval, maximum QRS interval ≥ 140 msec and a maximum IFB: Pctchg $\geq 50\%$, maximum QTcF interval (Fridericia's Correction) of 450 msec to ≤ 480 msec, 480 msec to ≤ 500 msec and a maximum change of <30 change ≤ 60 or >60 msec from baseline. The analysis population included all subjects who received at least 1 dose of study drug (PF-06826647 or placebo) and who had at least 1 ECG assessment.

End point type	Secondary
End point timeframe:	
Baseline up to Week 16	

End point values	Placebo QD Group	PF-06826647 50 mg QD Group	PF-06826647 100 mg QD Group	PF-06826647 200 mg QD Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	44	22	23	44
Units: Subjects				
PR interval, single beat (msec) ≥ 300	1	0	0	0
PR interval, single beat (msec) Pctchg $\geq 25/50\%$	0	0	2	1
QRS duration, single beat (msec) ≥ 140	1	0	0	0
QRS duration, single beat (msec) Pctchg $\geq 50\%$	1	0	1	0
450 < QTcF (msec) ≤ 480	1	0	2	2
480 < QTcF (msec) ≤ 500	1	0	0	0
30 < QTcF (msec) change ≤ 60	0	1	1	1
QTcF (msec) change > 60	1	0	1	0

End point values	PF-06826647 400 mg QD Group			
Subject group type	Subject analysis set			
Number of subjects analysed	43			
Units: Subjects				
PR interval, single beat (msec) ≥ 300	0			
PR interval, single beat (msec) Pctchg $\geq 25/50\%$	0			
QRS duration, single beat (msec) ≥ 140	0			
QRS duration, single beat (msec) Pctchg $\geq 50\%$	0			
450 < QTcF (msec) ≤ 480	0			
480 < QTcF (msec) ≤ 500	0			
30 < QTcF (msec) change ≤ 60	2			
QTcF (msec) change > 60	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Vital Sign Data Meeting Pre-defined Criteria, Up to Week 16 - Investigational Treatment Period

End point title	Number of Subjects With Vital Sign Data Meeting Pre-defined
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End point description:

The vital signs were obtained with subject in the seated position, after having sat calmly for at least 5 minutes. Criteria for vital signs abnormalities: pulse rate >120 beats per minute (BPM), sitting diastolic blood pressure (BP) change ≥ 20 millimeter of mercury (mmHg) increase, sitting diastolic BP change ≥ 20 mmHg decrease, sitting systolic BP <90 mmHg, sitting systolic BP change ≥ 30 mmHg increase, and sitting systolic BP change ≥ 30 mmHg decrease. The analysis population included all subjects who received at least 1 dose of study drug (PF-06826647 or placebo).

End point type	Secondary
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End point timeframe:

Baseline up to Week 16.

End point values	Placebo QD Group	PF-06826647 50 mg QD Group	PF-06826647 100 mg QD Group	PF-06826647 200 mg QD Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	22	23	45
Units: Subjects				
Pulse rate (BPM) >120	0	0	0	0
Sitting diastolic BP (mmHg) change ≥ 20 increase	4	3	1	4
Sitting diastolic BP (mmHg) change ≥ 20 decrease	4	2	0	2
Sitting systolic BP (mmHg) <90 increase	0	0	0	0
Sitting systolic BP (mmHg) change ≥ 30 increase	0	1	2	2
Sitting systolic BP (mmHg) change ≥ 30 decrease	4	0	1	1

End point values	PF-06826647 400 mg QD Group			
Subject group type	Subject analysis set			
Number of subjects analysed	43			
Units: Subjects				
Pulse rate (BPM) >120	1			
Sitting diastolic BP (mmHg) change ≥ 20 increase	4			
Sitting diastolic BP (mmHg) change ≥ 20 decrease	4			
Sitting systolic BP (mmHg) <90 increase	1			
Sitting systolic BP (mmHg) change ≥ 30 increase	2			
Sitting systolic BP (mmHg) change ≥ 30 decrease	2			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Laboratory Test Abnormality - Hematology (Normal Baseline), Up to Week 16 - Investigational Treatment Period

End point title	Number of Subjects With Laboratory Test Abnormality - Hematology (Normal Baseline), Up to Week 16 - Investigational Treatment Period
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End point description:

Following hematology parameters were analyzed for laboratory examination: hemoglobin, hematocrit, erythrocytes (Ery.), reticulocytes, Ery. mean corpuscular volume, Ery. mean corpuscular hemoglobin (MCH), Ery. mean corpuscular hemoglobin concentration (MCHC), platelets, reticulocytes/erythrocytes, leukocytes, lymphocytes/leukocytes, neutrophils/leukocytes, basophils, basophils/leukocytes, eosinophils, eosinophils/leukocytes, monocytes, monocytes/leukocytes, activated partial thromboplastin time (aPTT), prothrombin time, neutrophils total count, and lymphocytes total count. The analysis population included all subjects who received at least 1 dose of study drug (PF-06826647 or placebo) and had at least 1 laboratory assessment. ULN=upper limit of normal; LLN=lower limit of normal.

End point type	Secondary
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End point timeframe:

Baseline up to Week 16

End point values	Placebo QD Group	PF-06826647 50 mg QD Group	PF-06826647 100 mg QD Group	PF-06826647 200 mg QD Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	22	23	45
Units: Subjects				
Hemoglobin (g/dL) <0.8*LLN	0	0	0	2
Hematocrit (%) <0.8*LLN	0	0	0	2
Erythrocytes (10 ⁶ /mm ³) <0.8*LLN	0	0	0	1
Reticulocytes (10 ³ /mm ³) <0.5*LLN	0	0	0	0
Reticulocytes (10 ³ /mm ³) >1.5*ULN	0	0	0	0
Ery. Mean Corpuscular Volume (um ³) <0.9*LLN	0	0	0	0
Ery. Mean Corpuscular Volume (um ³) >1.1*ULN	0	0	0	0
Ery. MCH (pg/cell) <0.9*LLN	0	0	0	0
Ery. MCH (pg/cell) >1.1*ULN	0	0	0	0
Ery. MCHC (g/dL) <0.9*LLN	0	0	0	0
Ery. MCHC (g/dL) >1.1*ULN	0	0	0	0
Platelets (10 ³ /mm ³) <0.5*LLN	0	0	0	0
Platelets (10 ³ /mm ³) >1.75*ULN	0	0	0	0
Reticulocytes/Erythrocytes (%) <0.5*LLN	0	0	0	0
Reticulocytes/Erythrocytes (%) >1.5*ULN	0	0	0	1
Leukocytes(10 ³ /mm ³) <0.6*LLN	0	0	0	1
Leukocytes(10 ³ /mm ³) >1.5*ULN	0	0	0	0
Lymphocytes/Leukocytes (%) <0.8*LLN	0	1	0	1
Lymphocytes/Leukocytes (%) >1.2*ULN	0	0	0	3
Neutrophils/Leukocytes (%) <0.8* LLN	1	0	0	2
Neutrophils/Leukocytes (%) >1.2*ULN	0	0	0	0
Basophils (10 ³ /mm ³) >1.2*ULN	0	0	0	1
Basophils/Leukocytes (%) >1.2*ULN	2	1	1	1
Eosinophils (10 ³ /mm ³) >1.2*ULN	1	1	0	0
Eosinophils/Leukocytes (%) >1.2*ULN	2	1	0	0

Monocytes ($10^3/\text{mm}^3$) $>1.2 \times \text{ULN}$	1	0	1	0
Monocytes/Leukocytes (%) $>1.2 \times \text{ULN}$	2	0	0	1
aPTT (sec) $>1.1 \times \text{ULN}$	1	0	0	0
Prothrombin Time (sec) $>1.1 \times \text{ULN}$	1	0	0	0
Neutrophils total count ($10^3/\text{mm}^3$) $<0.8 \times \text{LLN}$	1	0	2	3
Neutrophils total count ($10^3/\text{mm}^3$) $>1.2 \times \text{ULN}$	3	1	1	2
Lymphocytes total count ($10^3/\text{mm}^3$) $<0.8 \times \text{LLN}$	0	0	0	1
Lymphocytes total count ($10^3/\text{mm}^3$) $>1.2 \times \text{ULN}$	0	0	1	1

End point values	PF-06826647 400 mg QD Group			
Subject group type	Subject analysis set			
Number of subjects analysed	43			
Units: Subjects				
Hemoglobin (g/dL) $<0.8 \times \text{LLN}$	3			
Hematocrit (%) $<0.8 \times \text{LLN}$	3			
Erythrocytes ($10^6/\text{mm}^3$) $<0.8 \times \text{LLN}$	4			
Reticulocytes ($10^3/\text{mm}^3$) $<0.5 \times \text{LLN}$	2			
Reticulocytes ($10^3/\text{mm}^3$) $>1.5 \times \text{ULN}$	2			
Ery. Mean Corpuscular Volume (μm^3) $<0.9 \times \text{LLN}$	0			
Ery. Mean Corpuscular Volume (μm^3) $>1.1 \times \text{ULN}$	1			
Ery. MCH (pg/cell) $<0.9 \times \text{LLN}$	0			
Ery. MCH (pg/cell) $>1.1 \times \text{ULN}$	0			
Ery. MCHC (g/dL) $<0.9 \times \text{LLN}$	0			
Ery. MCHC (g/dL) $>1.1 \times \text{ULN}$	0			
Platelets ($10^3/\text{mm}^3$) $<0.5 \times \text{LLN}$	1			
Platelets ($10^3/\text{mm}^3$) $>1.75 \times \text{ULN}$	0			
Reticulocytes/Erythrocytes (%) $<0.5 \times \text{LLN}$	2			
Reticulocytes/Erythrocytes (%) $>1.5 \times \text{ULN}$	2			
Leukocytes($10^3/\text{mm}^3$) $<0.6 \times \text{LLN}$	1			
Leukocytes($10^3/\text{mm}^3$) $>1.5 \times \text{ULN}$	0			
Lymphocytes/Leukocytes (%) $<0.8 \times \text{LLN}$	3			
Lymphocytes/Leukocytes (%) $>1.2 \times \text{ULN}$	4			
Neutrophils/Leukocytes (%) $<0.8 \times \text{LLN}$	2			
Neutrophils/Leukocytes (%) $>1.2 \times \text{ULN}$	0			
Basophils ($10^3/\text{mm}^3$) $>1.2 \times \text{ULN}$	0			
Basophils/Leukocytes (%) $>1.2 \times \text{ULN}$	1			
Eosinophils ($10^3/\text{mm}^3$) $>1.2 \times \text{ULN}$	0			
Eosinophils/Leukocytes (%) $>1.2 \times \text{ULN}$	0			
Monocytes ($10^3/\text{mm}^3$) $>1.2 \times \text{ULN}$	0			
Monocytes/Leukocytes (%) $>1.2 \times \text{ULN}$	0			
aPTT (sec) $>1.1 \times \text{ULN}$	1			
Prothrombin Time (sec) $>1.1 \times \text{ULN}$	3			

Neutrophils total count ($10^3/\text{mm}^3$) <0.8*LLN	4			
Neutrophils total count ($10^3/\text{mm}^3$) >1.2*ULN	2			
Lymphocytes total count ($10^3/\text{mm}^3$) <0.8*LLN	1			
Lymphocytes total count ($10^3/\text{mm}^3$) >1.2*ULN	1			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Laboratory Test Abnormality - Chemistry (Normal Baseline), Up to Week 16 - Investigational Treatment Period

End point title	Number of Subjects With Laboratory Test Abnormality - Chemistry (Normal Baseline), Up to Week 16 - Investigational Treatment Period
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End point description:

Following clinical chemistry parameters were analyzed for laboratory examination: bilirubin, indirect bilirubin, aspartate aminotransferase, alanine aminotransferase, gamma glutamyl transferase, alkaline phosphatase, protein, albumin, blood urea nitrogen, urea, creatinine, urate, HDL cholesterol, triglycerides, sodium, potassium, chloride, calcium, bicarbonate, glucose, creatine kinase, and cholesterol. The analysis population included all subjects who received at least 1 dose of study drug (PF-06826647 or placebo) and had at least 1 laboratory assessment. ULN=upper limit of normal; LLN=lower limit of normal.

End point type	Secondary
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End point timeframe:

Baseline up to Week 16

End point values	Placebo QD Group	PF-06826647 50 mg QD Group	PF-06826647 100 mg QD Group	PF-06826647 200 mg QD Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	22	23	45
Units: Subjects				
Bilirubin (mg/dL) >1.5*ULN	0	0	0	0
Indirect Bilirubin (mg/dL) >1.5*ULN	0	0	0	0
Aspartate Aminotransferase (U/L) > 3.0*ULN	1	0	1	0
Alanine Aminotransferase (U/L) > 3.0*ULN	1	0	0	0
Gamma Glutamyl Transferase (U/L) > 3.0*ULN	0	0	0	0
Alkaline Phosphatase (U/L) > 3.0*ULN	0	0	0	0
Protein (g/dL) <0.8*LLN	0	0	0	0
Protein (g/dL) >1.2*ULN	0	0	0	0
Albumin (g/dL) <0.8*LLN	0	0	0	0
Albumin (g/dL) >1.2*ULN	0	0	0	0
Blood Urea Nitrogen (mg/dL) >1.3*ULN	1	0	0	2
Urea (mg/dL) >1.3*ULN	0	0	0	0
Creatinine (mg/dL) >1.3*ULN	0	0	0	1

Urate (mg/dL) >1.2*ULN	0	0	0	0
HDL Cholesterol (mg/dL) <0.8*LLN	0	0	0	0
Triglycerides (mg/dL) >1.3*ULN	1	0	0	0
Sodium (Meq/L) <0.95*LLN	0	0	0	0
Sodium (Meq/L) >1.05*ULN	0	0	0	0
Potassium (Meq/L) <0.9*LLN	0	0	0	0
Potassium (Meq/L) >1.1*ULN	1	0	1	0
Chloride (Meq/L) <0.9*LLN	0	0	0	0
Chloride (Meq/L) >1.1*ULN	0	0	0	0
Calcium (mg/dL) <0.9*LLN	0	0	0	0
Calcium (mg/dL) >1.1*ULN	0	0	0	0
Bicarbonate (Meq/L) <0.9*LLN	0	0	1	0
Bicarbonate (Meq/L) >1.1*ULN	0	0	0	0
Glucose (mg/dL) <0.6*LLN	0	0	0	0
Glucose (mg/dL) >1.5*ULN	1	0	0	0
Creatine Kinase (U/L) >2.0*ULN	3	3	2	9
Cholesterol (mg/dL) >1.3*ULN	0	0	0	0

End point values	PF-06826647 400 mg QD Group			
Subject group type	Subject analysis set			
Number of subjects analysed	43			
Units: Subjects				
Bilirubin (mg/dL) >1.5*ULN	0			
Indirect Bilirubin (mg/dL) >1.5*ULN	0			
Aspartate Aminotransferase (U/L) > 3.0*ULN	0			
Alanine Aminotransferase (U/L) > 3.0*ULN	0			
Gamma Glutamyl Transferase (U/L) > 3.0*ULN	0			
Alkaline Phosphatase (U/L) > 3.0*ULN	0			
Protein (g/dL) <0.8*LLN	0			
Protein (g/dL) >1.2*ULN	0			
Albumin (g/dL) <0.8*LLN	0			
Albumin (g/dL) >1.2*ULN	0			
Blood Urea Nitrogen (mg/dL) >1.3*ULN	0			
Urea (mg/dL) >1.3*ULN	0			
Creatinine (mg/dL) >1.3*ULN	1			
Urate (mg/dL) >1.2*ULN	0			
HDL Cholesterol (mg/dL) <0.8*LLN	0			
Triglycerides (mg/dL) >1.3*ULN	3			
Sodium (Meq/L) <0.95*LLN	0			
Sodium (Meq/L) >1.05*ULN	0			
Potassium (Meq/L) <0.9*LLN	0			
Potassium (Meq/L) >1.1*ULN	0			
Chloride (Meq/L) <0.9*LLN	0			
Chloride (Meq/L) >1.1*ULN	0			
Calcium (mg/dL) <0.9*LLN	0			
Calcium (mg/dL) >1.1*ULN	0			

Bicarbonate (Meq/L) <0.9*LLN	0			
Bicarbonate (Meq/L) >1.1*ULN	0			
Glucose (mg/dL) <0.6*LLN	0			
Glucose (mg/dL) >1.5*ULN	1			
Creatine Kinase (U/L) >2.0*ULN	15			
Cholesterol (mg/dL) >1.3*ULN	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Laboratory Test Abnormality - Urinalysis (Normal Baseline), Up to Week 16 - Investigational Treatment Period

End point title	Number of Subjects With Laboratory Test Abnormality - Urinalysis (Normal Baseline), Up to Week 16 - Investigational Treatment Period
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End point description:

Following urinalysis parameters were analyzed for laboratory examination: urine pH, urine glucose, urine ketones, urine protein, urine hemoglobin, urine urobilinogen, urine bilirubin, urine nitrite, urine leukocyte esterase, urine erythrocytes, urine leukocytes, urine hyaline, and urine bacteria. The analysis population included all subjects who received at least 1 dose of study drug (PF-06826647 or placebo) and had at least 1 laboratory assessment.

End point type	Secondary
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End point timeframe:

Baseline up to Week 16

End point values	Placebo QD Group	PF-06826647 50 mg QD Group	PF-06826647 100 mg QD Group	PF-06826647 200 mg QD Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	45	22	23	45
Units: Subjects				
Urine pH (Scalar) <4.5	0	0	0	0
Urine pH (Scalar) >8	0	0	0	0
Urine Glucose >=1	0	0	0	1
Urine Ketones (Scalar) >=1	2	0	1	0
Urine Protein >=1	1	0	0	1
Urine Hemoglobin (Scalar) >=1	3	1	0	4
Urine Urobilinogen (EU/dL) >=1	1	0	0	1
Urine Bilirubin (Scalar) >=1	0	0	0	0
Urine Nitrite (Scalar) >=1	0	1	0	0
Urine Leukocyte Esterase (Scalar) >=1	1	2	0	1
Urine Erythrocytes (Scalar) >=20	1	0	0	1
Urine Leukocytes (/HPF) >=20	1	0	0	0
Urine Hyaline Casts (/LPF) >1	1	1	0	3
Urine Bacteria (/LPF) >20	0	0	0	0

End point values	PF-06826647 400 mg QD Group			
Subject group type	Subject analysis set			
Number of subjects analysed	43			
Units: Subjects				
Urine pH (Scalar) <4.5	0			
Urine pH (Scalar) >8	0			
Urine Glucose >=1	1			
Urine Ketones (Scalar) >=1	2			
Urine Protein >=1	2			
Urine Hemoglobin (Scalar) >=1	0			
Urine Urobilinogen (EU/dL) >=1	2			
Urine Bilirubin (Scalar) >=1	0			
Urine Nitrite (Scalar) >=1	0			
Urine Leukocyte Esterase (Scalar) >=1	0			
Urine Erythrocytes (Scalar) >=20	0			
Urine Leukocytes (/HPF) >=20	0			
Urine Hyaline Casts (/LPF) >1	1			
Urine Bacteria (/LPF) >20	0			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From the first dose of study treatment on Day 1 to 28 calendar days after the last dose of study treatment on Day 280.

Adverse event reporting additional description:

Each AE was to be assessed to determine if it met the criteria for SAEs. If an SAE occurred, expedited reporting followed local and international regulations, as appropriate. In Section End Points, there were 2 separate summary data for the 2 periods is because the investigational treatment period contains the data for the primary endpoint.

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	23.1
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Reporting groups

Reporting group title	Placebo QD->PF-06826647 200 mg QD Group
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Reporting group description:

This study included 2 treatment periods: 16-week investigational treatment period and 24-week extension treatment period. The enrolled subjects entered the investigational treatment period first and then the subjects who completed the investigational treatment period entered the extension treatment period. The subjects in this group received matching placebo (2*25 mg size placebo and 4*100 mg size placebo) once a day (QD) in the investigational treatment period (16 weeks) and PF-06826647 200 mg QD in the extension treatment period (24 weeks). The maximum duration of treatment was 116 days in investigational treatment period and 187 days in extension treatment period.

Reporting group title	Placebo QD->PF-06826647 400 mg QD Group
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Reporting group description:

This study included 2 treatment periods: 16-week investigational treatment period and 24-week extension treatment period. The enrolled subjects entered the investigational treatment period first and then the subjects who completed the investigational treatment period entered the extension treatment period. The subjects in this group received matching placebo (2*25 mg size placebo and 4*100 mg size placebo) once a day (QD) in the investigational treatment period (16 weeks) and PF-06826647 400 mg QD in the extension treatment period (24 weeks). The maximum duration of treatment was 116 days in investigational treatment period and 176 days in extension treatment period.

Reporting group title	PF-06826647 50 mg QD->PF-06826647 200 mg QD Group
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Reporting group description:

This study included 2 treatment periods: 16-week investigational treatment period and 24-week extension treatment period. The enrolled subjects entered the investigational treatment period first and then the subjects who completed the investigational treatment period entered the extension treatment period. The subjects in this group received PF-06826647 50 mg once a day (QD) in the investigational treatment period (16 weeks) and PF-06826647 200 mg QD in the extension treatment period (24 weeks). The maximum duration of treatment was 119 days in investigational treatment period and 182 days in extension treatment period.

Reporting group title	PF-06826647 50 mg QD->PF-06826647 400 mg QD Group
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Reporting group description:

This study includes 2 treatment periods: 16-week investigational treatment period and 24-week extension treatment period. The enrolled subjects entered the investigational treatment period first and then the subjects who completed the investigational treatment period entered the extension treatment period. The subjects in this group received PF-06826647 50 mg once a day (QD) in the investigational treatment period (16 weeks) and PF-06826647 400 mg QD in the extension treatment period (24 weeks). The maximum duration of treatment was 119 days in investigational treatment period and 183 days in extension treatment period.

Reporting group title	PF-06826647 100 mg QD->PF-06826647 200 mg QD Group
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Reporting group description:

This study included 2 treatment periods: 16-week investigational treatment period and 24-week extension treatment period. The enrolled subjects entered the investigational treatment period first and then the subjects who completed the investigational treatment period entered the extension treatment period. The subjects in this group received PF-06826647 100 mg once a day (QD) in the investigational treatment period (16 weeks) and PF-06826647 200 mg QD in the extension treatment period (24 weeks).

weeks). The maximum duration of treatment was 115 days in investigational treatment period and 171 days in extension treatment period.

Reporting group title	PF-06826647 100 mg QD->PF-06826647 400 mg QD Group
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Reporting group description:

This study included 2 treatment periods: 16-week investigational treatment period and 24-week extension treatment period. The enrolled subjects entered the investigational treatment period first and then the subjects who completed the investigational treatment period entered the extension treatment period. The subjects in this group received PF-06826647 100 mg once a day (QD) in the investigational treatment period (16 weeks) and PF-06826647 400 mg QD in the extension treatment period (24 weeks). The maximum duration of treatment was 115 days in investigational treatment period and 174 days in extension treatment period.

Reporting group title	PF-06826647 200 mg QD->PF-06826647 200 mg QD Group
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Reporting group description:

This study included 2 treatment periods: 16-week investigational treatment period and 24-week extension treatment period. The enrolled subjects entered the investigational treatment period first and then the subjects who completed the investigational treatment period entered the extension treatment period. The subjects in this group received PF-06826647 200 mg once a day (QD) in the investigational treatment period (16 weeks) and PF-06826647 200 mg QD in the extension treatment period (24 weeks). The maximum duration of treatment was 120 days in investigational treatment period and 186 days in extension treatment period.

Reporting group title	PF-06826647 400 mg QD->PF-06826647 400 mg QD Group
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Reporting group description:

This study included 2 treatment periods: 16-week investigational treatment period and 24-week extension treatment period. The enrolled subjects entered the investigational treatment period first and then the subjects who completed the investigational treatment period entered the extension treatment period. The subjects in this group received PF-06826647 400 mg once a day (QD) in the investigational treatment period (16 weeks) and PF-06826647 400 mg QD in the extension treatment period (24 weeks). The maximum duration of treatment was 119 days in investigational treatment period and 180 days in extension treatment period.

Serious adverse events	Placebo QD->PF-06826647 200 mg QD Group	Placebo QD->PF-06826647 400 mg QD Group	PF-06826647 50 mg QD->PF-06826647 200 mg QD Group
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 23 (0.00%)	1 / 22 (4.55%)	0 / 11 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 23 (0.00%)	1 / 22 (4.55%)	0 / 11 (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
Investigations			
Fibrin D dimer increased			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 11 (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
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 11 (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
Nervous system disorders			
Presyncope			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 11 (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			
Chest pain			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 11 (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
Ear and labyrinth disorders			
Hypoacusis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 11 (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			
Viral sepsis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Serious adverse events	PF-06826647 50 mg QD->PF-06826647 400 mg QD Group	PF-06826647 100 mg QD->PF-06826647 200 mg QD Group	PF-06826647 100 mg QD->PF-06826647 400 mg QD Group
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 11 (9.09%)	0 / 12 (0.00%)	1 / 11 (9.09%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 11 (0.00%)	0 / 12 (0.00%)	0 / 11 (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
Investigations			

Fibrin D dimer increased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 11 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Presyncope			
subjects affected / exposed	0 / 11 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 12 (0.00%)	0 / 11 (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
Ear and labyrinth disorders			
Hypoacusis			
subjects affected / exposed	1 / 11 (9.09%)	0 / 12 (0.00%)	0 / 11 (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
Infections and infestations			
Viral sepsis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Serious adverse events	PF-06826647 200 mg QD->PF-06826647 200 mg QD Group	PF-06826647 400 mg QD->PF-06826647 400 mg QD Group	
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 45 (6.67%)	0 / 43 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 45 (2.22%)	0 / 43 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Fibrin D dimer increased			
subjects affected / exposed	0 / 45 (0.00%)	0 / 43 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SARS-CoV-2 test positive			
subjects affected / exposed	1 / 45 (2.22%)	0 / 43 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Presyncope			
subjects affected / exposed	0 / 45 (0.00%)	0 / 43 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	1 / 45 (2.22%)	0 / 43 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Hypoacusis			
subjects affected / exposed	0 / 45 (0.00%)	0 / 43 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Viral sepsis			
subjects affected / exposed	0 / 45 (0.00%)	0 / 43 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Placebo QD->PF-06826647 200 mg QD Group	Placebo QD->PF-06826647 400 mg QD Group	PF-06826647 50 mg QD->PF-06826647 200 mg QD Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	14 / 23 (60.87%)	11 / 22 (50.00%)	10 / 11 (90.91%)
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 23 (4.35%)	1 / 22 (4.55%)	0 / 11 (0.00%)
occurrences (all)	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Melanocytic naevus			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Pregnancy, puerperium and perinatal conditions			
Pregnancy			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 23 (0.00%)	1 / 22 (4.55%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Feeling hot			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 23 (0.00%)	1 / 22 (4.55%)	1 / 11 (9.09%)
occurrences (all)	0	1	1
Peripheral swelling			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 11 (0.00%)

occurrences (all)	0	0	0
Vessel puncture site bruise subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Depression subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
Contusion subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Diffuse axonal injury subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hand fracture subjects affected / exposed	0 / 23 (0.00%)	1 / 22 (4.55%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Ligament sprain subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Road traffic accident subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Skin laceration subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Investigations			
Activated partial thromboplastin time prolonged subjects affected / exposed	1 / 23 (4.35%)	0 / 22 (0.00%)	1 / 11 (9.09%)
occurrences (all)	1	0	1
Alanine aminotransferase increased subjects affected / exposed	1 / 23 (4.35%)	0 / 22 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Aspartate aminotransferase increased			

subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 23 (4.35%)	1 / 22 (4.55%)	0 / 11 (0.00%)
occurrences (all)	1	1	0
Blood pressure diastolic increased			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Blood pressure increased			
subjects affected / exposed	1 / 23 (4.35%)	0 / 22 (0.00%)	1 / 11 (9.09%)
occurrences (all)	1	0	4
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Prothrombin time prolonged			
subjects affected / exposed	1 / 23 (4.35%)	0 / 22 (0.00%)	1 / 11 (9.09%)
occurrences (all)	1	0	1
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Serum ferritin increased			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	1 / 23 (4.35%)	0 / 22 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Epistaxis			

subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Nasal mucosal hypertrophy			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Nasal polyps			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Nasal septum deviation			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Lymphadenopathy			
subjects affected / exposed	2 / 23 (8.70%)	0 / 22 (0.00%)	0 / 11 (0.00%)
occurrences (all)	2	0	0
Lymphocytosis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	1 / 23 (4.35%)	0 / 22 (0.00%)	1 / 11 (9.09%)
occurrences (all)	1	0	1
Nervous system disorders			
Circadian rhythm sleep disorder			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 11 (0.00%)

occurrences (all)	0	0	0
Headache			
subjects affected / exposed	2 / 23 (8.70%)	1 / 22 (4.55%)	1 / 11 (9.09%)
occurrences (all)	2	1	2
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Syncope			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	2
Eye disorders			
Diplopia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Strabismus			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Vertigo			
subjects affected / exposed	1 / 23 (4.35%)	0 / 22 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Vestibular disorder			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 23 (0.00%)	2 / 22 (9.09%)	0 / 11 (0.00%)
occurrences (all)	0	2	0

Constipation			
subjects affected / exposed	1 / 23 (4.35%)	0 / 22 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Diarrhoea			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 23 (4.35%)	1 / 22 (4.55%)	0 / 11 (0.00%)
occurrences (all)	2	1	0
Toothache			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Pseudofolliculitis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Psoriasis			
subjects affected / exposed	1 / 23 (4.35%)	0 / 22 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 23 (8.70%)	1 / 22 (4.55%)	0 / 11 (0.00%)
occurrences (all)	3	1	0
Back pain			
subjects affected / exposed	1 / 23 (4.35%)	0 / 22 (0.00%)	1 / 11 (9.09%)
occurrences (all)	1	0	1
Joint swelling			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Limb discomfort			

subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Psoriatic arthropathy			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Autoimmune thyroiditis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Erythema migrans			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	2 / 23 (8.70%)	0 / 22 (0.00%)	0 / 11 (0.00%)
occurrences (all)	3	0	0
Fungal skin infection			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 23 (0.00%)	1 / 22 (4.55%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis viral			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	1 / 11 (9.09%)

occurrences (all)	0	0	1
Laryngitis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	6 / 23 (26.09%)	1 / 22 (4.55%)	3 / 11 (27.27%)
occurrences (all)	8	1	4
Pharyngitis			
subjects affected / exposed	0 / 23 (0.00%)	1 / 22 (4.55%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Pneumonia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 23 (4.35%)	1 / 22 (4.55%)	2 / 11 (18.18%)
occurrences (all)	1	1	3
Urinary tract infection			
subjects affected / exposed	1 / 23 (4.35%)	1 / 22 (4.55%)	1 / 11 (9.09%)
occurrences (all)	1	2	1
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 23 (4.35%)	0 / 22 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	PF-06826647 50 mg QD->PF-06826647 400 mg QD Group	PF-06826647 100 mg QD->PF-06826647 200 mg QD Group	PF-06826647 100 mg QD->PF-06826647 400 mg QD Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 11 (72.73%)	9 / 12 (75.00%)	9 / 11 (81.82%)
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 11 (9.09%)	1 / 12 (8.33%)	0 / 11 (0.00%)

occurrences (all)	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Melanocytic naevus			
subjects affected / exposed	0 / 11 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Pregnancy, puerperium and perinatal conditions			
Pregnancy			
subjects affected / exposed	0 / 11 (0.00%)	1 / 12 (8.33%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Fatigue			
subjects affected / exposed	0 / 11 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Feeling hot			
subjects affected / exposed	0 / 11 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Oedema peripheral			
subjects affected / exposed	0 / 11 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	1 / 11 (9.09%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Pyrexia			
subjects affected / exposed	0 / 11 (0.00%)	1 / 12 (8.33%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Vessel puncture site bruise			
subjects affected / exposed	1 / 11 (9.09%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 11 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0

Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 11 (0.00%)	0 / 12 (0.00%)	2 / 11 (18.18%)
occurrences (all)	0	0	2
Diffuse axonal injury			
subjects affected / exposed	0 / 11 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Hand fracture			
subjects affected / exposed	0 / 11 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Ligament sprain			
subjects affected / exposed	0 / 11 (0.00%)	1 / 12 (8.33%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Road traffic accident			
subjects affected / exposed	0 / 11 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Skin laceration			
subjects affected / exposed	0 / 11 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 11 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	2
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1

Blood pressure diastolic increased subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	1 / 12 (8.33%) 1	0 / 11 (0.00%) 0
Blood pressure increased subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	1 / 12 (8.33%) 1	2 / 11 (18.18%) 3
Gamma-glutamyltransferase increased subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0	0 / 11 (0.00%) 0
Prothrombin time prolonged subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0	0 / 11 (0.00%) 0
SARS-CoV-2 test positive subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0	0 / 11 (0.00%) 0
Serum ferritin increased subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0	1 / 11 (9.09%) 1
Transaminases increased subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0	1 / 11 (9.09%) 1
Cardiac disorders Atrial fibrillation subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	1 / 12 (8.33%) 1	0 / 11 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	1 / 12 (8.33%) 2	0 / 11 (0.00%) 0
Epistaxis subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0	0 / 11 (0.00%) 0
Nasal mucosal hypertrophy subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0	1 / 11 (9.09%) 1
Nasal polyps			

subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0	0 / 11 (0.00%) 0
Nasal septum deviation subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0	0 / 11 (0.00%) 0
Blood and lymphatic system disorders			
Anaemia subjects affected / exposed occurrences (all)	2 / 11 (18.18%) 2	0 / 12 (0.00%) 0	0 / 11 (0.00%) 0
Leukocytosis subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0	1 / 11 (9.09%) 1
Leukopenia subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0	0 / 11 (0.00%) 0
Lymphadenopathy subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	0 / 12 (0.00%) 0	1 / 11 (9.09%) 1
Lymphocytosis subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0	1 / 11 (9.09%) 1
Neutropenia subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	0 / 12 (0.00%) 0	0 / 11 (0.00%) 0
Nervous system disorders			
Circadian rhythm sleep disorder subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	1 / 12 (8.33%) 1	0 / 11 (0.00%) 0
Dysgeusia subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	1 / 12 (8.33%) 1	0 / 11 (0.00%) 0
Headache subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0	1 / 11 (9.09%) 2
Peripheral sensory neuropathy subjects affected / exposed	0 / 11 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)

occurrences (all)	0	0	1
Sciatica			
subjects affected / exposed	0 / 11 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 11 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Diplopia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Strabismus			
subjects affected / exposed	0 / 11 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	0 / 11 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 11 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Vestibular disorder			
subjects affected / exposed	0 / 11 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 11 (9.09%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Abdominal pain upper			
subjects affected / exposed	1 / 11 (9.09%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	1	0	1
Constipation			
subjects affected / exposed	0 / 11 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Diarrhoea			
subjects affected / exposed	0 / 11 (0.00%)	1 / 12 (8.33%)	1 / 11 (9.09%)
occurrences (all)	0	1	1

Dyspepsia subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0	1 / 11 (9.09%) 2
Nausea subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	1 / 12 (8.33%) 1	0 / 11 (0.00%) 0
Toothache subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	1 / 12 (8.33%) 1	0 / 11 (0.00%) 0
Vomiting subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	0 / 12 (0.00%) 0	1 / 11 (9.09%) 1
Skin and subcutaneous tissue disorders Pseudofolliculitis subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	0 / 12 (0.00%) 0	0 / 11 (0.00%) 0
Psoriasis subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0	1 / 11 (9.09%) 1
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	0 / 12 (0.00%) 0	2 / 11 (18.18%) 5
Back pain subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 2	1 / 12 (8.33%) 1	0 / 11 (0.00%) 0
Joint swelling subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0	1 / 11 (9.09%) 2
Limb discomfort subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	1 / 12 (8.33%) 1	0 / 11 (0.00%) 0
Myalgia subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0	1 / 11 (9.09%) 1
Pain in extremity			

subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	0 / 12 (0.00%) 0	0 / 11 (0.00%) 0
Psoriatic arthropathy subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	1 / 12 (8.33%) 1	0 / 11 (0.00%) 0
Endocrine disorders Autoimmune thyroiditis subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	0 / 12 (0.00%) 0	0 / 11 (0.00%) 0
Infections and infestations Bronchitis subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	0 / 12 (0.00%) 0	0 / 11 (0.00%) 0
Erythema migrans subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	0 / 12 (0.00%) 0	0 / 11 (0.00%) 0
Folliculitis subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0	0 / 11 (0.00%) 0
Fungal skin infection subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0	1 / 11 (9.09%) 1
Gastroenteritis subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	1 / 12 (8.33%) 1	0 / 11 (0.00%) 0
Gastroenteritis viral subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	1 / 12 (8.33%) 1	0 / 11 (0.00%) 0
Hordeolum subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0	0 / 11 (0.00%) 0
Laryngitis subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	0 / 12 (0.00%) 0	0 / 11 (0.00%) 0
Nasopharyngitis subjects affected / exposed	1 / 11 (9.09%)	3 / 12 (25.00%)	2 / 11 (18.18%)

occurrences (all)	1	4	3
Pharyngitis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 12 (8.33%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Pneumonia			
subjects affected / exposed	1 / 11 (9.09%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	1	0	1
Respiratory tract infection			
subjects affected / exposed	0 / 11 (0.00%)	1 / 12 (8.33%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Sinusitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Upper respiratory tract infection			
subjects affected / exposed	2 / 11 (18.18%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	2	0	1
Urinary tract infection			
subjects affected / exposed	1 / 11 (9.09%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 11 (0.00%)	2 / 12 (16.67%)	0 / 11 (0.00%)
occurrences (all)	0	2	0

Non-serious adverse events	PF-06826647 200 mg QD->PF-06826647 200 mg QD Group	PF-06826647 400 mg QD->PF-06826647 400 mg QD Group	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	29 / 45 (64.44%)	32 / 43 (74.42%)	
Vascular disorders			
Hypertension			
subjects affected / exposed	2 / 45 (4.44%)	5 / 43 (11.63%)	
occurrences (all)	2	5	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Melanocytic naevus			
subjects affected / exposed	0 / 45 (0.00%)	0 / 43 (0.00%)	
occurrences (all)	0	0	
Pregnancy, puerperium and perinatal conditions			

Pregnancy subjects affected / exposed occurrences (all)	0 / 45 (0.00%) 0	0 / 43 (0.00%) 0	
General disorders and administration site conditions			
Asthenia subjects affected / exposed occurrences (all)	0 / 45 (0.00%) 0	0 / 43 (0.00%) 0	
Fatigue subjects affected / exposed occurrences (all)	2 / 45 (4.44%) 2	2 / 43 (4.65%) 2	
Feeling hot subjects affected / exposed occurrences (all)	0 / 45 (0.00%) 0	0 / 43 (0.00%) 0	
Oedema peripheral subjects affected / exposed occurrences (all)	0 / 45 (0.00%) 0	0 / 43 (0.00%) 0	
Peripheral swelling subjects affected / exposed occurrences (all)	0 / 45 (0.00%) 0	0 / 43 (0.00%) 0	
Pyrexia subjects affected / exposed occurrences (all)	0 / 45 (0.00%) 0	0 / 43 (0.00%) 0	
Vessel puncture site bruise subjects affected / exposed occurrences (all)	0 / 45 (0.00%) 0	0 / 43 (0.00%) 0	
Psychiatric disorders			
Depression subjects affected / exposed occurrences (all)	0 / 45 (0.00%) 0	0 / 43 (0.00%) 0	
Injury, poisoning and procedural complications			
Contusion subjects affected / exposed occurrences (all)	1 / 45 (2.22%) 1	3 / 43 (6.98%) 3	
Diffuse axonal injury subjects affected / exposed occurrences (all)	0 / 45 (0.00%) 0	0 / 43 (0.00%) 0	

Hand fracture			
subjects affected / exposed	0 / 45 (0.00%)	0 / 43 (0.00%)	
occurrences (all)	0	0	
Ligament sprain			
subjects affected / exposed	0 / 45 (0.00%)	0 / 43 (0.00%)	
occurrences (all)	0	0	
Road traffic accident			
subjects affected / exposed	0 / 45 (0.00%)	0 / 43 (0.00%)	
occurrences (all)	0	0	
Skin laceration			
subjects affected / exposed	0 / 45 (0.00%)	0 / 43 (0.00%)	
occurrences (all)	0	0	
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 45 (0.00%)	0 / 43 (0.00%)	
occurrences (all)	0	0	
Alanine aminotransferase increased			
subjects affected / exposed	2 / 45 (4.44%)	3 / 43 (6.98%)	
occurrences (all)	2	3	
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 45 (0.00%)	2 / 43 (4.65%)	
occurrences (all)	0	2	
Blood creatine phosphokinase increased			
subjects affected / exposed	5 / 45 (11.11%)	6 / 43 (13.95%)	
occurrences (all)	8	13	
Blood pressure diastolic increased			
subjects affected / exposed	0 / 45 (0.00%)	0 / 43 (0.00%)	
occurrences (all)	0	0	
Blood pressure increased			
subjects affected / exposed	4 / 45 (8.89%)	4 / 43 (9.30%)	
occurrences (all)	8	4	
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 45 (0.00%)	3 / 43 (6.98%)	
occurrences (all)	0	3	

Prothrombin time prolonged subjects affected / exposed occurrences (all)	0 / 45 (0.00%) 0	0 / 43 (0.00%) 0	
SARS-CoV-2 test positive subjects affected / exposed occurrences (all)	2 / 45 (4.44%) 3	0 / 43 (0.00%) 0	
Serum ferritin increased subjects affected / exposed occurrences (all)	0 / 45 (0.00%) 0	0 / 43 (0.00%) 0	
Transaminases increased subjects affected / exposed occurrences (all)	0 / 45 (0.00%) 0	0 / 43 (0.00%) 0	
Cardiac disorders Atrial fibrillation subjects affected / exposed occurrences (all)	0 / 45 (0.00%) 0	0 / 43 (0.00%) 0	
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	1 / 45 (2.22%) 1	0 / 43 (0.00%) 0	
Epistaxis subjects affected / exposed occurrences (all)	0 / 45 (0.00%) 0	0 / 43 (0.00%) 0	
Nasal mucosal hypertrophy subjects affected / exposed occurrences (all)	0 / 45 (0.00%) 0	0 / 43 (0.00%) 0	
Nasal polyps subjects affected / exposed occurrences (all)	0 / 45 (0.00%) 0	0 / 43 (0.00%) 0	
Nasal septum deviation subjects affected / exposed occurrences (all)	0 / 45 (0.00%) 0	0 / 43 (0.00%) 0	
Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all)	1 / 45 (2.22%) 1	3 / 43 (6.98%) 3	

Leukocytosis			
subjects affected / exposed	0 / 45 (0.00%)	0 / 43 (0.00%)	
occurrences (all)	0	0	
Leukopenia			
subjects affected / exposed	1 / 45 (2.22%)	0 / 43 (0.00%)	
occurrences (all)	1	0	
Lymphadenopathy			
subjects affected / exposed	1 / 45 (2.22%)	2 / 43 (4.65%)	
occurrences (all)	1	2	
Lymphocytosis			
subjects affected / exposed	0 / 45 (0.00%)	0 / 43 (0.00%)	
occurrences (all)	0	0	
Neutropenia			
subjects affected / exposed	3 / 45 (6.67%)	2 / 43 (4.65%)	
occurrences (all)	3	3	
Nervous system disorders			
Circadian rhythm sleep disorder			
subjects affected / exposed	0 / 45 (0.00%)	0 / 43 (0.00%)	
occurrences (all)	0	0	
Dysgeusia			
subjects affected / exposed	1 / 45 (2.22%)	0 / 43 (0.00%)	
occurrences (all)	1	0	
Headache			
subjects affected / exposed	2 / 45 (4.44%)	6 / 43 (13.95%)	
occurrences (all)	2	7	
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 45 (0.00%)	0 / 43 (0.00%)	
occurrences (all)	0	0	
Sciatica			
subjects affected / exposed	0 / 45 (0.00%)	1 / 43 (2.33%)	
occurrences (all)	0	1	
Syncope			
subjects affected / exposed	0 / 45 (0.00%)	0 / 43 (0.00%)	
occurrences (all)	0	0	
Eye disorders			

Diplopia subjects affected / exposed occurrences (all)	0 / 45 (0.00%) 0	0 / 43 (0.00%) 0	
Strabismus subjects affected / exposed occurrences (all)	0 / 45 (0.00%) 0	0 / 43 (0.00%) 0	
Ear and labyrinth disorders			
Tinnitus subjects affected / exposed occurrences (all)	0 / 45 (0.00%) 0	0 / 43 (0.00%) 0	
Vertigo subjects affected / exposed occurrences (all)	0 / 45 (0.00%) 0	0 / 43 (0.00%) 0	
Vestibular disorder subjects affected / exposed occurrences (all)	0 / 45 (0.00%) 0	0 / 43 (0.00%) 0	
Gastrointestinal disorders			
Abdominal pain subjects affected / exposed occurrences (all)	2 / 45 (4.44%) 2	1 / 43 (2.33%) 1	
Abdominal pain upper subjects affected / exposed occurrences (all)	0 / 45 (0.00%) 0	3 / 43 (6.98%) 4	
Constipation subjects affected / exposed occurrences (all)	0 / 45 (0.00%) 0	0 / 43 (0.00%) 0	
Diarrhoea subjects affected / exposed occurrences (all)	0 / 45 (0.00%) 0	1 / 43 (2.33%) 1	
Dyspepsia subjects affected / exposed occurrences (all)	1 / 45 (2.22%) 1	0 / 43 (0.00%) 0	
Nausea subjects affected / exposed occurrences (all)	2 / 45 (4.44%) 2	1 / 43 (2.33%) 2	
Toothache subjects affected / exposed	0 / 45 (0.00%)	1 / 43 (2.33%)	

occurrences (all)	0	1	
Vomiting			
subjects affected / exposed	0 / 45 (0.00%)	2 / 43 (4.65%)	
occurrences (all)	0	2	
Skin and subcutaneous tissue disorders			
Pseudofolliculitis			
subjects affected / exposed	0 / 45 (0.00%)	0 / 43 (0.00%)	
occurrences (all)	0	0	
Psoriasis			
subjects affected / exposed	0 / 45 (0.00%)	0 / 43 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 45 (0.00%)	2 / 43 (4.65%)	
occurrences (all)	0	2	
Back pain			
subjects affected / exposed	1 / 45 (2.22%)	3 / 43 (6.98%)	
occurrences (all)	1	3	
Joint swelling			
subjects affected / exposed	0 / 45 (0.00%)	0 / 43 (0.00%)	
occurrences (all)	0	0	
Limb discomfort			
subjects affected / exposed	0 / 45 (0.00%)	0 / 43 (0.00%)	
occurrences (all)	0	0	
Myalgia			
subjects affected / exposed	0 / 45 (0.00%)	1 / 43 (2.33%)	
occurrences (all)	0	1	
Pain in extremity			
subjects affected / exposed	0 / 45 (0.00%)	1 / 43 (2.33%)	
occurrences (all)	0	1	
Psoriatic arthropathy			
subjects affected / exposed	0 / 45 (0.00%)	0 / 43 (0.00%)	
occurrences (all)	0	0	
Endocrine disorders			

Autoimmune thyroiditis subjects affected / exposed occurrences (all)	0 / 45 (0.00%) 0	0 / 43 (0.00%) 0	
Infections and infestations			
Bronchitis subjects affected / exposed occurrences (all)	3 / 45 (6.67%) 3	1 / 43 (2.33%) 1	
Erythema migrans subjects affected / exposed occurrences (all)	0 / 45 (0.00%) 0	0 / 43 (0.00%) 0	
Folliculitis subjects affected / exposed occurrences (all)	1 / 45 (2.22%) 1	0 / 43 (0.00%) 0	
Fungal skin infection subjects affected / exposed occurrences (all)	0 / 45 (0.00%) 0	0 / 43 (0.00%) 0	
Gastroenteritis subjects affected / exposed occurrences (all)	1 / 45 (2.22%) 1	0 / 43 (0.00%) 0	
Gastroenteritis viral subjects affected / exposed occurrences (all)	0 / 45 (0.00%) 0	0 / 43 (0.00%) 0	
Hordeolum subjects affected / exposed occurrences (all)	0 / 45 (0.00%) 0	0 / 43 (0.00%) 0	
Laryngitis subjects affected / exposed occurrences (all)	0 / 45 (0.00%) 0	0 / 43 (0.00%) 0	
Nasopharyngitis subjects affected / exposed occurrences (all)	6 / 45 (13.33%) 6	12 / 43 (27.91%) 13	
Pharyngitis subjects affected / exposed occurrences (all)	0 / 45 (0.00%) 0	1 / 43 (2.33%) 1	
Pneumonia subjects affected / exposed	0 / 45 (0.00%)	0 / 43 (0.00%)	

occurrences (all)	0	0	
Respiratory tract infection			
subjects affected / exposed	0 / 45 (0.00%)	0 / 43 (0.00%)	
occurrences (all)	0	0	
Sinusitis			
subjects affected / exposed	0 / 45 (0.00%)	1 / 43 (2.33%)	
occurrences (all)	0	1	
Upper respiratory tract infection			
subjects affected / exposed	3 / 45 (6.67%)	4 / 43 (9.30%)	
occurrences (all)	3	5	
Urinary tract infection			
subjects affected / exposed	1 / 45 (2.22%)	2 / 43 (4.65%)	
occurrences (all)	1	2	
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 45 (2.22%)	1 / 43 (2.33%)	
occurrences (all)	1	2	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
01 October 2019	Removed body mass index (BMI) in Inclusion Criteria #6.3. Added two exclusion criteria in Exclusion Criteria: #13.History of recurrent (>2) venous thrombosis or any arterial thromboembolism or known blood clotting disorders. #14.History of acute coronary syndrome (eg, myocardial infarction, unstable angina pectoris) and any history of cerebrovascular disease within 24 weeks before screening. Added language to Discontinuation of Study Intervention involving thromboembolic events. Added language to Safety Adjudication Committee Section 9.5.2. The content of five Protocol Administrative Clarification Letters (PACLs) # 1-5 was added.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported