Clinical trial results:
A Phase 2b Randomized, DoubleBlind, PlaceboControlled, Multicenter, DoseRanging Study to Evaluate the Efficacy and Safety Profile of PF06651600 With a Partially Blinded Extension Period to Evaluate the Efficacy and Safety of PF06651600 and PF06700841 in Subjects With Active NonSegmental Vitiligo

Summary

EudraCT number	2018-001271-20
Trial protocol	DE BE ES IT
Global end of trial date	05 February 2021

Results information

Result version number	v1 (current)
This version publication date	27 January 2022
First version publication date	27 January 2022

Trial information

Trial identification

Sponsor protocol code	B7981019

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03715829
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	15 September 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	05 February 2021
Global end of trial reached?	Yes
Global end of trial date	05 February 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

• To evaluate the efficacy of ritlecitinib dose/dosing regimens at Week 24 in adult participants with active non-segmental vitiligo.
• To evaluate the safety and tolerability of ritlecitinib over time in adult participants with active non-segmental vitiligo.
• To evaluate the safety and tolerability of ritlecitinib and brepocitinib in adult participants with active non-segmental vitiligo.

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 Conference on Harmonisation (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	26 November 2018
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	Australia: 21
Country: Number of subjects enrolled	Belgium: 8
Country: Number of subjects enrolled	Canada: 105
Country: Number of subjects enrolled	Germany: 21
Country: Number of subjects enrolled	Italy: 5
Country: Number of subjects enrolled	Japan: 23
Country: Number of subjects enrolled	Korea, Republic of: 16
Country: Number of subjects enrolled	Spain: 21
Country: Number of subjects enrolled	Taiwan: 7
Country: Number of subjects enrolled	United States: 137
Worldwide total number of subjects	364
EEA total number of subjects	55

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)	355
From 65 to 84 years	9
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 578 subjects were screened for this study; 366 were randomized to treatment and 364 (99.5%) subjects received treatment.

Period 1

Period 1 title	Dose Ranging Period
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Carer, Data analyst, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	PF-06651600 200 mg - 50 mg QD

Arm description:

Subjects were randomized to receive ritlecitinib (PF-06651600) induction dose of 200 mg QD for 4 weeks followed by ritlecitinib 50 mg QD for another 20 weeks.

Arm type	Experimental
Investigational medicinal product name	PF-06651600 200 mg
Investigational medicinal product code	
Other name	ritlecitinib
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects swallowed the tablet once daily with ambient temperature water to a total volume of approximately 240 mL after breakfast whenever possible.

Investigational medicinal product name	PF-06651600 50 mg
Investigational medicinal product code	
Other name	ritlecitinib
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects swallowed the tablet once daily with ambient temperature water to a total volume of approximately 240 mL after breakfast whenever possible.

Arm title	PF-06651600 100 mg - 50 mg QD

Arm description:

Subjects were randomized to receive ritlecitinib induction dose of 100 mg QD for 4 weeks followed by ritlecitinib 50 mg QD for another 20 weeks.

Arm type	Experimental
Investigational medicinal product name	PF06651600 50 mg
Investigational medicinal product code	
Other name	ritlecitinib
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects swallowed the tablet once daily with ambient temperature water to a total volume of approximately 240 mL after breakfast whenever possible.

Investigational medicinal product name	PF-06651600 100 mg
Investigational medicinal product code	
Other name	ritlecitinib
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects swallowed the tablet once daily with ambient temperature water to a total volume of approximately 240 mL after breakfast whenever possible.

Arm title	PF-06651600 50 mg QD

Arm description:

Subjects were randomized to receive ritlecitinib 50 mg QD for 24 weeks.

Arm type	Experimental
Investigational medicinal product name	PF-06651600 50 mg
Investigational medicinal product code	
Other name	ritlecitinib
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects swallowed the tablet once daily with ambient temperature water to a total volume of approximately 240 mL after breakfast whenever possible.

Arm title	PF-06651600 30 mg QD

Arm description:

Subjects were randomized to receive ritlecitinib 30 mg QD for 24 weeks.

Arm type	Experimental
Investigational medicinal product name	PF-06651600 30 mg
Investigational medicinal product code	
Other name	ritlecitinib
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects swallowed the tablet once daily with ambient temperature water to a total volume of approximately 240 mL after breakfast whenever possible.

Arm title	PF-06651600 10 mg QD

Arm description:

Subjects were randomized to receive ritlecitinib 10 mg QD for 24 weeks.

Arm type	Experimental
Investigational medicinal product name	PF-06651600 10 mg
Investigational medicinal product code	
Other name	ritlecitinib
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects swallowed the tablet once daily with ambient temperature water to a total volume of approximately 240 mL after breakfast whenever possible.

Arm title	Placebo

Arm description:

Subjects were randomized to receive placebo for 24 weeks.

Arm type	Placebo

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

Dosage and administration details:

Subjects swallowed the tablet once daily with ambient temperature water to a total volume of approximately 240 mL after breakfast whenever possible.

Number of subjects in period 1	PF-06651600 200 mg - 50 mg QD	PF-06651600 100 mg - 50 mg QD	PF-06651600 50 mg QD
Started	65	67	67
Completed	53	58	54
Not completed	12	9	13
Consent withdrawn by subject	8	4	3
Adverse event, non-fatal	2	4	5
Other	-	-	2
Medication Error Without Associated Adverse Event	-	-	1
Lost to follow-up	2	-	1
No Longer Meets Eligibility Criteria	-	-	1
Lack of efficacy	-	1	-
Protocol deviation	-	-	-

Number of subjects in period 1	PF-06651600 30 mg QD	PF-06651600 10 mg QD	Placebo
Started	50	49	66
Completed	36	42	55
Not completed	14	7	11
Consent withdrawn by subject	9	2	3
Adverse event, non-fatal	2	3	3
Other	-	-	3
Medication Error Without Associated Adverse Event	-	-	-
Lost to follow-up	1	1	2
No Longer Meets Eligibility Criteria	-	1	-
Lack of efficacy	1	-	-
Protocol deviation	1	-	-

Period 2

Period 2 title	Extension Period
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Carer, Data analyst, Assessor

Blinding implementation details:

In the Extension (EXT) Period, the brepocitinib 60 mg - 30 mg QD group and ritlecitinib 200-50 mg QD+ nbUVB group were open-label; the rest of groups were double-blinded.

Arms

Are arms mutually exclusive?	Yes
Arm title	Extension (EXT) PF-06700841 60 mg - 30 mg QD

Arm description:

After a 4-week drug holiday, subjects received induction dose of brepocitinib (PF-06700841) 60 mg QD for 4 weeks followed by brepocitinib 30 mg QD for 16 weeks. This arm is open label.

Arm type	Experimental
Investigational medicinal product name	PF-06700841 30 mg
Investigational medicinal product code	
Other name	brepocitinib
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects swallowed the tablet once daily with ambient temperature water to a total volume of approximately 240 mL after breakfast whenever possible.

Investigational medicinal product name	PF-06700841 60 mg
Investigational medicinal product code	
Other name	brepocitinib
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects swallowed the tablet once daily with ambient temperature water to a total volume of approximately 240 mL after breakfast whenever possible.

Arm title	EXT PF-06651600 200 mg - 50 mg QD + nbUVB

Arm description:

Induction dose of ritlecitinib 200 mg QD plus standardized narrow band UVB (nbUVB) add-on therapy for 4 weeks followed by ritlecitinib 50 mg QD plus standardized nbUVB add-on therapy for 20 weeks (only for subjects who provided nbUVB consent). Subjects who had <10% improvement in percent change in VASI at Extension Week 12 from the baseline value at Dose Ranging Period Week 24 were discontinued from the treatment and entered Follow-up Period. This arm is open label.

Arm type	Experimental
Investigational medicinal product name	PF-06651600 200 mg
Investigational medicinal product code	
Other name	ritlecitinib
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects swallowed the tablet once daily with ambient temperature water to a total volume of approximately 240 mL after breakfast whenever possible.

Investigational medicinal product name	PF-06651600 50 mg
Investigational medicinal product code	
Other name	ritlecitinib
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects swallowed the tablet once daily with ambient temperature water to a total volume of approximately 240 mL after breakfast whenever possible.

Arm title	EXT PF-06651600 200 mg - 50 mg QD

Arm description:

Induction dose of ritlecitinib 200 mg QD of for 4 weeks followed by ritlecitinib 50 mg QD for 20 weeks. This arm is double blinded.

Arm type	Experimental
Investigational medicinal product name	PF-06651600 50 mg
Investigational medicinal product code	
Other name	ritlecitinib
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects swallowed the tablet once daily with ambient temperature water to a total volume of approximately 240 mL after breakfast whenever possible.

Investigational medicinal product name	PF-06651600 200 mg
Investigational medicinal product code	
Other name	ritlecitinib
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects swallowed the tablet once daily with ambient temperature water to a total volume of approximately 240 mL after breakfast whenever possible.

Arm title	EXT PF-06651600 50 mg QD

Arm description:

Ritlecitinib 50 mg QD for 24 weeks. This arm is double blinded.

Arm type	Experimental
Investigational medicinal product name	PF-06651600 50 mg
Investigational medicinal product code	
Other name	ritlecitinib
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects swallowed the tablet once daily with ambient temperature water to a total volume of approximately 240 mL after breakfast whenever possible.

Arm title	EXT PF-06651600 30 mg QD

Arm description:

Ritlecitinib 30 mg QD of for 24 weeks. This arm is double blinded.

Arm type	Experimental
Investigational medicinal product name	PF-06651600 30 mg
Investigational medicinal product code	
Other name	ritlecitinib
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects swallowed the tablet once daily with ambient temperature water to a total volume of approximately 240 mL after breakfast whenever possible.

Number of subjects in period 2[1]	Extension (EXT) PF-06700841 60 mg - 30 mg QD	EXT PF-06651600 200 mg - 50 mg QD + nbUVB	EXT PF-06651600 200 mg - 50 mg QD
Started	55	43	187
Completed	47	27	158
Not completed	8	16	29
Consent withdrawn by subject	3	3	12
Adverse event, non-fatal	3	1	6
Other	1	2	4
Medication Error Without Associated Adverse Event	-	1	1
Lost to follow-up	-	-	2
No Longer Meets Eligibility Criteria	-	-	1
Lack of efficacy	1	9	2
Protocol deviation	-	-	1

Number of subjects in period 2[1]	EXT PF-06651600 50 mg QD	EXT PF-06651600 30 mg QD
Started	6	2
Completed	3	2
Not completed	3	0
Consent withdrawn by subject	3	-
Adverse event, non-fatal	-	-
Other	-	-
Medication Error Without Associated Adverse Event	-	-
Lost to follow-up	-	-
No Longer Meets Eligibility Criteria	-	-
Lack of efficacy	-	-
Protocol deviation	-	-

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: Not all of the participants completing the dose ranging period entered the extension period

Baseline characteristics

Reporting groups	
Reporting group title	PF-06651600 200 mg - 50 mg QD
Reporting group description:	
Subjects were randomized to receive ritlecitinib (PF-06651600) induction dose of 200 mg QD for 4 weeks followed by ritlecitinib 50 mg QD for another 20 weeks.	
Reporting group title	PF-06651600 100 mg - 50 mg QD
Reporting group description:	
Subjects were randomized to receive ritlecitinib induction dose of 100 mg QD for 4 weeks followed by ritlecitinib 50 mg QD for another 20 weeks.	
Reporting group title	PF-06651600 50 mg QD
Reporting group description:	
Subjects were randomized to receive ritlecitinib 50 mg QD for 24 weeks.	
Reporting group title	PF-06651600 30 mg QD
Reporting group description:	
Subjects were randomized to receive ritlecitinib 30 mg QD for 24 weeks.	
Reporting group title	PF-06651600 10 mg QD
Reporting group description:	
Subjects were randomized to receive ritlecitinib 10 mg QD for 24 weeks.	
Reporting group title	Placebo
Reporting group description:	
Subjects were randomized to receive placebo for 24 weeks.	

Reporting group values	PF-06651600 200 mg - 50 mg QD	PF-06651600 100 mg - 50 mg QD	PF-06651600 50 mg QD
Number of subjects	65	67	67
Age Categorical Units: Subjects			
< 18 years	0	0	0
18 - 44 years	33	29	33
45 - 64 years	30	37	34
≥ 65 years	2	1	0
Age continuous Units: years			
arithmetic mean	45.37	44.15	43.34
standard deviation	± 12.21	± 11.15	± 10.42
Sex: Female, Male Units: Subjects			
Female	30	31	39
Male	35	36	28
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	15	17	17
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	3	0	0
White	44	47	45
More than one race	0	1	1

Unknown or Not Reported	3	2	4
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	11	9	11
Not Hispanic or Latino	54	58	54
Unknown or Not Reported	0	0	2

Reporting group values	PF-06651600 30 mg QD	PF-06651600 10 mg QD	Placebo
Number of subjects	50	49	66
Age Categorical Units: Subjects			
< 18 years	0	0	0
18 - 44 years	20	16	30
45 - 64 years	30	31	32
≥ 65 years	0	2	4
Age continuous Units: years			
arithmetic mean	44.74	46.57	46.09
standard deviation	± 13.51	± 10.03	± 11.51
Sex: Female, Male Units: Subjects			
Female	28	25	40
Male	22	24	26
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	1	0	0
Asian	5	11	21
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	4	1	2
White	39	33	38
More than one race	0	2	1
Unknown or Not Reported	1	2	4
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	12	7	7
Not Hispanic or Latino	38	41	58
Unknown or Not Reported	0	1	1

Reporting group values	Total		
Number of subjects	364		
Age Categorical Units: Subjects			
< 18 years	0		
18 - 44 years	161		
45 - 64 years	194		
≥ 65 years	9		
Age continuous Units: years			
arithmetic mean			
standard deviation	-		

Sex: Female, Male Units: Subjects			
Female	193		
Male	171		
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	1		
Asian	86		
Native Hawaiian or Other Pacific Islander	0		
Black or African American	10		
White	246		
More than one race	5		
Unknown or Not Reported	16		
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	57		
Not Hispanic or Latino	303		
Unknown or Not Reported	4		

End points

End points reporting groups

Reporting group title	PF-06651600 200 mg - 50 mg QD
Reporting group description:	
Subjects were randomized to receive ritlecitinib (PF-06651600) induction dose of 200 mg QD for 4 weeks followed by ritlecitinib 50 mg QD for another 20 weeks.	
Reporting group title	PF-06651600 100 mg - 50 mg QD
Reporting group description:	
Subjects were randomized to receive ritlecitinib induction dose of 100 mg QD for 4 weeks followed by ritlecitinib 50 mg QD for another 20 weeks.	
Reporting group title	PF-06651600 50 mg QD
Reporting group description:	
Subjects were randomized to receive ritlecitinib 50 mg QD for 24 weeks.	
Reporting group title	PF-06651600 30 mg QD
Reporting group description:	
Subjects were randomized to receive ritlecitinib 30 mg QD for 24 weeks.	
Reporting group title	PF-06651600 10 mg QD
Reporting group description:	
Subjects were randomized to receive ritlecitinib 10 mg QD for 24 weeks.	
Reporting group title	Placebo
Reporting group description:	
Subjects were randomized to receive placebo for 24 weeks.	
Reporting group title	Extension (EXT) PF-06700841 60 mg - 30 mg QD
Reporting group description:	
After a 4-week drug holiday, subjects received induction dose of brepocitinib (PF-06700841) 60 mg QD for 4 weeks followed by brepocitinib 30 mg QD for 16 weeks. This arm is open label.	
Reporting group title	EXT PF-06651600 200 mg - 50 mg QD + nbUVB
Reporting group description:	
Induction dose of ritlecitinib 200 mg QD plus standardized narrow band UVB (nbUVB) add-on therapy for 4 weeks followed by ritlecitinib 50 mg QD plus standardized nbUVB add-on therapy for 20 weeks (only for subjects who provided nbUVB consent). Subjects who had <10% improvement in percent change in VASI at Extension Week 12 from the baseline value at Dose Ranging Period Week 24 were discontinued from the treatment and entered Follow-up Period. This arm is open label.	
Reporting group title	EXT PF-06651600 200 mg - 50 mg QD
Reporting group description:	
Induction dose of ritlecitinib 200 mg QD of for 4 weeks followed by ritlecitinib 50 mg QD for 20 weeks. This arm is double blinded.	
Reporting group title	EXT PF-06651600 50 mg QD
Reporting group description:	
Ritlecitinib 50 mg QD for 24 weeks. This arm is double blinded.	
Reporting group title	EXT PF-06651600 30 mg QD
Reporting group description:	
Ritlecitinib 30 mg QD of for 24 weeks. This arm is double blinded.	

Primary: Percent Change From Baseline in Central Read Facial-Vitiligo Area Scoring Index (F-VASI) at Week 24 - Dose Ranging (DR) Period

End point title	Percent Change From Baseline in Central Read Facial-Vitiligo Area Scoring Index (F-VASI) at Week 24 - Dose Ranging (DR) Period

End point description:

Central read F-VASI was assessed based on the facial photographs taken at the site. The central read F-VASI was calculated using a formula that included contribution of affected facial surface areas showing 6 different depigmentation rates (0.1, 0.25, 0.5, 0.75, 0.9 and 1): F-VASI (central read) = [Affected Facial Surface Area]×4×[Depigmentation Rates]. Face was defined as the area from the hairline on top of the forehead to the jawline at the bottom of the cheeks. F-VASI (central read) ranged from 0.000 to 4.000 by defining the affected Facial Surface Area (expressed as the value between 0.0 to 1.0) being 4% of total Body Surface Area. The higher score of F-VASI signified severer symptoms of non-segmental vitiligo. Percent change from baseline in F-VASI =((post-baseline F-VASI - baseline F-VASI)/baseline F-VASI)×100. The analysis population included all subjects who received at least 1 dose of randomized study medication and had a baseline and at least 1 post-baseline measurement.

End point type	Primary

End point timeframe:

Baseline, Week 24. Baseline was defined as the last measurement prior to Study Day 18.

End point values	PF-06651600 200 mg - 50 mg QD	PF-06651600 100 mg - 50 mg QD	PF-06651600 50 mg QD	PF-06651600 30 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	62	63	59	45
Units: Percentage				
least squares mean (standard error)	-21.2 (± 4.13)	-21.2 (± 4.16)	-18.5 (± 4.44)	-14.6 (± 5.47)

End point values	PF-06651600 10 mg QD	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	48	57		
Units: Percentage				
least squares mean (standard error)	-3.0 (± 4.65)	2.1 (± 4.06)		

Statistical analyses

Statistical analysis title	PF-06651600 200mg - 50mg QD vs Placebo
Comparison groups	PF-06651600 200 mg - 50 mg QD v Placebo
Number of subjects included in analysis	119
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001 [1]
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	-23.2
Confidence interval	
level	90 %
sides	2-sided
lower limit	-32.53
upper limit	-13.96

Variability estimate	Standard error of the mean
Dispersion value	5.62

Notes:

[1] - Hochberg’s step-up procedure was conducted to compare the ritlecitinib 200mg - 50mg QD dose group vs placebo using observed p-values. The familywise Type 1 error rate was controlled at one-sided 0.05. Hochberg adjusted p-value is presented here.

Statistical analysis title	PF-06651600 100 mg - 50 mg QD vs Placebo
Comparison groups	PF-06651600 100 mg - 50 mg QD v Placebo
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001 [2]
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	-23.2
Confidence interval	
level	90 %
sides	2-sided
lower limit	-32.53
upper limit	-13.93
Variability estimate	Standard error of the mean
Dispersion value	5.63

Notes:

[2] - Hochberg’s step-up procedure was conducted to compare the ritlecitinib 100mg - 50mg QD dose group vs placebo using observed p-values. The familywise Type 1 error rate was controlled at one-sided 0.05. Hochberg adjusted p-value is presented here.

Statistical analysis title	PF-06651600 30 mg QD vs Placebo
Comparison groups	PF-06651600 30 mg QD v Placebo
Number of subjects included in analysis	102
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0068 [3]
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	-16.7
Confidence interval	
level	90 %
sides	2-sided
lower limit	-27.77
upper limit	-5.61
Variability estimate	Standard error of the mean
Dispersion value	6.71

Notes:

[3] - Hochberg’s step-up procedure was conducted to compare the ritlecitinib 30 mg QD dose group vs placebo using observed p-values. The familywise Type 1 error rate was controlled at one-sided 0.05. One-sided unadjusted p-value is presented here.

Statistical analysis title	PF-06651600 10 mg QD vs Placebo
Comparison groups	PF-06651600 10 mg QD v Placebo

Number of subjects included in analysis	105
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2015 [4]
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	-5.1
Confidence interval	
level	90 %
sides	2-sided
lower limit	-15.02
upper limit	4.91
Variability estimate	Standard error of the mean
Dispersion value	6.03

Notes:

[4] - Hochberg's step-up procedure was conducted to compare the ritlecitinib 10 mg QD dose group vs placebo using observed p-values. The familywise Type 1 error rate was controlled at one-sided 0.05. One-sided unadjusted p-value is presented here.

Statistical analysis title	PF-06651600 50 mg QD vs Placebo
Comparison groups	PF-06651600 50 mg QD v Placebo
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0003 [5]
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	-20.6
Confidence interval	
level	90 %
sides	2-sided
lower limit	-30.23
upper limit	-10.93
Variability estimate	Standard error of the mean
Dispersion value	5.84

Notes:

[5] - Hochberg's step-up procedure was conducted to compare the ritlecitinib 50 mg QD dose group vs placebo using observed p-values. The familywise Type 1 error rate was controlled at one-sided 0.05. Hochberg adjusted p-value is presented here.

Primary: Number of Subjects With Treatment Emergent Adverse Events (TEAEs) and Serious Adverse Events (SAEs) up to Week 24 - DR Period

End point title	Number of Subjects With Treatment Emergent Adverse Events (TEAEs) and Serious Adverse Events (SAEs) up to Week 24 - DR Period[6]

End point description:

AE was any untoward medical occurrence in a subject administered a product; the event did not need to have a causal relationship with the treatment. An AE was considered a TEAE if the event started during the effective duration of treatment. All events started on or after the first dosing day and time, if collected, but before the last dose plus the lag time were flagged as TEAEs. SAE was any untoward medical occurrence at any dose that resulted in death; was life threatening (immediate risk of death); required inpatient hospitalization or prolongation of existing hospitalization; resulted in persistent or significant disability/incapacity (substantial disruption of the ability to conduct normal life functions); resulted in congenital anomaly/birth defect; or that was considered to be an important medical event. Causality to study treatment was determined by the investigator. The safety analysis population included all subjects who received at least 1 dose of investigational product.

End point type	Primary

End point timeframe:

24 weeks

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	PF-06651600 200 mg - 50 mg QD	PF-06651600 100 mg - 50 mg QD	PF-06651600 50 mg QD	PF-06651600 30 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	65	67	67	50
Units: Subjects				
Subjects With TEAEs (All-Causality)	56	45	54	30
Subjects With TEAEs (Treatment-Related)	32	19	20	17
Subjects With SAEs (All-Causality)	0	0	1	1
Subjects With SAEs (Treatment-Related)	0	0	0	0

End point values	PF-06651600 10 mg QD	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49	66		
Units: Subjects				
Subjects With TEAEs (All-Causality)	40	52		
Subjects With TEAEs (Treatment-Related)	18	20		
Subjects With SAEs (All-Causality)	1	1		
Subjects With SAEs (Treatment-Related)	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With the TEAEs of Anaemia, Neutropenia, Thrombocytopenia and Lymphopenia - DR Period

End point title	Number of Subjects With the TEAEs of Anaemia, Neutropenia, Thrombocytopenia and Lymphopenia - DR Period[7]

End point description:

An AE was any untoward medical occurrence in a study subject administered a product or medical device; the event did not necessarily need to have a causal relationship with the treatment or usage. The abnormal test findings, clinically significant signs and symptoms of anaemia, neutropenia, thrombocytopenia and lymphopenia were reported as AEs. The clinical significance was determined by the investigator.
An AE was considered a TEAE if the event started during the effective duration of treatment. All events that started on or after the first dosing day and time/start time, if collected, but before the last dose plus the lag time were flagged as TEAEs.

End point type	Primary

End point timeframe:

Baseline up to Week 24 (Baseline was defined as the last measurement prior to first dosing [Day 1])

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	PF-06651600 200 mg - 50 mg QD	PF-06651600 100 mg - 50 mg QD	PF-06651600 50 mg QD	PF-06651600 30 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	65	67	67	50
Units: Subjects				
Subjects With Anaemia	0	0	0	0
Subjects With Neutropenia	0	1	0	0
Subjects With Thrombocytopenia	1	0	0	0
Subjects With Lymphopenia	1	0	0	0

End point values	PF-06651600 10 mg QD	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49	66		
Units: Subjects				
Subjects With Anaemia	0	0		
Subjects With Neutropenia	1	1		
Subjects With Thrombocytopenia	0	0		
Subjects With Lymphopenia	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Clinically Meaningful Changes From Baseline in Lipid Profile up to Week 24 - DR Period

End point title	Number of Subjects With Clinically Meaningful Changes From Baseline in Lipid Profile up to Week 24 - DR Period[8]

End point description:

Subjects had to abstain from all food and drink (except water and non-investigational products) for an 8-hour overnight fast prior to fasting lipid profile panel collection. Fasting lipid assessment included total cholesterol, low-density lipoprotein (LDL) cholesterol, high-density lipoprotein (HDL) cholesterol, and triglycerides. The clinical meaningfulness was determined by the investigator. The safety analysis population included all subjects who received at least 1 dose of investigational product.

End point type	Primary

End point timeframe:

Baseline up to Week 24 (Baseline was defined as the last measurement prior to first dosing [Day 1])

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	PF-06651600 200 mg - 50 mg QD	PF-06651600 100 mg - 50 mg QD	PF-06651600 50 mg QD	PF-06651600 30 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	65	67	67	50
Units: Subjects	0	0	0	0

End point values	PF-06651600 10 mg QD	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49	66		
Units: Subjects	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Liver Function Test Values Meeting the Protocol-Specified Discontinuation Criteria - DR Period

End point title	Number of Subjects With Liver Function Test Values Meeting the Protocol-Specified Discontinuation Criteria - DR Period[9]

End point description:

Liver function tests included tests of alanine aminotransferase (ALT), aspartate aminotransferase (AST) and total bilirubin.
The safety analysis population included all subjects who received at least 1 dose of investigational product.

End point type	Primary

End point timeframe:

24 weeks

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	PF-06651600 200 mg - 50 mg QD	PF-06651600 100 mg - 50 mg QD	PF-06651600 50 mg QD	PF-06651600 30 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	65	67	67	50
Units: Subjects				
Bilirubin > 1.5 x upper limit of normal (ULN)	0	0	0	0
AST > 2.5 x ULN	1	0	1	0
ALT > 2.5 x ULN	0	0	1	1

End point values	PF-06651600 10 mg QD	Placebo		

Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49	66		
Units: Subjects				
Bilirubin > 1.5 x upper limit of normal (ULN)	0	0		
AST > 2.5 x ULN	1	0		
ALT > 2.5 x ULN	1	1		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With TEAEs and SAEs - Extension (Ext) Period

End point title	Number of Subjects With TEAEs and SAEs - Extension (Ext) Period[10]

End point description:

AE was any untoward medical occurrence in a subject administered a product; the event did not need to have a causal relationship with the treatment. An AE was considered a TEAE if the event started during the effective duration of treatment. All events started on or after the first dosing day and time, if collected, but before the last dose plus the lag time were flagged as TEAEs. SAE was any untoward medical occurrence at any dose that resulted in death; was life threatening (immediate risk of death); required inpatient hospitalization or prolongation of existing hospitalization; resulted in persistent or significant disability/incapacity (substantial disruption of the ability to conduct normal life functions); resulted in congenital anomaly/birth defect; or that was considered to be an important medical event. Causality to study treatment was determined by the investigator. The safety analysis population included all subjects who received at least 1 dose of investigational product.

End point type	Primary

End point timeframe:

24 weeks

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	Extension (EXT) PF-06700841 60 mg - 30 mg QD	EXT PF-06651600 200 mg - 50 mg QD + nbUVB	EXT PF-06651600 200 mg - 50 mg QD	EXT PF-06651600 50 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	55	43	187	6
Units: Subjects				
Subjects With All-Causality TEAEs	38	32	119	3
Subjects With Treatment-Related TEAEs	20	12	36	0
Subjects With All-Causality SAEs	1	0	1	0
Subjects With Treatment-Related SAEs	1	0	0	0

End point values	EXT PF-06651600 30 mg QD			
Subject group type	Reporting group			
Number of subjects analysed	2			

Units: Subjects				
Subjects With All-Causality TEAEs	2			
Subjects With Treatment-Related TEAEs	0			
Subjects With All-Causality SAEs	0			
Subjects With Treatment-Related SAEs	0			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With the TEAEs of Anaemia, Neutropenia, Thrombocytopenia and Lymphopenia - Ext Period

End point title	Number of Subjects With the TEAEs of Anaemia, Neutropenia, Thrombocytopenia and Lymphopenia - Ext Period[11]

End point description:

An AE was any untoward medical occurrence in a study subject administered a product or medical device; the event did not necessarily need to have a causal relationship with the treatment or usage. The abnormal test findings, clinically significant signs and symptoms of anaemia, neutropenia, thrombocytopenia and lymphopenia were reported as AEs. The clinical significance was determined by the investigator.
An AE was considered a TEAE if the event started during the effective duration of treatment. All events that started on or after the first dosing day and time/start time, if collected, but before the last dose plus the lag time were flagged as TEAEs.

End point type	Primary

End point timeframe:

24 weeks

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	Extension (EXT) PF-06700841 60 mg - 30 mg QD	EXT PF-06651600 200 mg - 50 mg QD + nbUVB	EXT PF-06651600 200 mg - 50 mg QD	EXT PF-06651600 50 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	55	43	187	6
Units: Subjects				
Subjects With Anemia	0	0	0	1
Subjects With Neutropenia	1	0	1	0
Subjects With Thrombocytopenia	0	0	0	0
Subjects With Lymphopenia	0	0	0	0

End point values	EXT PF-06651600 30 mg QD			
Subject group type	Reporting group			
Number of subjects analysed	2			
Units: Subjects				
Subjects With Anemia	0			
Subjects With Neutropenia	0			

Subjects With Thrombocytopenia	0			
Subjects With Lymphopenia	0			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Clinically Meaningful Changes From Baseline in Lipid Profile - Ext Period

End point title	Number of Subjects With Clinically Meaningful Changes From Baseline in Lipid Profile - Ext Period[12]

End point description:

Subjects had to abstain from all food and drink (except water and non-investigational products) for an 8-hour overnight fast prior to fasting lipid profile panel collection. Fasting lipid assessment included total cholesterol, LDL cholesterol, HDL cholesterol, and triglycerides. The clinical meaningfulness was determined by the investigator. The safety analysis population included all subjects who received at least 1 dose of investigational product.

End point type	Primary

End point timeframe:

24 weeks

Notes:

[12] - 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	Extension (EXT) PF-06700841 60 mg - 30 mg QD	EXT PF-06651600 200 mg - 50 mg QD + nbUVB	EXT PF-06651600 200 mg - 50 mg QD	EXT PF-06651600 50 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	55	43	187	6
Units: Subjects	0	0	0	0

End point values	EXT PF-06651600 30 mg QD			
Subject group type	Reporting group			
Number of subjects analysed	2			
Units: Subjects	0			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Liver Function Test Values Meeting the Protocol-Specified Discontinuation Criteria - Ext Period

End point title	Number of Subjects With Liver Function Test Values Meeting

	the Protocol-Specified Discontinuation Criteria - Ext Period[13]

End point description:

Liver function tests included tests of alanine aminotransferase (ALT), aspartate aminotransferase (AST) and total bilirubin.
The safety analysis population included all subjects who received at least 1 dose of investigational product.

End point type	Primary

End point timeframe:

24 weeks

Notes:

[13] - 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	Extension (EXT) PF-06700841 60 mg - 30 mg QD	EXT PF-06651600 200 mg - 50 mg QD + nbUVB	EXT PF-06651600 200 mg - 50 mg QD	EXT PF-06651600 50 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	55	42	186	6
Units: Subjects				
Bilirubin > 1.5 x ULN	0	0	0	0
AST > 2.5 x ULN	0	0	0	0
ALT > 2.5 x ULN	0	0	1	0

End point values	EXT PF-06651600 30 mg QD			
Subject group type	Reporting group			
Number of subjects analysed	2			
Units: Subjects				
Bilirubin > 1.5 x ULN	0			
AST > 2.5 x ULN	0			
ALT > 2.5 x ULN	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of Subjects Achieving Central F-VASI75 at Week 24 - DR Period

End point title	Proportion of Subjects Achieving Central F-VASI75 at Week 24 - DR Period

End point description:

This endpoint was the proportion of subjects achieving at least 75% improvement from baseline in central read F-VASI (F-VASI75) at Week 24. A negative percent change from baseline in central read F-VASI signified an improvement. The central read F-VASI75 response rate was analyzed by first treating the missing data (non-COVID-19 related) as non responders and then applying Chan and Zhang exact confidence interval (CI) method at Week 24.
Central read F-VASI75=1 if percent change from baseline ≥75; central read F-VASI75=0 if percent change from baseline <75. Percent change from baseline in F-VASI=((post-baseline F-VASI - baseline F-VASI)/baseline F-VASI)×100. The analysis population included all subjects who received at least 1 dose

of randomized study medication and had a baseline and at least 1 post-baseline measurement (after taking randomization study medication).

End point type	Secondary

End point timeframe:

Baseline, Week 24. Baseline was defined as the last measurement prior to study Day 18.

End point values	PF-06651600 200 mg - 50 mg QD	PF-06651600 100 mg - 50 mg QD	PF-06651600 50 mg QD	PF-06651600 30 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	58	59	52	37
Units: Percentage of Subjects				
number (not applicable)	12.1	8.5	7.7	2.7

End point values	PF-06651600 10 mg QD	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	43	57		
Units: Percentage of Subjects				
number (not applicable)	2.3	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of Subjects Achieving T-VASI50 at Week 24 - DR Period

End point title	Proportion of Subjects Achieving T-VASI50 at Week 24 - DR Period

End point description:

T-VASI was calculated using a formula that included contribution from 6 body regions (possible range, 0-100): T-VASI = [Hand Units]×[Depigmentation]. One hand unit, which encompassed the palm plus the volar surface of all the digits, was approximately 1% of the total body surface area and was used as a guide to estimate the baseline percentage of vitiligo involvement of each body region. The body was divided into 6 separate and mutually exclusive regions: face/neck, hands, upper extremities, trunk, lower extremities, and feet. The extent of depigmentation was expressed by the percentages: 0, 10%, 25%, 50%, 75%, 90% or 100%. This endpoint was the proportion of subjects achieving at least 50% improvement from baseline in T-VASI (T-VASI50) at Week 24. Negative percent change from baseline in T-VASI signified an improvement. Analysis population included all subjects who received at least 1 dose of randomized study medication and had a baseline and at least 1 post-baseline measurement.

End point type	Secondary

End point timeframe:

Baseline, Week 24. Baseline was defined as the last measurement prior to first dosing (Day 1).

End point values	PF-06651600 200 mg - 50 mg QD	PF-06651600 100 mg - 50 mg QD	PF-06651600 50 mg QD	PF-06651600 30 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	63	65	65	47
Units: Percentage of Subjects				
number (not applicable)	7.9	4.6	4.6	10.6

End point values	PF-06651600 10 mg QD	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49	66		
Units: Percentage of Subjects				
number (not applicable)	4.1	9.1		

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change From Baseline in T-VASI at Designated Time Points - DR Period

End point title	Percent Change From Baseline in T-VASI at Designated Time Points - DR Period

End point description:

The total body VASI (T-VASI) was calculated using a formula that included contribution from all 6 body regions (possible range, 0-100) with a modified method: VASI = [Hand Units] × [Depigmentation]. The body was divided into 6 separate and mutually exclusive regions: face/neck, hands, upper extremities (excluding hands), trunk, lower extremities (excluding the feet), and feet. The extent of depigmentation was expressed by the following percentages: 0, 10%, 25%, 50%, 75%, 90%, or 100%. Percent change from baseline in T-VASI = ((post-baseline T-VASI - baseline T-VASI)/baseline T-VASI)×100. Negative percent change from baseline in T-VASI signified an improvement. The analysis population included all subjects who received at least 1 dose of randomized study medication and had a baseline and at least 1 post-baseline measurement (after taking randomization study medication). The n in the parentheses below represents the number of evaluable subjects analyzed in each arm.

End point type	Secondary

End point timeframe:

Baseline, Weeks 4, 8, 12, 16, 20 and 24. Baseline was defined as the last measurement prior to first dosing (Day 1).

End point values	PF-06651600 200 mg - 50 mg QD	PF-06651600 100 mg - 50 mg QD	PF-06651600 50 mg QD	PF-06651600 30 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	64	67	67	50
Units: Percentage				
least squares mean (standard error)				
Week 4 (n = 64, 66, 64, 50, 47 and 63)	-2.4 (± 1.51)	-3.0 (± 1.50)	-2.6 (± 1.50)	-5.1 (± 1.72)
Week 8 (n = 63, 65, 63, 48, 48, 64)	-6.2 (± 2.03)	-5.4 (± 2.01)	-5.1 (± 2.01)	-6.6 (± 2.33)

Week 12 (n = 59, 62, 60, 44, 46 and 61)	-7.2 (± 2.44)	-11.9 (± 2.40)	-9.1 (± 2.40)	-11.4 (± 2.82)
Week 16 (n = 56, 57, 55, 43, 43 and 58)	-10.0 (± 2.66)	-13.1 (± 2.67)	-12.6 (± 2.66)	-11.9 (± 3.03)
Week 20 (n = 52, 59, 53, 43, 41 and 55)	-13.8 (± 3.13)	-16.0 (± 2.98)	-14.2 (± 3.07)	-12.0 (± 3.43)
Week 24 (n = 52, 58, 52, 36, 41 and 56)	-14.7 (± 3.49)	-19.2 (± 3.29)	-14.7 (± 3.44)	-14.0 (± 4.15)

End point values	PF-06651600 10 mg QD	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49	66		
Units: Percentage				
least squares mean (standard error)				
Week 4 (n = 64, 66, 64, 50, 47 and 63)	-2.9 (± 1.76)	-1.4 (± 1.52)		
Week 8 (n = 63, 65, 63, 48, 48, 64)	-3.0 (± 2.32)	-5.8 (± 2.02)		
Week 12 (n = 59, 62, 60, 44, 46 and 61)	-4.9 (± 2.76)	-8.0 (± 2.40)		
Week 16 (n = 56, 57, 55, 43, 43 and 58)	-5.7 (± 3.03)	-12.0 (± 2.62)		
Week 20 (n = 52, 59, 53, 43, 41 and 55)	-9.2 (± 3.51)	-13.3 (± 3.04)		
Week 24 (n = 52, 58, 52, 36, 41 and 56)	-12.1 (± 3.88)	-11.0 (± 3.34)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change From Baseline in Central Read F-VASI at Designated Time Points - DR Period

End point title	Percent Change From Baseline in Central Read F-VASI at Designated Time Points - DR Period

End point description:

Central read F-VASI was assessed based on the facial photographs taken at the site. Central read F-VASI was calculated using a formula that included contribution of affected facial surface areas showing all 6 different depigmentation rates (0.1, 0.25, 0.5, 0.75, 0.9 and 1) with a modified method: F-VASI (central read)= [Affected Facial Surface Area]× 4 ×[Depigmentation Rates]. F-VASI (central read) ranged from 0.000 to 4.000 by defining the affected Facial Surface Area (expressed as the value between 0.0 to 1.0) being 4% of total Body Surface Area. Percent change from baseline in F-VASI = ((post-baseline F-VASI - baseline F-VASI)/baseline F-VASI)×100. Negative percent change from baseline in F-VASI signified an improvement. The analysis population included all subjects who received at least 1 dose of randomized study medication and had a baseline and at least 1 post-baseline measurement. The n in the parentheses below represents the number of evaluable subjects analyzed in each arm.

End point type	Secondary

End point timeframe:

Baseline, Weeks 4, 8, 16 and 24. Baseline was defined as the last measurement prior to Study Day 18.

End point values	PF-06651600 200 mg - 50 mg QD	PF-06651600 100 mg - 50 mg QD	PF-06651600 50 mg QD	PF-06651600 30 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	62	63	59	45
Units: Percentage				
least squares mean (standard error)				
Week 4 (n = 61, 60, 55, 44, 47 and 56)	0.1 (± 0.80)	0.4 (± 0.82)	-0.2 (± 0.84)	-1.2 (± 0.94)
Week 8 (n = 57, 57, 52, 43, 47 and 55)	-7.0 (± 1.42)	-5.3 (± 1.44)	-1.8 (± 1.46)	-1.4 (± 1.62)
Week 16 (n = 51, 49, 49, 34, 37 and 47)	-17.0 (± 3.16)	-16.4 (± 3.25)	-10.7 (± 3.19)	-13.3 (± 3.87)
Week 24 (n = 49, 49, 41, 27, 37 and 50)	-21.2 (± 4.13)	-21.2 (± 4.16)	-18.5 (± 4.44)	-14.6 (± 5.47)

End point values	PF-06651600 10 mg QD	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	48	57		
Units: Percentage				
least squares mean (standard error)				
Week 4 (n = 61, 60, 55, 44, 47 and 56)	0.0 (± 0.91)	0.6 (± 0.83)		
Week 8 (n = 57, 57, 52, 43, 47 and 55)	-0.1 (± 1.55)	-0.2 (± 1.44)		
Week 16 (n = 51, 49, 49, 34, 37 and 47)	-5.6 (± 3.67)	-0.2 (± 3.27)		
Week 24 (n = 49, 49, 41, 27, 37 and 50)	-3.0 (± 4.65)	2.1 (± 4.06)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change From Baseline in Local F-VASI at Designated Time Points - DR Period

End point title	Percent Change From Baseline in Local F-VASI at Designated Time Points - DR Period

End point description:

Site assessment of the F-VASI was calculated by a formula that included contribution from face (possible range 0 to 4): Local F-VASI=[Digit Units] × [Depigmentation]×0.1. Scalp, neck, eyebrows, eyelashes, and vermilion were excluded from this calculation. The volar surface of 1 digit (the subject's thumb) was approximately 0.1% of the total body surface area and was used as a guide to estimate the baseline percentage of vitiligo involvement of face. The extent of depigmentation was expressed by the percentages of 0, 10%, 25%, 50%, 75%, 90%, or 100%. Percent change from baseline in F-VASI = ((post baseline F-VASI - baseline F-VASI)/baseline F-VASI)×100. Negative percent change from baseline in F-VASI signified an improvement. Analysis population included all participants who received at least 1 dose of randomized study medication and had a baseline and at least 1 post-baseline measurement. The n in the parentheses below represents the number of evaluable subjects analyzed in each arm.

End point type	Secondary

End point timeframe:

Baseline, Weeks 4, 8, 12, 16, 20 and 24. Baseline was defined as the last measurement prior to first dosing (Day 1).

End point values	PF-06651600 200 mg - 50 mg QD	PF-06651600 100 mg - 50 mg QD	PF-06651600 50 mg QD	PF-06651600 30 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	64	67	67	50
Units: Percentage				
least squares mean (standard error)				
Week 4 (n = 64, 66, 64, 50, 47 and 63)	-4.9 (± 2.63)	3.1 (± 2.61)	-5.0 (± 2.60)	0.4 (± 2.96)
Week 8 (n = 63, 65, 63, 48, 48 and 64)	-11.3 (± 5.35)	0.4 (± 5.32)	-8.8 (± 5.30)	10.1 (± 6.09)
Week 12 (n = 59, 62, 60, 44, 46 and 61)	-15.9 (± 4.16)	-6.5 (± 4.11)	-12.2 (± 4.10)	-7.1 (± 4.77)
Week 16 (n = 56, 57, 56, 43, 44 and 58)	-19.4 (± 4.85)	-6.2 (± 4.88)	-19.7 (± 4.82)	-6.4 (± 5.48)
Week 20 (n = 52, 59, 53, 43, 41 and 55)	-21.9 (± 5.59)	-12.9 (± 5.35)	-23.2 (± 5.52)	0 (± 6.11)
Week 24 (n = 52, 58, 52, 36, 41 and 56)	-28.3 (± 5.70)	-20.6 (± 5.38)	-26.2 (± 5.61)	-4.3 (± 6.70)

End point values	PF-06651600 10 mg QD	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49	66		
Units: Percentage				
least squares mean (standard error)				
Week 4 (n = 64, 66, 64, 50, 47 and 63)	-5.3 (± 3.05)	-6.3 (± 2.63)		
Week 8 (n = 63, 65, 63, 48, 48 and 64)	-7.3 (± 6.12)	-7.5 (± 5.31)		
Week 12 (n = 59, 62, 60, 44, 46 and 61)	-9.8 (± 4.72)	-11.4 (± 4.08)		
Week 16 (n = 56, 57, 56, 43, 44 and 58)	-10.3 (± 5.46)	-13.3 (± 4.75)		
Week 20 (n = 52, 59, 53, 43, 41 and 55)	-14.4 (± 6.30)	-15.3 (± 5.44)		
Week 24 (n = 52, 58, 52, 36, 41 and 56)	-13.9 (± 6.32)	-18.1 (± 5.43)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change From Baseline in SA-VES at Designated Time Points - DR Period

End point title	Percent Change From Baseline in SA-VES at Designated Time Points - DR Period

End point description:

The Self-Assessment Vitiligo Extent Score (SA-VES) was a validated patient report outcome measurement instrument to provide information about disease extent. Vitiligo Extent Score (VES) was a measure to express the overall vitiligo involvement of the body (extent). Clinical illustrations for 19 separate body areas that reflected different degrees of involvement (1%, 5%, 10%, 25%, 50% and

75% depigmentation) were chosen to represent the participant's skin lesions to get the total extent of the disease. VES was a sum of all surface measurement that was similar to VASI. The analysis population included all subjects who received at least 1 dose of randomized study medication and had a baseline and at least 1 post-baseline measurement (after taking randomization study medication). The n in the parentheses below represents the number of evaluable subjects analyzed in each arm.

End point type	Secondary

End point timeframe:

Baseline, Weeks 4, 16 and 24. Baseline was defined as the last measurement prior to first dosing (Day 1).

End point values	PF-06651600 200 mg - 50 mg QD	PF-06651600 100 mg - 50 mg QD	PF-06651600 50 mg QD	PF-06651600 30 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	64	67	67	50
Units: Percentage				
least squares mean (standard error)				
Week 4 (n = 62, 66, 64, 50, 47 and 63)	2.7 (± 17.19)	1.1 (± 16.71)	-1.1 (± 16.74)	4.9 (± 19.25)
Week 16 (n = 54, 55, 56, 41, 44 and 58)	4.7 (± 13.82)	-0.5 (± 13.48)	-3.7 (± 13.45)	6.9 (± 15.53)
Week 24 (n = 50, 56, 49, 32, 40 and 55)	0 (± 10.35)	-3.5 (± 10.02)	-4.3 (± 10.11)	-4.4 (± 11.89)

End point values	PF-06651600 10 mg QD	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49	66		
Units: Percentage				
least squares mean (standard error)				
Week 4 (n = 62, 66, 64, 50, 47 and 63)	4.9 (± 19.84)	50.4 (± 17.13)		
Week 16 (n = 54, 55, 56, 41, 44 and 58)	-0.5 (± 15.87)	52.5 (± 13.72)		
Week 24 (n = 50, 56, 49, 32, 40 and 55)	-1.6 (± 11.77)	44.0 (± 10.16)		

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Change From Baseline in T-VASI at Designated Time Points - DR Period

End point title	Absolute Change From Baseline in T-VASI at Designated Time Points - DR Period

End point description:

The T-VASI was calculated using a formula that included contribution from 6 different body regions (possible range, 0-100) with a modified method: VASI = [Hand Units] × [Depigmentation]. The body was divided into 6 separate and mutually exclusive regions: face/neck, hands, upper extremities (excluding hands), trunk, lower extremities (excluding the feet), and feet. The extent of depigmentation was expressed by the following percentages: 0, 10%, 25%, 50%, 75%, 90%, or 100%. The absolute

change from baseline in T-VASI was analyzed using the ANCOVA analysis. Negative change from baseline in T-VASI signified an improvement. The analysis population included all participants who received at least 1 dose of randomized study medication and had a baseline and at least 1 post-baseline measurement. The n in the parentheses below represents the number of evaluable subjects analyzed in each arm.

End point type	Secondary

End point timeframe:

Baseline, Weeks 4, 8, 12, 16, 20 and 24. Baseline was defined as the last measurement prior to first dosing (Day 1).

End point values	PF-06651600 200 mg - 50 mg QD	PF-06651600 100 mg - 50 mg QD	PF-06651600 50 mg QD	PF-06651600 30 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	64	67	67	50
Units: Units on a Scale				
least squares mean (standard error)				
Week 4 (n = 64, 67, 67, 50, 49 and 66)	-0.3 (± 0.25)	-0.5 (± 0.25)	-0.6 (± 0.25)	-1.0 (± 0.28)
Week 8 (n = 63, 65, 63, 48, 48 and 64)	-0.9 (± 0.32)	-0.9 (± 0.32)	-0.9 (± 0.32)	-1.2 (± 0.37)
Week 12 (n = 59, 62, 60, 44, 46 and 61)	-1.1 (± 0.41)	-2.0 (± 0.40)	-1.6 (± 0.40)	-1.8 (± 0.47)
Week 16 (n = 56, 57, 55, 43, 43 and 58)	-1.5 (± 0.46)	-2.1 (± 0.46)	-1.9 (± 0.46)	-1.9 (± 0.53)
Week 20 (n = 52, 59, 53, 43, 41 and 55)	-2.0 (± 0.55)	-2.8 (± 0.53)	-2.3 (± 0.54)	-2.0 (± 0.61)
Week 24 (n = 52, 58, 52, 36, 41 and 56)	-2.3 (± 0.62)	-3.4 (± 0.59)	-2.4 (± 0.61)	-2.7 (± 0.74)

End point values	PF-06651600 10 mg QD	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49	66		
Units: Units on a Scale				
least squares mean (standard error)				
Week 4 (n = 64, 67, 67, 50, 49 and 66)	-0.4 (± 0.29)	-0.2 (± 0.25)		
Week 8 (n = 63, 65, 63, 48, 48 and 64)	-0.5 (± 0.36)	-0.9 (± 0.32)		
Week 12 (n = 59, 62, 60, 44, 46 and 61)	-0.9 (± 0.46)	-1.6 (± 0.40)		
Week 16 (n = 56, 57, 55, 43, 43 and 58)	-0.9 (± 0.53)	-2.2 (± 0.46)		
Week 20 (n = 52, 59, 53, 43, 41 and 55)	-1.7 (± 0.62)	-2.2 (± 0.54)		
Week 24 (n = 52, 58, 52, 36, 41 and 56)	-2.0 (± 0.69)	-1.8 (± 0.60)		

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of Subjects Achieving T-VASI50 at Designated Time Points - DR Period

End point title	Proportion of Subjects Achieving T-VASI50 at Designated Time Points - DR Period

End point description:

The T-VASI was calculated using a formula that included contribution from 6 different body regions (possible range, 0-100) with a modified method: T-VASI = [Hand Units]×[Depigmentation]. The body was divided into 6 separate and mutually exclusive regions: face/neck, hands, upper extremities, trunk, lower extremities, and feet. The extent of depigmentation was expressed by the percentages: 0, 10%, 25%, 50%, 75%, 90% or 100%. This endpoint was the proportion of subjects achieving at least 50% improvement from baseline in T-VASI (T-VASI50). Negative percent change from baseline in T-VASI signified an improvement. Percent change from baseline in T-VASI = ((post-baseline T-VASI - baseline T-VASI)/baseline T-VASI)×100. The analysis population included all participants who received at least 1 dose of randomized study medication and had a baseline and at least 1 post-baseline measurement. The n in the parentheses below represents the number of evaluable subjects analyzed in each arm.

End point type	Secondary

End point timeframe:

Baseline, Weeks 4, 8, 12, 16, 20 and 24. Baseline was defined as the last measurement prior to first dosing (Day 1).

End point values	PF-06651600 200 mg - 50 mg QD	PF-06651600 100 mg - 50 mg QD	PF-06651600 50 mg QD	PF-06651600 30 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	64	67	67	50
Units: Percentage of Subjects				
number (not applicable)				
Week 4 (n = 64, 67, 67, 50, 49 and 66)	1.6	1.5	0	2.0
Week 8 (n = 64, 67, 67, 50, 49 and 66)	1.6	1.5	1.5	4.0
Week 12 (n = 62, 66, 66, 49, 48 and 66)	1.6	1.5	1.5	4.1
Week 16 (n = 63, 62, 66, 47, 46 and 63)	0	3.2	0	2.1
Week 20 (n = 61, 67, 64, 49, 48 and 63)	4.9	1.5	1.6	6.1
Week 24 (n = 63, 65, 65, 47, 49 and 66)	7.9	4.6	4.6	10.6

End point values	PF-06651600 10 mg QD	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49	66		
Units: Percentage of Subjects				
number (not applicable)				
Week 4 (n = 64, 67, 67, 50, 49 and 66)	0	0		
Week 8 (n = 64, 67, 67, 50, 49 and 66)	0	1.5		
Week 12 (n = 62, 66, 66, 49, 48 and 66)	0	4.5		
Week 16 (n = 63, 62, 66, 47, 46 and 63)	0	6.3		
Week 20 (n = 61, 67, 64, 49, 48 and 63)	2.1	9.5		

Week 24 (n = 63, 65, 65, 47, 49 and 66)	4.1	9.1		

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of Subjects Achieving T-VASI75 at Designated Time Points - DR Period

End point title	Proportion of Subjects Achieving T-VASI75 at Designated Time Points - DR Period

End point description:

The T-VASI was calculated using a formula that included contribution from 6 different body regions (possible range, 0-100) with a modified method: T-VASI = [Hand Units]×[Depigmentation]. The body was divided into 6 separate and mutually exclusive regions: face/neck, hands, upper extremities, trunk, lower extremities, and feet. The extent of depigmentation was expressed by the percentages: 0, 10%, 25%, 50%, 75%, 90% or 100%. This endpoint was the proportion of subjects achieving at least 75% improvement from baseline in T-VASI (T-VASI75). Negative percent change from baseline in T-VASI signified an improvement. Percent change from baseline in T-VASI = ((post-baseline T-VASI - baseline T-VASI)/baseline T-VASI)×100. The analysis population included all participants who received at least 1 dose of randomized study medication and had a baseline and at least 1 post-baseline measurement. The n in the parentheses below represents the number of evaluable subjects analyzed in each arm.

End point type	Secondary

End point timeframe:

Baseline, Weeks 4, 8, 12, 16, 20 and 24. Baseline was defined as the last measurement prior to first dosing (Day 1).

End point values	PF-06651600 200 mg - 50 mg QD	PF-06651600 100 mg - 50 mg QD	PF-06651600 50 mg QD	PF-06651600 30 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	64	67	67	50
Units: Percentage of Subjects				
number (not applicable)				
Week 4 (n = 64, 67, 67, 50, 49 and 66)	0	0	0	0
Week 8 (n = 64, 67, 67, 50, 49 and 66)	0	0	0	0
Week 12 (n = 62, 66, 66, 49, 48 and 66)	0	0	0	0
Week 16 (n = 63, 62, 66, 47, 46 and 63)	0	0	0	0
Week 20 (n = 61, 67, 64, 49, 48 and 63)	0	0	0	0
Week 24 (n = 63, 65, 65, 47, 49 and 66)	0	0	0	0

End point values	PF-06651600 10 mg QD	Placebo		

Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49	66		
Units: Percentage of Subjects				
number (not applicable)				
Week 4 (n = 64, 67, 67, 50, 49 and 66)	0	0		
Week 8 (n = 64, 67, 67, 50, 49 and 66)	0	0		
Week 12 (n = 62, 66, 66, 49, 48 and 66)	0	0		
Week 16 (n = 63, 62, 66, 47, 46 and 63)	0	0		
Week 20 (n = 61, 67, 64, 49, 48 and 63)	0	0		
Week 24 (n = 63, 65, 65, 47, 49 and 66)	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of Subjects Achieving T-VASI90 at Designated Time Points - DR Period

End point title	Proportion of Subjects Achieving T-VASI90 at Designated Time Points - DR Period

End point description:

The T-VASI was calculated using a formula that included contribution from 6 different body regions (possible range, 0-100) with a modified method: T-VASI = [Hand Units]×[Depigmentation]. The body was divided into 6 separate and mutually exclusive regions: face/neck, hands, upper extremities, trunk, lower extremities, and feet. The extent of depigmentation was expressed by the percentages: 0, 10%, 25%, 50%, 75%, 90% or 100%. This endpoint was the proportion of subjects achieving at least 90% improvement from baseline in T-VASI (T-VASI90). Negative percent change from baseline in T-VASI signified an improvement. Percent change from baseline in T-VASI = ((post-baseline T-VASI - baseline T-VASI)/baseline T-VASI)×100. The analysis population included all participants who received at least 1 dose of randomized study medication and had a baseline and at least 1 post-baseline measurement. The n in the parentheses below represents the number of evaluable subjects analyzed in each arm.

End point type	Secondary

End point timeframe:

Baseline, Weeks 4, 8, 12, 16, 20 and 24. Baseline was defined as the last measurement prior to first dosing (Day 1).

End point values	PF-06651600 200 mg - 50 mg QD	PF-06651600 100 mg - 50 mg QD	PF-06651600 50 mg QD	PF-06651600 30 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	64	67	67	50
Units: Percentage of Subjects				
number (not applicable)				
Week 4 (n = 64, 67, 67, 50, 49 and 66)	0	0	0	0
Week 8 (n = 64, 67, 67, 50, 49 and 66)	0	0	0	0
Week 12 (n = 62, 66, 66, 49, 48 and 66)	0	0	0	0
Week 16 (n = 63, 62, 66, 47, 46 and 63)	0	0	0	0

Week 20 (n = 61, 67, 64, 49, 48 and 63)	0	0	0	0
Week 24 (n = 63, 65, 65, 47, 49 and 66)	0	0	0	0

End point values	PF-06651600 10 mg QD	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49	66		
Units: Percentage of Subjects				
number (not applicable)				
Week 4 (n = 64, 67, 67, 50, 49 and 66)	0	0		
Week 8 (n = 64, 67, 67, 50, 49 and 66)	0	0		
Week 12 (n = 62, 66, 66, 49, 48 and 66)	0	0		
Week 16 (n = 63, 62, 66, 47, 46 and 63)	0	0		
Week 20 (n = 61, 67, 64, 49, 48 and 63)	0	0		
Week 24 (n = 63, 65, 65, 47, 49 and 66)	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of Subjects Achieving T-VASI100 at Designated Time Points - DR Period

End point title	Proportion of Subjects Achieving T-VASI100 at Designated Time Points - DR Period

End point description:

The T-VASI was calculated using a formula that included contribution from 6 different body regions (possible range, 0-100) with a modified method: T-VASI = [Hand Units]×[Depigmentation]. The body was divided into 6 separate and mutually exclusive regions: face/neck, hands, upper extremities, trunk, lower extremities, and feet. The extent of depigmentation was expressed by the percentages: 0, 10%, 25%, 50%, 75%, 90% or 100%. This endpoint was the proportion of subjects achieving at least 100% improvement from baseline in T-VASI (T-VASI100). Negative percent change from baseline in T-VASI signified an improvement. Percent change from baseline in T-VASI = ((post-baseline T-VASI - baseline T-VASI)/baseline T-VASI)×100. The analysis population included all participants who received at least 1 dose of randomized study medication and had a baseline and at least 1 post-baseline measurement. The n in the parentheses below represents the number of evaluable subjects analyzed in each arm.

End point type	Secondary

End point timeframe:

Baseline, Weeks 4, 8, 12, 16, 20 and 24. Baseline was defined as the last measurement prior to first dosing (Day 1).

End point values	PF-06651600 200 mg - 50 mg QD	PF-06651600 100 mg - 50 mg QD	PF-06651600 50 mg QD	PF-06651600 30 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	64	67	67	50
Units: Percentage of Subjects				
number (not applicable)				
Week 4 (n = 64, 67, 67, 50, 49 and 66)	0	0	0	0
Week 8 (n = 64, 67, 67, 50, 49 and 66)	0	0	0	0
Week 12 (n = 62, 66, 66, 49, 48 and 66)	0	0	0	0
Week 16 (n = 63, 62, 66, 47, 46 and 63)	0	0	0	0
Week 20 (n = 61, 67, 64, 49, 48 and 63)	0	0	0	0
Week 24 (n = 63, 65, 65, 47, 49 and 66)	0	0	0	0

End point values	PF-06651600 10 mg QD	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49	66		
Units: Percentage of Subjects				
number (not applicable)				
Week 4 (n = 64, 67, 67, 50, 49 and 66)	0	0		
Week 8 (n = 64, 67, 67, 50, 49 and 66)	0	0		
Week 12 (n = 62, 66, 66, 49, 48 and 66)	0	0		
Week 16 (n = 63, 62, 66, 47, 46 and 63)	0	0		
Week 20 (n = 61, 67, 64, 49, 48 and 63)	0	0		
Week 24 (n = 63, 65, 65, 47, 49 and 66)	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of Subjects Achieving Central Read F-VASI50 at Designated Time Points - DR Period

End point title	Proportion of Subjects Achieving Central Read F-VASI50 at Designated Time Points - DR Period

End point description:

The central read F-VASI was calculated using a formula that included contribution of affected facial surface areas showing all 6 different depigmentation rates (0.1, 0.25, 0.5, 0.75, 0.9 and 1): F-VASI (central read)= [Affected Facial Surface Area] × 4 × [Depigmentation Rates]. F-VASI (central read) ranged from 0.000 to 4.000 by defining the affected Facial Surface Area (expressed as the value between 0.0 to 1.0) being 4% of total Body Surface Area. This endpoint was the proportion of subjects achieving at least 50% improvement in central read F-VASI from baseline (F-VASI50). Negative percent change from baseline in F-VASI signified an improvement. The analysis population included all subjects who received at least 1 dose of randomized study medication and had a baseline and at least 1 post-baseline measurement. The n in the parentheses below represents the number of evaluable subjects

analyzed in each arm.

End point type	Secondary

End point timeframe:

Baseline, Weeks 4, 8, 16 and 24. Baseline was defined as the last measurement prior to Study Day 18.

End point values	PF-06651600 200 mg - 50 mg QD	PF-06651600 100 mg - 50 mg QD	PF-06651600 50 mg QD	PF-06651600 30 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	62	63	59	45
Units: Percentage of Subjects				
number (not applicable)				
Week 4 (n = 62, 63, 59, 45, 48 and 57)	0	0	0	2.2
Week 8 (n = 62, 63, 59, 45, 48 and 57)	3.2	0	0	2.2
Week 16 (n = 61, 58, 58, 39, 42 and 52)	14.8	13.8	6.9	10.3
Week 24 (n = 58, 59, 52, 37, 43 and 57)	22.4	25.4	15.4	18.9

End point values	PF-06651600 10 mg QD	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	48	57		
Units: Percentage of Subjects				
number (not applicable)				
Week 4 (n = 62, 63, 59, 45, 48 and 57)	0	0		
Week 8 (n = 62, 63, 59, 45, 48 and 57)	0	0		
Week 16 (n = 61, 58, 58, 39, 42 and 52)	2.4	1.9		
Week 24 (n = 58, 59, 52, 37, 43 and 57)	7.0	1.8		

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of Subjects Achieving Central Read F-VASI75 at Designated Time Points - DR Period

End point title	Proportion of Subjects Achieving Central Read F-VASI75 at Designated Time Points - DR Period

End point description:

The central read F-VASI was calculated using a formula that included contribution of affected facial surface areas showing all 6 different depigmentation rates (0.1, 0.25, 0.5, 0.75, 0.9 and 1): F-VASI (central read)= [Affected Facial Surface Area] × 4 × [Depigmentation Rates]. F-VASI (central read) ranged from 0.000 to 4.000 by defining the affected Facial Surface Area (expressed as the value between 0.0 to 1.0) being 4% of total Body Surface Area. This endpoint was the proportion of subjects achieving at least 75% improvement in central read F-VASI from baseline (F-VASI75). Negative percent change from baseline in F-VASI signified an improvement. The analysis population included all subjects

who received at least 1 dose of randomized study medication and had a baseline and at least 1 post-baseline measurement. The n in the parentheses below represents the number of evaluable subjects analyzed in each arm.

End point type	Secondary

End point timeframe:

Baseline, Weeks 4, 8, 16 and 24. Baseline was defined as the last measurement prior to Study Day 18.

End point values	PF-06651600 200 mg - 50 mg QD	PF-06651600 100 mg - 50 mg QD	PF-06651600 50 mg QD	PF-06651600 30 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	62	63	59	45
Units: Percentage of Subjects				
number (not applicable)				
Week 4 (n = 62, 63, 59, 45, 48 and 57)	0	0	0	0
Week 8 (n = 62, 63, 59, 45, 48 and 57)	0	0	0	0
Week 16 (n = 61, 58, 58, 39, 42 and 52)	1.6	1.7	5.2	2.6
Week 24 (n = 58, 59, 52, 37, 43 and 57)	12.1	8.5	7.7	2.7

End point values	PF-06651600 10 mg QD	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	48	57		
Units: Percentage of Subjects				
number (not applicable)				
Week 4 (n = 62, 63, 59, 45, 48 and 57)	0	0		
Week 8 (n = 62, 63, 59, 45, 48 and 57)	0	0		
Week 16 (n = 61, 58, 58, 39, 42 and 52)	2.4	0		
Week 24 (n = 58, 59, 52, 37, 43 and 57)	2.3	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of Subjects Achieving Central Read F-VASI90 at Designated Time Points - DR Period

End point title	Proportion of Subjects Achieving Central Read F-VASI90 at Designated Time Points - DR Period

End point description:

The central read F-VASI was calculated using a formula that included contribution of affected facial surface areas showing all 6 different depigmentation rates (0.1, 0.25, 0.5, 0.75, 0.9 and 1): F-VASI (central read)= [Affected Facial Surface Area] × 4 × [Depigmentation Rates]. F-VASI (central read) ranged from 0.000 to 4.000 by defining the affected Facial Surface Area (expressed as the value between 0.0 to 1.0) being 4% of total Body Surface Area. This endpoint was the proportion of subjects

achieving at least 90% improvement in central read F-VASI from baseline (F-VASI90). Negative percent change from baseline in F-VASI signified an improvement. The analysis population included all subjects who received at least 1 dose of randomized study medication and had a baseline and at least 1 post-baseline measurement. The n in the parentheses below represents the number of evaluable subjects analyzed in each arm.

End point type	Secondary

End point timeframe:

Baseline, Weeks 4, 8, 16 and 24. Baseline was defined as the last measurement prior to Study Day 18.

End point values	PF-06651600 200 mg - 50 mg QD	PF-06651600 100 mg - 50 mg QD	PF-06651600 50 mg QD	PF-06651600 30 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	62	63	59	45
Units: Percentage of Subjects				
number (not applicable)				
Week 4 (n = 62, 63, 59, 45, 48 and 57)	0	0	0	0
Week 8 (n = 62, 63, 59, 45, 48 and 57)	0	0	0	0
Week 16 (n = 61, 58, 58, 39, 42 and 52)	0	0	1.7	0
Week 24 (n = 58, 59, 52, 37, 43 and 57)	1.7	0	3.8	0

End point values	PF-06651600 10 mg QD	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	48	57		
Units: Percentage of Subjects				
number (not applicable)				
Week 4 (n = 62, 63, 59, 45, 48 and 57)	0	0		
Week 8 (n = 62, 63, 59, 45, 48 and 57)	0	0		
Week 16 (n = 61, 58, 58, 39, 42 and 52)	0	0		
Week 24 (n = 58, 59, 52, 37, 43 and 57)	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of Subjects Achieving Central Read F-VASI100 at Designated Time Points - DR Period

End point title	Proportion of Subjects Achieving Central Read F-VASI100 at Designated Time Points - DR Period

End point description:

The central read F-VASI was calculated using a formula that included contribution of affected facial surface areas showing all 6 different depigmentation rates (0.1, 0.25, 0.5, 0.75, 0.9 and 1): F-VASI (central read)= [Affected Facial Surface Area] × 4 × [Depigmentation Rates]. F-VASI (central read)

ranged from 0.000 to 4.000 by defining the affected Facial Surface Area (expressed as the value between 0.0 to 1.0) being 4% of total Body Surface Area. This endpoint was the proportion of subjects achieving at least 100% improvement in central read F-VASI from baseline (F-VASI100). Negative percent change from baseline in F-VASI signified an improvement. The analysis population included all subjects who received at least 1 dose of randomized study medication and had a baseline and at least 1 post-baseline measurement. The n in the parentheses below represents the number of evaluable subjects analyzed in each arm.

End point type	Secondary

End point timeframe:

Baseline, Weeks 4, 8, 16 and 24. Baseline was defined as the last measurement prior to Study Day 18.

End point values	PF-06651600 200 mg - 50 mg QD	PF-06651600 100 mg - 50 mg QD	PF-06651600 50 mg QD	PF-06651600 30 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	62	63	59	45
Units: Percentage of Subjects				
number (not applicable)				
Week 4 (n = 62, 63, 59, 45, 48 and 57)	0	0	0	0
Week 8 (n = 62, 63, 59, 45, 48 and 57)	0	0	0	0
Week 16 (n = 61, 58, 58, 39, 42 and 52)	0	0	0	0
Week 24 (n = 58, 59, 52, 37, 43 and 57)	0	0	0	0

End point values	PF-06651600 10 mg QD	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	48	57		
Units: Percentage of Subjects				
number (not applicable)				
Week 4 (n = 62, 63, 59, 45, 48 and 57)	0	0		
Week 8 (n = 62, 63, 59, 45, 48 and 57)	0	0		
Week 16 (n = 61, 58, 58, 39, 42 and 52)	0	0		
Week 24 (n = 58, 59, 52, 37, 43 and 57)	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of Subjects Achieving Local F-VASI50 at Designated Time Points - DR Period

End point title	Proportion of Subjects Achieving Local F-VASI50 at Designated Time Points - DR Period

End point description:

The site assessment of the F-VASI was calculated using a formula that included contribution from face

(possible range, 0-4): Local F-VASI = [Digit Units] × [Depigmentation] × 0.1. The volar surface of 1 digit (the subject's thumb) was approximately 0.1% of the total body surface area and was used as a guide to estimate the baseline percentage of vitiligo involvement of face. The extent of depigmentation was expressed by the percentages: 0, 10%, 25%, 50%, 75%, 90%, or 100%. This endpoint was the proportion of subjects achieving at least 50% improvement in site assessment F-VASI from baseline (F-VASI50). Negative percent change from baseline in F-VASI signified an improvement. The analysis population included all subjects who received at least 1 dose of randomized study medication and had a baseline and at least 1 post-baseline measurement. The n in the parentheses below represents the number of evaluable subjects analyzed in each arm.

End point type	Secondary

End point timeframe:

Baseline, Weeks 4, 8, 12, 16, 20 and 24. Baseline was defined as the last measurement prior to first dosing (Day 1).

End point values	PF-06651600 200 mg - 50 mg QD	PF-06651600 100 mg - 50 mg QD	PF-06651600 50 mg QD	PF-06651600 30 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	64	67	67	50
Units: Percentage of Subjects				
number (not applicable)				
Week 4 (n = 64, 67, 67, 50, 49 and 66)	3.1	3.0	1.5	2.0
Week 8 (n = 64, 67, 67, 50, 49 and 66)	9.4	3.0	4.5	2.0
Week 12 (n = 62, 66, 66, 49, 48 and 66)	16.1	9.1	9.1	8.2
Week 16 (n = 63, 62, 66, 47, 47 and 63)	14.3	9.7	13.6	8.5
Week 20 (n = 61, 67, 64, 49, 48, 63)	18.0	14.9	17.2	12.2
Week 24 (n = 63, 65, 65, 47, 49 and 66)	20.6	21.5	15.4	10.6

End point values	PF-06651600 10 mg QD	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49	66		
Units: Percentage of Subjects				
number (not applicable)				
Week 4 (n = 64, 67, 67, 50, 49 and 66)	0	3.0		
Week 8 (n = 64, 67, 67, 50, 49 and 66)	4.1	4.5		
Week 12 (n = 62, 66, 66, 49, 48 and 66)	8.3	9.1		
Week 16 (n = 63, 62, 66, 47, 47 and 63)	10.6	14.3		
Week 20 (n = 61, 67, 64, 49, 48, 63)	16.7	17.5		
Week 24 (n = 63, 65, 65, 47, 49 and 66)	18.4	16.7		

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of Subjects Achieving Local F-VASI75 at Designated Time Points - DR Period

End point title	Proportion of Subjects Achieving Local F-VASI75 at Designated Time Points - DR Period

End point description:

The site assessment of the F-VASI was calculated using a formula that included contribution from face (possible range, 0-4): Local F-VASI = [Digit Units] × [Depigmentation] × 0.1. The volar surface of 1 digit (the subject's thumb) was approximately 0.1% of the total body surface area and was used as a guide to estimate the baseline percentage of vitiligo involvement of face. The extent of depigmentation was expressed by the percentages: 0, 10%, 25%, 50%, 75%, 90%, or 100%. This endpoint was the proportion of subjects achieving at least 75% improvement in site assessment F-VASI from baseline (F-VASI75). Negative percent change from baseline in F-VASI signified an improvement. The analysis population included all subjects who received at least 1 dose of randomized study medication and had a baseline and at least 1 post-baseline measurement. The n in the parentheses below represents the number of evaluable subjects analyzed in each arm.

End point type	Secondary

End point timeframe:

Baseline, Weeks 4, 8, 12, 16, 20 and 24. Baseline was defined as the last measurement prior to first dosing (Day 1).

End point values	PF-06651600 200 mg - 50 mg QD	PF-06651600 100 mg - 50 mg QD	PF-06651600 50 mg QD	PF-06651600 30 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	64	67	67	50
Units: Percentage of Subjects				
number (not applicable)				
Week 4 (n = 64, 67, 67, 50, 49 and 66)	0	0	0	0
Week 8 (n = 64, 67, 67, 50, 49 and 66)	0	0	3.0	2.0
Week 12 (n = 62, 66, 66, 49, 48 and 66)	1.6	3.0	4.5	6.1
Week 16 (n = 63, 62, 66, 47, 47 and 63)	3.2	0	4.5	4.3
Week 20 (n = 61, 67, 64, 49, 48 and 63)	6.6	1.5	9.4	6.1
Week 24 (n = 63, 65, 65, 47, 49 and 66)	11.1	4.6	6.2	4.3

End point values	PF-06651600 10 mg QD	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49	66		
Units: Percentage of Subjects				
number (not applicable)				
Week 4 (n = 64, 67, 67, 50, 49 and 66)	0	1.5		
Week 8 (n = 64, 67, 67, 50, 49 and 66)	0	0		
Week 12 (n = 62, 66, 66, 49, 48 and 66)	2.1	1.5		
Week 16 (n = 63, 62, 66, 47, 47 and 63)	4.3	7.9		

Week 20 (n = 61, 67, 64, 49, 48 and 63)	6.3	11.1		
Week 24 (n = 63, 65, 65, 47, 49 and 66)	4.1	13.6		

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of Subjects Achieving Local F-VASI90 at Designated Time Points - DR Period

End point title	Proportion of Subjects Achieving Local F-VASI90 at Designated Time Points - DR Period

End point description:

The site assessment of the F-VASI was calculated using a formula that included contribution from face (possible range, 0-4): Local F-VASI = [Digit Units] × [Depigmentation] × 0.1. The volar surface of 1 digit (the subject's thumb) was approximately 0.1% of the total body surface area and was used as a guide to estimate the baseline percentage of vitiligo involvement of face. The extent of depigmentation was expressed by the percentages: 0, 10%, 25%, 50%, 75%, 90%, or 100%. This endpoint was the proportion of subjects achieving at least 90% improvement in site assessment F-VASI from baseline (F-VASI90). Negative percent change from baseline in F-VASI signified an improvement. The analysis population included all subjects who received at least 1 dose of randomized study medication and had a baseline and at least 1 post-baseline measurement. The n in the parentheses below represents the number of evaluable subjects analyzed in each arm.

End point type	Secondary

End point timeframe:

Baseline, Weeks 4, 8, 12, 16, 20 and 24. Baseline was defined as the last measurement prior to first dosing (Day 1).

End point values	PF-06651600 200 mg - 50 mg QD	PF-06651600 100 mg - 50 mg QD	PF-06651600 50 mg QD	PF-06651600 30 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	64	67	67	50
Units: Percentage of Subjects				
number (not applicable)				
Week 4 (n = 64, 67, 67, 50, 49 and 66)	0	0	0	0
Week 8 (n = 64, 67, 67, 50, 49 and 66)	0	0	1.5	2.0
Week 12 (n = 62, 66, 66, 49, 48 and 66)	0	0	1.5	2.0
Week 16 (n = 63, 62, 66, 47, 47 and 63)	1.6	0	3.0	2.1
Week 20 (n = 61, 67, 64, 49, 48 and 63)	1.6	1.5	4.7	2.0
Week 24 (n = 63, 65, 65, 47, 49 and 66)	1.6	1.5	3.1	0

End point values	PF-06651600 10 mg QD	Placebo		

Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49	66		
Units: Percentage of Subjects				
number (not applicable)				
Week 4 (n = 64, 67, 67, 50, 49 and 66)	0	0		
Week 8 (n = 64, 67, 67, 50, 49 and 66)	0	0		
Week 12 (n = 62, 66, 66, 49, 48 and 66)	0	0		
Week 16 (n = 63, 62, 66, 47, 47 and 63)	2.1	0		
Week 20 (n = 61, 67, 64, 49, 48 and 63)	2.1	1.6		
Week 24 (n = 63, 65, 65, 47, 49 and 66)	4.1	1.5		

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of Subjects Achieving Local F-VASI100 at Designated Time Points - DR Period

End point title	Proportion of Subjects Achieving Local F-VASI100 at Designated Time Points - DR Period

End point description:

The site assessment of the F-VASI was calculated using a formula that included contribution from face (possible range, 0-4): Local F-VASI = [Digit Units] × [Depigmentation] × 0.1. The volar surface of 1 digit (the subject's thumb) was approximately 0.1% of the total body surface area and was used as a guide to estimate the baseline percentage of vitiligo involvement of face. The extent of depigmentation was expressed by the percentages: 0, 10%, 25%, 50%, 75%, 90%, or 100%. This endpoint was the proportion of subjects achieving at least 100% improvement in site assessment F-VASI from baseline (F-VASI100). Negative percent change from baseline in F-VASI signified an improvement. The analysis population included all subjects who received at least 1 dose of randomized study medication and had a baseline and at least 1 post-baseline measurement. The n in the parentheses below represents the number of evaluable subjects analyzed in each arm.

End point type	Secondary

End point timeframe:

Baseline, Weeks 4, 8, 12, 16, 20 and 24. Baseline was defined as the last measurement prior to first dosing (Day 1).

End point values	PF-06651600 200 mg - 50 mg QD	PF-06651600 100 mg - 50 mg QD	PF-06651600 50 mg QD	PF-06651600 30 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	64	67	67	50
Units: Percentage of Subjects				
number (not applicable)				
Week 4 (n = 64, 67, 67, 50, 49 and 66)	0	0	0	0
Week 8 (n = 64, 67, 67, 50, 49 and 66)	0	0	0	2.0
Week 12 (n = 62, 66, 66, 49, 48 and 66)	0	0	0	0
Week 16 (n = 63, 62, 66, 47, 47 and 63)	0	0	0	0

Week 20 (n = 61, 67, 64, 49, 48 and 63)	0	0	1.6	0
Week 24 (n = 63, 65, 65, 47, 49 and 66)	0	0	1.5	0

End point values	PF-06651600 10 mg QD	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49	66		
Units: Percentage of Subjects				
number (not applicable)				
Week 4 (n = 64, 67, 67, 50, 49 and 66)	0	0		
Week 8 (n = 64, 67, 67, 50, 49 and 66)	0	0		
Week 12 (n = 62, 66, 66, 49, 48 and 66)	0	0		
Week 16 (n = 63, 62, 66, 47, 47 and 63)	0	0		
Week 20 (n = 61, 67, 64, 49, 48 and 63)	0	0		
Week 24 (n = 63, 65, 65, 47, 49 and 66)	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Total Vitiligo-Specific Quality of Life (VitiQoL) Score at Designated Time Points - DR Period

End point title	Change From Baseline in Total Vitiligo-Specific Quality of Life (VitiQoL) Score at Designated Time Points - DR Period

End point description:

The VitiQoL instrument was a reliable and validated vitiligo disease-specific health-related quality of life (HRQoL) instrument which measured concepts relevant to vitiligo participants. The VitiQoL was a 15-item patient reported outcomes (PRO) measure which measured concepts of symptoms, daily activities, leisure activities, work, personal relationships and treatment. Responses ranged from "not at all" (scored 0) to "most of the time" (scored 6) and gave a minimum and maximum score from 0 90, with higher scores representing greater burden. VitiQoL total score was calculated as sum of items 1-15. The change from baseline in total VitiQoL score was analyzed using the mixed-effect models repeated measures (MMRM) analysis. The analysis population included all subjects who received at least 1 dose of randomized study medication and had a baseline and at least 1 post-baseline measurement. The n in the parentheses below represents the number of evaluable subjects analyzed in each arm.

End point type	Secondary

End point timeframe:

Baseline, Weeks 4, 16 and 24. Baseline was defined as the last measurement prior to first dosing (Day 1).

End point values	PF-06651600 200 mg - 50 mg QD	PF-06651600 100 mg - 50 mg QD	PF-06651600 50 mg QD	PF-06651600 30 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	64	67	67	50
Units: Units on a Scale				
least squares mean (standard error)				
Week 4 (n = 62, 66, 64, 50, 47 and 63)	-3.9 (± 1.34)	-2.9 (± 1.31)	-4.4 (± 1.31)	-4.4 (± 1.50)
Week 16 (n = 54, 56, 56, 41, 44 and 59)	-6.5 (± 1.83)	-4.9 (± 1.79)	-6.3 (± 1.82)	-4.8 (± 2.07)
Week 24 (n = 50, 56, 50, 34, 41 and 56)	-6.5 (± 1.99)	-3.6 (± 1.92)	-7.7 (± 1.99)	-7.0 (± 2.30)

End point values	PF-06651600 10 mg QD	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49	66		
Units: Units on a Scale				
least squares mean (standard error)				
Week 4 (n = 62, 66, 64, 50, 47 and 63)	-3.5 (± 1.54)	-5.1 (± 1.33)		
Week 16 (n = 54, 56, 56, 41, 44 and 59)	-10.5 (± 2.06)	-7.1 (± 1.78)		
Week 24 (n = 50, 56, 50, 34, 41 and 56)	-9.7 (± 2.22)	-6.4 (± 1.92)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in VitiQoL Participation Limitation Domain Score at Designated Time Points - DR Period

End point title	Change From Baseline in VitiQoL Participation Limitation Domain Score at Designated Time Points - DR Period

End point description:

The VitiQoL was a reliable and validated vitiligo disease specific health-related quality of life (HRQoL) instrument which measured concepts relevant to vitiligo participants. The VitiQoL was a 15-item PRO measure which measured concepts of symptoms, daily activities, leisure activities, work, personal relationships and treatment. Responses ranged from “not at all” (scored 0) to “most of the time” (scored 6) and gave a minimum and maximum score from 0 90, with higher scores representing greater burden. The VitiQoL Participation Limitation domain score was the sum of items 3, 4, 6, 9, 10, 11, 14. The change from baseline in VitiQoL Participation Limitation domain score was analyzed using the MMRM analysis. The analysis population included all subjects who received at least 1 dose of randomized study medication and had a baseline and at least 1 post-baseline measurement. The n in the parentheses below represents the number of evaluable subjects analyzed in each arm.

End point type	Secondary

End point timeframe:

Baseline, Weeks 4, 16 and 24. Baseline was defined as the last measurement prior to first dosing (Day 1).

End point values	PF-06651600 200 mg - 50 mg QD	PF-06651600 100 mg - 50 mg QD	PF-06651600 50 mg QD	PF-06651600 30 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	64	67	67	50
Units: Units on a Scale				
least squares mean (standard error)				
Week 4 (n = 62, 66, 64, 50, 47 and 63)	-1.2 (± 0.71)	-1.1 (± 0.69)	-1.7 (± 0.69)	-1.8 (± 0.79)
Week 16 (n = 54, 56, 56, 41, 44 and 59)	-2.1 (± 0.88)	-1.9 (± 0.86)	-2.6 (± 0.87)	-2.3 (± 1.00)
Week 24 (n = 50, 56, 50, 34, 41 and 56)	-1.4 (± 0.98)	-1.7 (± 0.94)	-3.2 (± 0.97)	-2.8 (± 1.14)

End point values	PF-06651600 10 mg QD	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49	66		
Units: Units on a Scale				
least squares mean (standard error)				
Week 4 (n = 62, 66, 64, 50, 47 and 63)	-1.0 (± 0.81)	-2.5 (± 0.70)		
Week 16 (n = 54, 56, 56, 41, 44 and 59)	-4.1 (± 0.99)	-3.1 (± 0.85)		
Week 24 (n = 50, 56, 50, 34, 41 and 56)	-3.9 (± 1.09)	-2.2 (± 0.94)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in VitiQoL Stigma Domain Score at Designated Time Points - DR Period

End point title	Change From Baseline in VitiQoL Stigma Domain Score at Designated Time Points - DR Period

End point description:

The VitiQoL was a reliable and validated vitiligo disease specific HRQoL instrument which measured concepts relevant to vitiligo participants. The VitiQoL was a 15-item PRO measure which measured concepts of symptoms, daily activities, leisure activities, work, personal relationships and treatment. Responses ranged from "not at all" (scored 0) to "most of the time" (scored 6) and gave a minimum and maximum score from 0 90, with higher scores representing greater burden. The VitiQoL Stigma domain score was the sum of items 1, 2, 5, 7 and 15. The change from baseline in VitiQoL Stigma domain score was analyzed using the MMRM analysis. The analysis population included all subjects who received at least 1 dose of randomized study medication and had a baseline and at least 1 post-baseline measurement. The n in the parentheses below represents the number of evaluable subjects analyzed in each arm.

End point type	Secondary

End point timeframe:

Baseline, Weeks 4, 16 and 24. Baseline was defined as the last measurement prior to first dosing (Day 1).

End point values	PF-06651600 200 mg - 50 mg QD	PF-06651600 100 mg - 50 mg QD	PF-06651600 50 mg QD	PF-06651600 30 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	64	67	67	50
Units: Units on a Scale				
least squares mean (standard error)				
Week 4 (n = 62, 66, 64, 50, 47 and 63)	-1.9 (± 0.56)	-1.6 (± 0.55)	-2.4 (± 0.55)	-1.7 (± 0.62)
Week 16 (n = 54, 56, 56, 41, 44 and 59)	-3.4 (± 0.71)	-2.3 (± 0.70)	-3.2 (± 0.71)	-1.7 (± 0.80)
Week 24 (n = 50, 56, 50, 34, 41 and 56)	-3.8 (± 0.76)	-2.1 (± 0.73)	-3.7 (± 0.76)	-3.1 (± 0.88)

End point values	PF-06651600 10 mg QD	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49	66		
Units: Units on a Scale				
least squares mean (standard error)				
Week 4 (n = 62, 66, 64, 50, 47 and 63)	-1.7 (± 0.64)	-1.8 (± 0.56)		
Week 16 (n = 54, 56, 56, 41, 44 and 59)	-4.3 (± 0.80)	-2.9 (± 0.69)		
Week 24 (n = 50, 56, 50, 34, 41 and 56)	-4.5 (± 0.84)	-3.2 (± 0.73)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in VitiQoL Behaviors Domain Score at Designated Time Points - DR Period

End point title	Change From Baseline in VitiQoL Behaviors Domain Score at Designated Time Points - DR Period

End point description:

The VitiQoL was a reliable and validated vitiligo disease specific HRQoL instrument which measured concepts relevant to vitiligo participants. The VitiQoL was a 15-item PRO measure which measured concepts of symptoms, daily activities, leisure activities, work, personal relationships and treatment. Responses ranged from "not at all" (scored 0) to "most of the time" (scored 6) and gave a minimum and maximum score from 0 90, with higher scores representing greater burden. The VitiQoL Behaviors domain score was the sum of items 8, 12 and 13. The change from baseline in VitiQoL Behaviors domain score was analyzed using the MMRM analysis.
The analysis population included all subjects who received at least 1 dose of randomized study medication and had a baseline and at least 1 post-baseline measurement. The n in the parentheses below represents the number of evaluable subjects analyzed in each arm.

End point type	Secondary

End point timeframe:

Baseline, Weeks 4, 16 and 24. Baseline was defined as the last measurement prior to first dosing (Day 1).

End point values	PF-06651600 200 mg - 50 mg QD	PF-06651600 100 mg - 50 mg QD	PF-06651600 50 mg QD	PF-06651600 30 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	64	67	67	50
Units: Units on a Scale				
least squares mean (standard error)				
Week 4 (n = 62, 66, 64, 50, 47 and 63)	-0.8 (± 0.37)	-0.3 (± 0.36)	-0.2 (± 0.36)	-0.9 (± 0.41)
Week 16 (n = 54, 56, 56, 41, 44 and 59)	-1.1 (± 0.50)	-0.8 (± 0.49)	-0.5 (± 0.50)	-0.9 (± 0.57)
Week 24 (n = 50, 56, 50, 34, 41 and 56)	-1.4 (± 0.53)	0 (± 0.52)	-0.7 (± 0.53)	-1.3 (± 0.62)

End point values	PF-06651600 10 mg QD	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49	66		
Units: Units on a Scale				
least squares mean (standard error)				
Week 4 (n = 62, 66, 64, 50, 47 and 63)	-0.7 (± 0.42)	-0.7 (± 0.37)		
Week 16 (n = 54, 56, 56, 41, 44 and 59)	-2.1 (± 0.56)	-1.0 (± 0.49)		
Week 24 (n = 50, 56, 50, 34, 41 and 56)	-1.3 (± 0.60)	-0.9 (± 0.51)		

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of Subjects Achieving sIGA 0 or 1 and at Least a 2-Point Improvement at Week 24 - DR Period

End point title	Proportion of Subjects Achieving sIGA 0 or 1 and at Least a 2-Point Improvement at Week 24 - DR Period

End point description:

The proportion of participants achieving a static Investigator Global Assessment (sIGA) Score 0/1 and sIGA ≥2-point improvement at Week 24 was presented in this outcome measure. The sIGA score ranged from 0 to 4.
The sIGA Score 0 represented "Clear" with no signs of loss of pigmentation with natural light or with Woods lamp examination.
The sIGA Score 1 represented "Almost Clear" with the following descriptors:
• Faint, barely detectable loss of pigmentation mainly located on dorsal hands, feet, bony prominences, and/or limited areas.
• Approximately 90% pigmentation within lesions.
• No or rare signs of Koebner phenomenon, confetti like or trichrome lesions could be present.
The sIGA Scores 2, 3 and 4 represented "Mild Vitiligo", "Moderate Vitiligo" and "Severe Vitiligo", respectively.
The analysis population included all subjects who received at least 1 dose of randomized study medication and had a baseline and at least 1 post-baseline measurement.

End point type	Secondary

End point timeframe:

Week 24

End point values	PF-06651600 200 mg - 50 mg QD	PF-06651600 100 mg - 50 mg QD	PF-06651600 50 mg QD	PF-06651600 30 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	62	64	65	46
Units: Percentage of Subjects				
number (not applicable)	0	0	0	0

End point values	PF-06651600 10 mg QD	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	48	65		
Units: Percentage of Subjects				
number (not applicable)	0	0		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

48 weeks

Adverse event reporting additional description:

The same event may appear as both an AE and a SAE. However, what is presented are distinct events. An event may be categorized as serious in one subject and as non-serious in another subject, or one subject may have experienced both a serious and non-serious event during the study.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.0

Reporting groups

Reporting group title	PF-06651600 200 mg - 50 mg QD

Reporting group description:

Subjects were randomized to receive ritlecitinib induction dose (200 mg QD) for 4 weeks followed by maintenance dosing of 50 mg QD for 20 weeks

Reporting group title	PF-06651600 100 mg - 50 mg QD

Reporting group description:

Subjects were randomized to receive ritlecitinib induction dose (100 mg QD) for 4 weeks followed by maintenance dosing of 50 mg QD for 20 weeks

Reporting group title	PF-06651600 50 mg QD

Reporting group description:

Subjects were randomized to receive ritlecitinib 50 mg QD for 24 weeks

Reporting group title	PF-06651600 30 mg QD

Reporting group description:

Subjects were randomized to receive ritlecitinib 30 mg QD for 24 weeks

Reporting group title	PF-06651600 10 mg QD

Reporting group description:

Subjects were randomized to receive ritlecitinib 10 mg QD for 24 weeks

Reporting group title	Placebo

Reporting group description:

Subjects were randomized to receive placebo for 24 weeks

Reporting group title	EXT PF-06700841 60 mg - 30 mg QD

Reporting group description:

After a 4-week drug holiday (with no investigational product), subjects received induction dose of PF-06700841 60 mg QD for 4 weeks followed by maintenance dosing of PF-06700841 30 mg QD for 16 weeks. This arm is open label.

Reporting group title	EXT PF-06651600 200 mg - 50 mg QD + nbUVB

Reporting group description:

Induction dose of PF-06651600 200 mg QD plus standardized narrow band UVB (nbUVB) add-on therapy for 4 weeks followed by maintenance dosing of PF-06651600 50 mg QD plus standardized nbUVB add-on therapy for 20 weeks (only for participants who provide nbUVB consent). Subjects who had <10% improvement in percent change in VASI at Extension Week 12 from the baseline value at Dose Ranging Period Week 24 were discontinued from the treatment and entered Follow-up Period. This arm is open label.

Reporting group title	EXT PF-06651600 200 mg - 50 mg QD

Reporting group description:

Induction dose of 200 mg QD of PF 06651600 for 4 weeks followed by maintenance dosing of 50 mg QD of PF 06651600 for 20 weeks. This arm is double blinded.

Reporting group title	EXT PF-06651600 50 mg QD

Reporting group description:

50 mg QD of PF 06651600 for 24 weeks. This arm is double blinded.

Reporting group title	EXT PF-06651600 30 mg QD
Reporting group description:	
30 mg QD of PF 06651600 for 24 weeks. This arm is double blinded.	

Serious adverse events	PF-06651600 200 mg - 50 mg QD	PF-06651600 100 mg - 50 mg QD	PF-06651600 50 mg QD
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 65 (0.00%)	0 / 67 (0.00%)	1 / 67 (1.49%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Uterine leiomyoma			
subjects affected / exposed	0 / 65 (0.00%)	0 / 67 (0.00%)	0 / 67 (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			
Migraine			
subjects affected / exposed	0 / 65 (0.00%)	0 / 67 (0.00%)	1 / 67 (1.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Oesophageal spasm			
subjects affected / exposed	0 / 65 (0.00%)	0 / 67 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Neurogenic bladder			
subjects affected / exposed	0 / 65 (0.00%)	0 / 67 (0.00%)	0 / 67 (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			
Disseminated varicella zoster virus infection			
subjects affected / exposed	0 / 65 (0.00%)	0 / 67 (0.00%)	0 / 67 (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-06651600 30 mg QD	PF-06651600 10 mg QD	Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 50 (2.00%)	1 / 49 (2.04%)	1 / 66 (1.52%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Uterine leiomyoma			
subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	0 / 66 (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			
Migraine			
subjects affected / exposed	0 / 50 (0.00%)	1 / 49 (2.04%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Oesophageal spasm			
subjects affected / exposed	1 / 50 (2.00%)	0 / 49 (0.00%)	0 / 66 (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
Renal and urinary disorders			
Neurogenic bladder			
subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	1 / 66 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Disseminated varicella zoster virus infection			
subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	0 / 66 (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	EXT PF-06700841 60 mg - 30 mg QD	EXT PF-06651600 200 mg - 50 mg QD + nbUVB	EXT PF-06651600 200 mg - 50 mg QD
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 55 (1.82%)	0 / 43 (0.00%)	1 / 187 (0.53%)
number of deaths (all causes)	0	0	0

number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Uterine leiomyoma			
subjects affected / exposed	0 / 55 (0.00%)	0 / 43 (0.00%)	1 / 187 (0.53%)
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			
Migraine			
subjects affected / exposed	0 / 55 (0.00%)	0 / 43 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Oesophageal spasm			
subjects affected / exposed	0 / 55 (0.00%)	0 / 43 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Neurogenic bladder			
subjects affected / exposed	0 / 55 (0.00%)	0 / 43 (0.00%)	0 / 187 (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			
Disseminated varicella zoster virus infection			
subjects affected / exposed	1 / 55 (1.82%)	0 / 43 (0.00%)	0 / 187 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	EXT PF-06651600 50 mg QD	EXT PF-06651600 30 mg QD	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Uterine leiomyoma			

subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Migraine			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Oesophageal spasm			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Neurogenic bladder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (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			
Disseminated varicella zoster virus infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (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	PF-06651600 200 mg - 50 mg QD	PF-06651600 100 mg - 50 mg QD	PF-06651600 50 mg QD
Total subjects affected by non-serious adverse events			
subjects affected / exposed	31 / 65 (47.69%)	35 / 67 (52.24%)	32 / 67 (47.76%)
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 65 (0.00%)	0 / 67 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			

Fatigue			
subjects affected / exposed	6 / 65 (9.23%)	1 / 67 (1.49%)	2 / 67 (2.99%)
occurrences (all)	6	1	2
Influenza like illness			
subjects affected / exposed	0 / 65 (0.00%)	0 / 67 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 65 (0.00%)	0 / 67 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 65 (0.00%)	0 / 67 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	1 / 65 (1.54%)	0 / 67 (0.00%)	1 / 67 (1.49%)
occurrences (all)	1	0	1
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 65 (0.00%)	0 / 67 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	4 / 65 (6.15%)	7 / 67 (10.45%)	8 / 67 (11.94%)
occurrences (all)	4	9	8
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 65 (0.00%)	0 / 67 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 65 (0.00%)	0 / 67 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 65 (0.00%)	1 / 67 (1.49%)	2 / 67 (2.99%)
occurrences (all)	0	1	3

Diarrhoea			
subjects affected / exposed	0 / 65 (0.00%)	5 / 67 (7.46%)	2 / 67 (2.99%)
occurrences (all)	0	7	2
Dyspepsia			
subjects affected / exposed	1 / 65 (1.54%)	0 / 67 (0.00%)	0 / 67 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	4 / 65 (6.15%)	1 / 67 (1.49%)	4 / 67 (5.97%)
occurrences (all)	4	1	4
Dry skin			
subjects affected / exposed	1 / 65 (1.54%)	4 / 67 (5.97%)	0 / 67 (0.00%)
occurrences (all)	1	4	0
Pruritus			
subjects affected / exposed	3 / 65 (4.62%)	2 / 67 (2.99%)	2 / 67 (2.99%)
occurrences (all)	3	2	2
Urticaria			
subjects affected / exposed	2 / 65 (3.08%)	3 / 67 (4.48%)	1 / 67 (1.49%)
occurrences (all)	3	6	1
Photosensitivity reaction			
subjects affected / exposed	0 / 65 (0.00%)	0 / 67 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 65 (0.00%)	0 / 67 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	3 / 65 (4.62%)	3 / 67 (4.48%)	6 / 67 (8.96%)
occurrences (all)	3	3	8
Spinal segmental dysfunction			
subjects affected / exposed	0 / 65 (0.00%)	0 / 67 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 65 (0.00%)	1 / 67 (1.49%)	1 / 67 (1.49%)
occurrences (all)	0	1	1

Folliculitis			
subjects affected / exposed	0 / 65 (0.00%)	1 / 67 (1.49%)	1 / 67 (1.49%)
occurrences (all)	0	2	1
Gastroenteritis			
subjects affected / exposed	2 / 65 (3.08%)	0 / 67 (0.00%)	1 / 67 (1.49%)
occurrences (all)	2	0	1
Nasopharyngitis			
subjects affected / exposed	8 / 65 (12.31%)	10 / 67 (14.93%)	16 / 67 (23.88%)
occurrences (all)	9	11	20
Upper respiratory tract infection			
subjects affected / exposed	5 / 65 (7.69%)	10 / 67 (14.93%)	5 / 67 (7.46%)
occurrences (all)	6	11	8
Urinary tract infection			
subjects affected / exposed	4 / 65 (6.15%)	4 / 67 (5.97%)	2 / 67 (2.99%)
occurrences (all)	5	6	2
COVID-19			
subjects affected / exposed	0 / 65 (0.00%)	0 / 67 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 65 (0.00%)	0 / 67 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Onychomycosis			
subjects affected / exposed	0 / 65 (0.00%)	0 / 67 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed	0 / 65 (0.00%)	0 / 67 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	PF-06651600 30 mg QD	PF-06651600 10 mg QD	Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	23 / 50 (46.00%)	22 / 49 (44.90%)	37 / 66 (56.06%)
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
General disorders and administration			

site conditions			
Fatigue			
subjects affected / exposed	0 / 50 (0.00%)	1 / 49 (2.04%)	1 / 66 (1.52%)
occurrences (all)	0	1	1
Influenza like illness			
subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	3 / 50 (6.00%)	0 / 49 (0.00%)	1 / 66 (1.52%)
occurrences (all)	3	0	1
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 50 (2.00%)	4 / 49 (8.16%)	8 / 66 (12.12%)
occurrences (all)	2	5	10
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			

subjects affected / exposed	0 / 50 (0.00%)	1 / 49 (2.04%)	4 / 66 (6.06%)
occurrences (all)	0	1	4
Diarrhoea			
subjects affected / exposed	4 / 50 (8.00%)	1 / 49 (2.04%)	1 / 66 (1.52%)
occurrences (all)	5	1	2
Dyspepsia			
subjects affected / exposed	0 / 50 (0.00%)	3 / 49 (6.12%)	3 / 66 (4.55%)
occurrences (all)	0	4	3
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	1 / 50 (2.00%)	0 / 49 (0.00%)	0 / 66 (0.00%)
occurrences (all)	1	0	0
Dry skin			
subjects affected / exposed	2 / 50 (4.00%)	1 / 49 (2.04%)	2 / 66 (3.03%)
occurrences (all)	2	1	2
Pruritus			
subjects affected / exposed	1 / 50 (2.00%)	2 / 49 (4.08%)	5 / 66 (7.58%)
occurrences (all)	1	2	5
Urticaria			
subjects affected / exposed	0 / 50 (0.00%)	3 / 49 (6.12%)	0 / 66 (0.00%)
occurrences (all)	0	4	0
Photosensitivity reaction			
subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 50 (0.00%)	1 / 49 (2.04%)	3 / 66 (4.55%)
occurrences (all)	0	1	3
Spinal segmental dysfunction			
subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			

Bronchitis			
subjects affected / exposed	3 / 50 (6.00%)	0 / 49 (0.00%)	0 / 66 (0.00%)
occurrences (all)	6	0	0
Folliculitis			
subjects affected / exposed	1 / 50 (2.00%)	0 / 49 (0.00%)	4 / 66 (6.06%)
occurrences (all)	1	0	4
Gastroenteritis			
subjects affected / exposed	3 / 50 (6.00%)	1 / 49 (2.04%)	1 / 66 (1.52%)
occurrences (all)	3	1	1
Nasopharyngitis			
subjects affected / exposed	5 / 50 (10.00%)	5 / 49 (10.20%)	14 / 66 (21.21%)
occurrences (all)	8	5	20
Upper respiratory tract infection			
subjects affected / exposed	8 / 50 (16.00%)	6 / 49 (12.24%)	8 / 66 (12.12%)
occurrences (all)	8	7	8
Urinary tract infection			
subjects affected / exposed	2 / 50 (4.00%)	3 / 49 (6.12%)	3 / 66 (4.55%)
occurrences (all)	2	3	3
COVID-19			
subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Onychomycosis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 49 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	EXT PF-06700841 60 mg - 30 mg QD	EXT PF-06651600 200 mg - 50 mg QD + nbUVB	EXT PF-06651600 200 mg - 50 mg QD
Total subjects affected by non-serious adverse events			
subjects affected / exposed	17 / 55 (30.91%)	14 / 43 (32.56%)	46 / 187 (24.60%)

Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 55 (1.82%)	0 / 43 (0.00%)	2 / 187 (1.07%)
occurrences (all)	1	0	2
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 55 (0.00%)	0 / 43 (0.00%)	0 / 187 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 55 (0.00%)	0 / 43 (0.00%)	0 / 187 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	3 / 55 (5.45%)	2 / 43 (4.65%)	3 / 187 (1.60%)
occurrences (all)	3	2	3
Epistaxis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 43 (0.00%)	0 / 187 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 55 (0.00%)	0 / 43 (0.00%)	0 / 187 (0.00%)
occurrences (all)	0	0	0
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	3 / 55 (5.45%)	4 / 43 (9.30%)	3 / 187 (1.60%)
occurrences (all)	3	5	3
Nervous system disorders			
Headache			
subjects affected / exposed	4 / 55 (7.27%)	3 / 43 (6.98%)	8 / 187 (4.28%)
occurrences (all)	4	3	8
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 55 (0.00%)	0 / 43 (0.00%)	0 / 187 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			

subjects affected / exposed	0 / 55 (0.00%)	0 / 43 (0.00%)	0 / 187 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 55 (0.00%)	0 / 43 (0.00%)	0 / 187 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 55 (0.00%)	0 / 43 (0.00%)	0 / 187 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 55 (0.00%)	0 / 43 (0.00%)	0 / 187 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 55 (0.00%)	0 / 43 (0.00%)	0 / 187 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 55 (0.00%)	0 / 43 (0.00%)	0 / 187 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 55 (0.00%)	3 / 43 (6.98%)	5 / 187 (2.67%)
occurrences (all)	0	3	6
Urticaria			
subjects affected / exposed	0 / 55 (0.00%)	0 / 43 (0.00%)	0 / 187 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction			
subjects affected / exposed	0 / 55 (0.00%)	3 / 43 (6.98%)	0 / 187 (0.00%)
occurrences (all)	0	4	0
Rash			
subjects affected / exposed	0 / 55 (0.00%)	1 / 43 (2.33%)	1 / 187 (0.53%)
occurrences (all)	0	1	3
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 55 (0.00%)	0 / 43 (0.00%)	0 / 187 (0.00%)
occurrences (all)	0	0	0
Spinal segmental dysfunction			

subjects affected / exposed	0 / 55 (0.00%)	0 / 43 (0.00%)	0 / 187 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	1 / 55 (1.82%)	0 / 43 (0.00%)	0 / 187 (0.00%)
occurrences (all)	1	0	0
Folliculitis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 43 (0.00%)	0 / 187 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 43 (0.00%)	0 / 187 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	3 / 55 (5.45%)	0 / 43 (0.00%)	8 / 187 (4.28%)
occurrences (all)	3	0	10
Upper respiratory tract infection			
subjects affected / exposed	4 / 55 (7.27%)	2 / 43 (4.65%)	9 / 187 (4.81%)
occurrences (all)	4	2	10
Urinary tract infection			
subjects affected / exposed	1 / 55 (1.82%)	3 / 43 (6.98%)	12 / 187 (6.42%)
occurrences (all)	2	4	16
COVID-19			
subjects affected / exposed	0 / 55 (0.00%)	0 / 43 (0.00%)	2 / 187 (1.07%)
occurrences (all)	0	0	2
Influenza			
subjects affected / exposed	3 / 55 (5.45%)	0 / 43 (0.00%)	2 / 187 (1.07%)
occurrences (all)	3	0	2
Onychomycosis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 43 (0.00%)	0 / 187 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed	0 / 55 (0.00%)	0 / 43 (0.00%)	0 / 187 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	EXT PF-06651600 50 mg QD	EXT PF-06651600 30 mg QD	

Total subjects affected by non-serious adverse events subjects affected / exposed	3 / 6 (50.00%)	2 / 2 (100.00%)	
Vascular disorders Hypertension subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1	0 / 2 (0.00%) 0	
General disorders and administration site conditions Fatigue subjects affected / exposed occurrences (all) Influenza like illness subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0 1 / 6 (16.67%) 1	0 / 2 (0.00%) 0 0 / 2 (0.00%) 0	
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all) Epistaxis subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0 1 / 6 (16.67%) 1	0 / 2 (0.00%) 0 0 / 2 (0.00%) 0	
Psychiatric disorders Insomnia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 2 (0.00%) 0	
Investigations Blood creatine phosphokinase increased subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 2 (0.00%) 0	
Nervous system disorders Headache subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 2 (0.00%) 0	
Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1	0 / 2 (0.00%) 0	
Ear and labyrinth disorders			

Ear pain			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Diarrhoea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Dyspepsia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Dry skin			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Pruritus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Urticaria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Photosensitivity reaction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Rash			
subjects affected / exposed	0 / 6 (0.00%)	1 / 2 (50.00%)	
occurrences (all)	0	1	
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	

Spinal segmental dysfunction			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 2 (50.00%)	
occurrences (all)	0	1	
Folliculitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Gastroenteritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Nasopharyngitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Upper respiratory tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Urinary tract infection			
subjects affected / exposed	1 / 6 (16.67%)	1 / 2 (50.00%)	
occurrences (all)	1	1	
COVID-19			
subjects affected / exposed	0 / 6 (0.00%)	1 / 2 (50.00%)	
occurrences (all)	0	1	
Influenza			
subjects affected / exposed	0 / 6 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Onychomycosis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 2 (50.00%)	
occurrences (all)	0	1	
Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 2 (0.00%)	
occurrences (all)	1	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
04 March 2019	Updated Schedule of Activities; updated exploratory endpoints; added new non-clinical safety information to Section 1.2.3.1 Nonclinical Safety; emerging data was added demonstrating a drug interaction (DDI) with oral contraceptives containing ethinyl estradiol (EE) in Section 1.2.3.2 Clinical Experience; Section 4.4.1 Contraception Requirements were modified; updated Section 1.2.4 Study Rationale, Section 4 Subject Eligibility Criteria, Section 4.4.1 Contraception Requirements, and Section 4.4 Lifestyle Requirements; updated description of static investigator global assessment (sIGA) in Section 7.4 Clinical Efficacy Assessments; safety adjudication committees were added to Section 9 Data Analysis/Statistical Methods; updated Appendix 10 Country Specific Requirements; minor administrative changes and sentence revisions made throughout the document.
14 June 2019	updated Schedule of Activities; updated Section 1.2.4.1 PF-06651600 Dose Rationale and Section 4.2 Exclusion Criteria; added definitions of adverse reaction (AR), serious adverse reaction (SAR), and suspected unexpected serious adverse reactions (SUSAR) to Section 8 Adverse Event Reporting; updated Appendix 2 Prohibited Concomitant Medications; minor administrative changes and sentence revisions made throughout the document.
02 July 2019	Added risk-benefit assessment to Section 1.2.5 Summary of Benefits and Risks; updated Section 4.2 Exclusion Criteria.
04 November 2019	Added IND number for PF-06700841 to cover page; updated Schedule of Activities; added B7931019 study data and safety information from phase 2 studies to Section 1.2.3.2 Clinical Experience; updated exploratory endpoints; details of Section 7.11.1 Skin Biopsies have been modified; updated Section 7 Assessments and Appendix 2; minor administrative changes and sentence revisions made throughout the document.
26 June 2020	Updated Schedule of Activities; updated exploratory endpoints; clarification that the site assessment F-VASI will be performed by the investigator(s) was added to Section 7.4.3 Facial Vitiligo Area Scoring Index Site Assessment; the sample size rationale was updated in Section 9.1; the analysis of the primary endpoint and secondary endpoints were updated in Section 9.2; the detail of the analysis was removed from Section 9.5 Safety Analysis during the Dose Ranging Period; added Alternative Measures During Public Emergencies to Appendix 11; minor administrative changes and sentence revisions made throughout the document.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported