



Clinical trial results:

A Phase 2b Randomized, Double-Blind, Placebo-Controlled, Parallel, Multicenter, Dose-Ranging, Study to Evaluate the Efficacy and Safety Profile of PF-04965842 in Subjects With Moderate to Severe Atopic Dermatitis

Summary

EudraCT number	2015-005513-72
Trial protocol	DE HU
Global end of trial date	04 April 2017

Results information

Result version number	v1 (current)
This version publication date	11 March 2018
First version publication date	11 March 2018

Trial information

Trial identification

Sponsor protocol code	B7451006
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02780167
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, Inc, Pfizer Clinical Trials.gov Call Center, +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	25 September 2017
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	04 April 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study was to evaluate the efficacy of 4 once daily (QD) dose levels (10, 30, 100 and 200 mg) of PF-04965842 relative to placebo in adult subjects with moderate to severe atopic dermatitis (AD), using the Investigator's Global Assessment (IGA).

Protection of trial subjects:

This study used an Internal Review Committee (IRC) to monitor the safety of the subjects throughout the study and to make recommendations to the study team. Composition of the IRC and processes under which the IRC operated were documented in an IRC charter.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	15 April 2016
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 49
Country: Number of subjects enrolled	Canada: 68
Country: Number of subjects enrolled	Germany: 14
Country: Number of subjects enrolled	Hungary: 13
Country: Number of subjects enrolled	United States: 123
Worldwide total number of subjects	267
EEA total number of subjects	27

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)	239
From 65 to 84 years	28
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

269 subjects were randomized. There were 2 subjects who were randomized but did not receive any study treatment. A total of 267 subjects were randomized and treated.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Treatment Group Description

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

Dosage and administration details:

0 mg

Arm title	PF-04965842 10mg QD
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Arm description:

Treatment Group Description

Arm type	Experimental
Investigational medicinal product name	PF-04965842
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Coated tablet
Routes of administration	Oral use

Dosage and administration details:

10 mg

Arm title	PF-04965842 30mg QD
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Arm description:

Treatment Group Description

Arm type	Experimental
Investigational medicinal product name	PF-04965842
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Coated tablet
Routes of administration	Oral use

Dosage and administration details:

30 mg

Arm title	PF-04965842 100mg QD
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Arm description:

Treatment Group Description

Arm type	Experimental
Investigational medicinal product name	PF-04965842
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Coated tablet
Routes of administration	Oral use

Dosage and administration details:

100 mg

Arm title	PF-04965842 200mg QD
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Arm description:

Treatment Group Description

Arm type	Experimental
Investigational medicinal product name	PF-04965842
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Coated tablet
Routes of administration	Oral use

Dosage and administration details:

200 mg

Number of subjects in period 1	Placebo	PF-04965842 10mg QD	PF-04965842 30mg QD
Started	56	49	51
Completed	28	27	27
Not completed	28	22	24
Consent withdrawn by subject	6	4	4
Does not meet entrance criteria	-	-	1
Adverse event, non-fatal	9	8	8
No longer meets eligibility criteria	-	-	-
Unspecified	-	-	3
Lost to follow-up	2	-	1
Lack of efficacy	6	5	6
Protocol deviation	5	5	1

Number of subjects in period 1	PF-04965842 100mg QD	PF-04965842 200mg QD
Started	56	55

Completed	37	38
Not completed	19	17
Consent withdrawn by subject	3	4
Does not meet entrance criteria	-	-
Adverse event, non-fatal	12	8
No longer meets eligibility criteria	1	1
Unspecified	1	2
Lost to follow-up	-	-
Lack of efficacy	1	-
Protocol deviation	1	2

Baseline characteristics

Reporting groups

Reporting group title	Placebo
Reporting group description:	
Treatment Group Description	
Reporting group title	PF-04965842 10mg QD
Reporting group description:	
Treatment Group Description	
Reporting group title	PF-04965842 30mg QD
Reporting group description:	
Treatment Group Description	
Reporting group title	PF-04965842 100mg QD
Reporting group description:	
Treatment Group Description	
Reporting group title	PF-04965842 200mg QD
Reporting group description:	
Treatment Group Description	

Reporting group values	Placebo	PF-04965842 10mg QD	PF-04965842 30mg QD
Number of subjects	56	49	51
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	51	44	48
From 65-84 years	5	5	3
85 years and over	0	0	0
Age Continuous			
Units: years			
arithmetic mean	42.6	44.3	37.6
standard deviation	± 15.1	± 15.9	± 15.9
Gender, Male/Female			
Units: Subjects			
Female	35	28	29
Male	21	21	22
Race/Ethnicity			
Units: Subjects			
White	40	38	39
Black	10	5	4
Asian	4	5	5
Other	2	1	3

Reporting group values	PF-04965842 100mg QD	PF-04965842 200mg QD	Total
Number of subjects	56	55	267
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	49	47	239
From 65-84 years	7	8	28
85 years and over	0	0	0
Age Continuous Units: years			
arithmetic mean	41.1	38.7	
standard deviation	± 15.6	± 17.6	-
Gender, Male/Female Units: Subjects			
Female	25	27	144
Male	31	28	123
Race/Ethnicity Units: Subjects			
White	40	37	194
Black	7	13	39
Asian	8	5	27
Other	1	0	7

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description:	
Treatment Group Description	
Reporting group title	PF-04965842 10mg QD
Reporting group description:	
Treatment Group Description	
Reporting group title	PF-04965842 30mg QD
Reporting group description:	
Treatment Group Description	
Reporting group title	PF-04965842 100mg QD
Reporting group description:	
Treatment Group Description	
Reporting group title	PF-04965842 200mg QD
Reporting group description:	
Treatment Group Description	

Primary: Percentage of subjects achieving the Investigator's Global Assessment (IGA) for clear (0) or almost clear (1) and ≥ 2 points improvement from baseline at Week 12

End point title	Percentage of subjects achieving the Investigator's Global Assessment (IGA) for clear (0) or almost clear (1) and ≥ 2 points improvement from baseline at Week 12
End point description:	The IGA score quantifies the severity of subjects' atopic dermatitis (AD). Scores range from 0 to 4 and correspond to a category (clear, almost clear, mild, moderate and severe, respectively).
End point type	Primary
End point timeframe:	Baseline and Week 12

End point values	Placebo	PF-04965842 10mg QD	PF-04965842 30mg QD	PF-04965842 100mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	52 ^[1]	46	45	54
Units: percentage of subjects				
least squares mean (standard error)	6.3 (\pm 2.55)	8.2 (\pm 2.32)	12.3 (\pm 2.88)	27.8 (\pm 5.07)

Notes:

[1] - "Number of Subjects Analyzed" represents the number of evaluable subjects at Week 12.

End point values	PF-04965842 200mg QD			
Subject group type	Reporting group			
Number of subjects analysed	48			
Units: percentage of subjects				
least squares mean (standard error)	44.5 (\pm 6.92)			

Statistical analyses

Statistical analysis title	Treatment difference (PF-04965842 10 mg/placebo)
Comparison groups	Placebo v PF-04965842 10mg QD
Number of subjects included in analysis	98
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.121
Method	Emax model
Parameter estimate	Difference
Point estimate	1.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.7
upper limit	4.4
Variability estimate	Standard error of the mean
Dispersion value	0.99

Statistical analysis title	Treatment difference (PF-04965842 30 mg/placebo)
Comparison groups	Placebo v PF-04965842 30mg QD
Number of subjects included in analysis	97
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1065
Method	Emax model
Parameter estimate	Difference
Point estimate	6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.8
upper limit	13.8
Variability estimate	Standard error of the mean
Dispersion value	3.05

Statistical analysis title	Treatment difference (PF-04965842 100 mg/placebo)
Comparison groups	Placebo v PF-04965842 100mg QD

Number of subjects included in analysis	106
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0184
Method	Emax model
Parameter estimate	Difference
Point estimate	21.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.5
upper limit	37.6
Variability estimate	Standard error of the mean
Dispersion value	6.25

Statistical analysis title	Treatment difference (PF-04965842 200 mg/placebo)
Comparison groups	Placebo v PF-04965842 200mg QD
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0032
Method	Emax model
Parameter estimate	Difference
Point estimate	38.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	19.7
upper limit	56.6
Variability estimate	Standard error of the mean
Dispersion value	7.18

Secondary: Percent change from baseline in the eczema area and severity index (EASI) at Week 12

End point title	Percent change from baseline in the eczema area and severity index (EASI) at Week 12
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End point description:

The EASI quantifies the severity of subjects' AD based on both severity of lesion clinical signs and the percent of body surface area (BSA) affected. EASI is a composite scoring by the AD clinical evaluator of the degree of erythema, induration/population, excoriation, and lichenification (each scored separately) for each of four regions, with adjustment for the percent of BSA involved for each body region and for the proportion of the body region to the whole body. The EASI score can vary in increments of 0.1 and range from 0.0 to 72.0, with higher scores representing greater severity of AD.

End point type	Secondary
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End point timeframe:

Baseline and Week 12

End point values	Placebo	PF-04965842 10mg QD	PF-04965842 30mg QD	PF-04965842 100mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	35 ^[2]	29	30	43
Units: percent change				
least squares mean (standard error)	-35.22 (± 6.572)	-31.13 (± 7.090)	-40.73 (± 6.823)	-59.04 (± 6.212)

Notes:

[2] - "Number of Subjects Analyzed" represents the number of evaluable subjects at Week 12.

End point values	PF-04965842 200mg QD			
Subject group type	Reporting group			
Number of subjects analysed	42			
Units: percent change				
least squares mean (standard error)	-82.57 (± 6.161)			

Statistical analyses

Statistical analysis title	Treatment difference (PF-04965842 10 mg/placebo)
Comparison groups	Placebo v PF-04965842 10mg QD
Number of subjects included in analysis	64
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.6731
Method	Mixed-Effect Model Repeated Measures
Parameter estimate	Difference
Point estimate	4.08
Confidence interval	
level	90 %
sides	2-sided
lower limit	-11.88
upper limit	20.05
Variability estimate	Standard error of the mean
Dispersion value	9.667

Statistical analysis title	Treatment difference (PF-04965842 30 mg/placebo)
Comparison groups	Placebo v PF-04965842 30mg QD

Number of subjects included in analysis	65
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.561
Method	Mixed-Effect Model Repeated Measures
Parameter estimate	Difference
Point estimate	-5.52
Confidence interval	
level	90 %
sides	2-sided
lower limit	-21.16
upper limit	10.13
Variability estimate	Standard error of the mean
Dispersion value	9.474

Statistical analysis title	Treatment difference (PF-04965842 100 mg/placebo)
Comparison groups	Placebo v PF-04965842 100mg QD
Number of subjects included in analysis	78
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0091
Method	Mixed-Effect Model Repeated Measures
Parameter estimate	Difference
Point estimate	-23.82
Confidence interval	
level	90 %
sides	2-sided
lower limit	-38.76
upper limit	-8.88
Variability estimate	Standard error of the mean
Dispersion value	9.043

Statistical analysis title	Treatment difference (PF-04965842 200 mg/placebo)
Comparison groups	Placebo v PF-04965842 200mg QD
Number of subjects included in analysis	77
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Mixed-Effect Model Repeated Measures
Parameter estimate	Difference
Point estimate	-47.35
Confidence interval	
level	90 %
sides	2-sided
lower limit	-62.23
upper limit	-32.47

Variability estimate	Standard error of the mean
Dispersion value	9.008

Secondary: Percentage of subjects achieving the IGA for clear (0) or almost clear (1) and ≥ 2 points improvement from baseline at all scheduled time points except Week 12

End point title	Percentage of subjects achieving the IGA for clear (0) or almost clear (1) and ≥ 2 points improvement from baseline at all scheduled time points except Week 12
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End point description:

The IGA score quantifies the severity of subjects' AD. Scores range from 0 to 4 and correspond to a category (clear, almost clear, mild, moderate and severe, respectively).

End point type	Secondary
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End point timeframe:

Baseline and all scheduled time points except Week 12, including Weeks 1, 2, 4, 6, 8, 13, 14, 16.

End point values	Placebo	PF-04965842 10mg QD	PF-04965842 30mg QD	PF-04965842 100mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56 ^[3]	49	51	56
Units: percentage of subjects				
number (not applicable)				
Week 1 (n = 54, 48, 50, 55, 54)	0.0	2.1	2.0	1.8
Week 2 (n = 55, 49, 50, 55, 52)	3.6	6.1	6.0	3.6
Week 4 (n = 55, 49, 50, 55, 54)	1.8	8.2	8.0	16.4
Week 6 (n = 55, 49, 50, 55, 54)	14.5	14.3	14.0	12.7
Week 8 (n = 55, 49, 50, 55, 53)	5.5	8.2	12.0	16.4
Week 13 (n = 30, 29, 31, 38, 45)	10.0	20.7	12.9	23.7
Week 14 (n = 32, 28, 29, 40, 44)	18.8	10.7	3.4	12.5
Week 16 (n = 28, 26, 27, 36, 38)	10.7	23.1	7.4	13.9

Notes:

[3] - "n" represents the number of evaluable subjects at each visit.

End point values	PF-04965842 200mg QD			
Subject group type	Reporting group			
Number of subjects analysed	55			
Units: percentage of subjects				
number (not applicable)				
Week 1 (n = 54, 48, 50, 55, 54)	3.7			
Week 2 (n = 55, 49, 50, 55, 52)	11.5			
Week 4 (n = 55, 49, 50, 55, 54)	40.7			
Week 6 (n = 55, 49, 50, 55, 54)	40.7			
Week 8 (n = 55, 49, 50, 55, 53)	41.5			
Week 13 (n = 30, 29, 31, 38, 45)	26.7			
Week 14 (n = 32, 28, 29, 40, 44)	15.9			
Week 16 (n = 28, 26, 27, 36, 38)	18.4			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects achieving ≥ 2 points improvement in the IGA from baseline at all scheduled time points

End point title	Percentage of subjects achieving ≥ 2 points improvement in the IGA from baseline at all scheduled time points
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End point description:

The IGA score quantifies the severity of subjects' AD. Scores range from 0 to 4 and correspond to a category (clear, almost clear, mild, moderate and severe, respectively).

End point type	Secondary
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End point timeframe:

All scheduled time points, including Weeks 1, 2, 4, 6, 8, 12, 13, 14, 16

End point values	Placebo	PF-04965842 10mg QD	PF-04965842 30mg QD	PF-04965842 100mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56 ^[4]	49	51	56
Units: percentage of subjects				
number (not applicable)				
Week 1 (n = 54, 48, 49, 55, 53)	1.9	4.2	6.1	5.5
Week 2 (n = 55, 48, 47, 53, 50)	7.3	10.4	10.6	11.3
Week 4 (n = 50, 45, 47, 52, 52)	8.0	11.1	12.8	25.0
Week 6 (n = 44, 38, 43, 48, 52)	22.7	23.7	18.6	29.2
Week 8 (n = 41, 36, 43, 47, 49)	14.6	19.4	23.3	34.0
Week 12 (n = 35, 29, 30, 43, 42)	17.1	17.2	23.3	51.2
Week 13 (n = 30, 29, 31, 38, 45)	13.3	24.1	12.9	26.3
Week 14 (n = 32, 28, 29, 40, 44)	21.9	17.9	10.3	20.0
Week 16 (n = 28, 26, 27, 36, 38)	14.3	26.9	11.1	22.2

Notes:

[4] - "n" represents the number of evaluable subjects at each visit.

End point values	PF-04965842 200mg QD			
Subject group type	Reporting group			
Number of subjects analysed	55			
Units: percentage of subjects				
number (not applicable)				
Week 1 (n = 54, 48, 49, 55, 53)	9.4			
Week 2 (n = 55, 48, 47, 53, 50)	24.0			
Week 4 (n = 50, 45, 47, 52, 52)	51.9			
Week 6 (n = 44, 38, 43, 48, 52)	59.6			

Week 8 (n = 41, 36, 43, 47, 49)	59.2			
Week 12 (n = 35, 29, 30, 43, 42)	57.1			
Week 13 (n = 30, 29, 31, 38, 45)	37.8			
Week 14 (n = 32, 28, 29, 40, 44)	25.0			
Week 16 (n = 28, 26, 27, 36, 38)	31.6			

Statistical analyses

No statistical analyses for this end point

Secondary: Percent change from baseline in the EASI total score at all scheduled time points except Week 12.

End point title	Percent change from baseline in the EASI total score at all scheduled time points except Week 12.
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End point description:

The EASI quantifies the severity of subjects' AD based on both severity of lesion clinical signs and the percent of body surface area (BSA) affected. EASI is a composite scoring by the AD clinical evaluator of the degree of erythema, induration/population, excoriation, and lichenification (each scored separately) for each of 4 regions, with adjustment for the percent of BSA involved for each body region and for the proportion of the body region to the whole body. The EASI score can vary in increments of 0.1 and range from 0.0 to 72.0, with higher scores representing greater severity of AD.

End point type	Secondary
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End point timeframe:

Baseline and all scheduled time points except Week 12, including Weeks 1, 2, 4, 6, 8, 13, 14, 16

End point values	Placebo	PF-04965842 10mg QD	PF-04965842 30mg QD	PF-04965842 100mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56 ^[5]	49	51	56
Units: percent change				
arithmetic mean (standard deviation)				
Week 1 (n = 54, 48, 49, 55, 53)	-12.28 (± 27.205)	-13.80 (± 26.526)	-14.85 (± 33.721)	-19.85 (± 30.379)
Week 2 (n = 55, 48, 47, 53, 50)	-23.54 (± 33.348)	-14.79 (± 40.474)	-26.29 (± 33.298)	-38.26 (± 39.176)
Week 4 (n = 50, 45, 47, 52, 52)	-24.58 (± 40.520)	-30.06 (± 40.852)	-32.81 (± 40.255)	-53.59 (± 35.274)
Week 6 (n = 44, 38, 43, 48, 52)	-39.17 (± 39.299)	-35.18 (± 43.498)	-40.16 (± 43.849)	-54.16 (± 53.212)
Week 8 (n = 41, 36, 43, 47, 49)	-36.69 (± 42.629)	-39.43 (± 46.270)	-36.83 (± 52.632)	-53.96 (± 53.689)
Week 13 (n = 30, 29, 31, 38, 45)	-29.82 (± 50.404)	-34.11 (± 51.089)	-32.97 (± 45.223)	-51.23 (± 45.968)
Week 14 (n = 32, 28, 29, 40, 44)	-35.51 (± 43.357)	-31.54 (± 62.829)	-26.25 (± 49.184)	-38.80 (± 49.085)
Week 16 (n = 28, 26, 27, 36, 38)	-35.91 (± 47.713)	-45.24 (± 44.576)	-20.80 (± 47.915)	-27.66 (± 54.570)

Notes:

[5] - "n" represents the number of evaluable subjects at each visit.

End point values	PF-04965842 200mg QD			
Subject group type	Reporting group			
Number of subjects analysed	55			
Units: percent change				
arithmetic mean (standard deviation)				
Week 1 (n = 54, 48, 49, 55, 53)	-41.26 (± 32.064)			
Week 2 (n = 55, 48, 47, 53, 50)	-63.28 (± 25.754)			
Week 4 (n = 50, 45, 47, 52, 52)	-78.16 (± 20.666)			
Week 6 (n = 44, 38, 43, 48, 52)	-83.14 (± 17.267)			
Week 8 (n = 41, 36, 43, 47, 49)	-84.48 (± 16.226)			
Week 13 (n = 30, 29, 31, 38, 45)	-66.34 (± 34.951)			
Week 14 (n = 32, 28, 29, 40, 44)	-57.15 (± 36.739)			
Week 16 (n = 28, 26, 27, 36, 38)	-55.82 (± 32.833)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects achieving ≥ 3 points improvement in the pruritus numerical rating scale (NRS) from baseline at all scheduled time points

End point title	Percentage of subjects achieving ≥ 3 points improvement in the pruritus numerical rating scale (NRS) from baseline at all scheduled time points
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End point description:

The severity of itch (pruritus) due to AD was assessed using a horizontal NRS. Subjects were asked to assess their "worst itching due to AD over the past 24 hours" on a NRS anchored by the terms "no itching" (0) and "worst possible itching" (10).

The frequency of itch (pruritus) due to AD was assessed using a horizontal NRS. Subjects were asked to assess "frequency of itching due to AD over the past 24 hours" on a NRS anchored by the terms "never/no itching" (0) and "always/constant itching" (10).

End point type	Secondary
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End point timeframe:

Baseline and all scheduled time points, including Days 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 29, 43, 57, 85, 99, 113

End point values	Placebo	PF-04965842 10mg QD	PF-04965842 30mg QD	PF-04965842 100mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56 ^[6]	49	51	56
Units: percentage of subjects				
number (not applicable)				
Itching due to AD Day 2 (n = 50, 45, 47, 54, 53)	4.0	6.7	17.0	14.8

Itching due to AD Day 3 (n = 50, 45, 47, 54, 53)	8.0	2.2	14.9	22.2
Itching due to AD Day 4 (n = 50, 45, 47, 54, 52)	2.0	2.2	21.3	22.2
Itching due to AD Day 5 (n = 50, 45, 47, 54, 52)	2.0	6.7	29.8	24.1
Itching due to AD Day 6 (n = 50, 45, 47, 54, 52)	10.0	8.9	25.5	24.1
Itching due to AD Day 7 (n = 51, 45, 47, 53, 52)	11.8	13.3	25.5	30.2
Itching due to AD Day 8 (n = 50, 45, 48, 55, 51)	10.0	13.3	25.0	43.6
Itching due to AD Day 9 (n = 48, 45, 46, 55, 52)	8.3	11.1	26.1	45.5
Itching due to AD Day 10 (n = 49, 45, 47, 55, 52)	8.2	11.1	34.0	43.6
Itching due to AD Day 11 (n = 50, 45, 47, 55, 52)	16.0	15.6	27.7	43.6
Itching due to AD Day 12 (n = 50, 45, 47, 55, 51)	22.0	17.8	38.3	49.1
Itching due to AD Day 13 (n = 50, 45, 46, 52, 50)	24.0	15.6	28.3	53.8
Itching due to AD Day 14 (n = 49, 42, 45, 52, 49)	22.4	19.0	26.7	48.1
Itching due to AD Day 15 (n = 40, 39, 39, 44, 40)	25.0	17.9	30.8	54.5
Itching due to AD Day 29 (n = 52, 45, 45, 55, 51)	32.7	31.1	37.8	60.0
Itching due to AD Day 43 (n = 51, 48, 47, 54, 52)	31.4	35.4	38.3	53.7
Itching due to AD Day 57 (n = 52, 47, 47, 55, 50)	28.8	31.9	38.3	54.5
Itching due to AD Day 85 (n = 52, 47, 46, 54, 50)	26.9	21.3	41.3	53.7
Itching due to AD Day 99 (n = 30, 27, 27, 40, 41)	33.3	25.9	33.3	47.5
Itching due to AD Day 113 (n = 23, 24, 25, 36, 34)	52.2	29.2	24.0	44.4
Frequency Day 2 (n = 50, 45, 47, 54, 53)	6.0	8.9	19.1	22.2
Frequency Day 3 (n = 50, 45, 47, 54, 53)	10.0	8.9	19.1	25.9
Frequency Day 4 (n = 50, 45, 47, 54, 52)	8.0	4.4	23.4	25.9
Frequency Day 5 (n = 50, 45, 47, 54, 52)	10.0	6.7	31.9	29.6
Frequency Day 6 (n = 50, 45, 47, 54, 52)	14.0	8.9	27.7	33.3
Frequency Day 7 (n = 51, 45, 47, 53, 52)	15.7	11.1	31.9	34.0
Frequency Day 8 (n = 50, 45, 48, 55, 51)	16.0	11.1	29.2	45.5
Frequency Day 9 (n = 48, 45, 46, 55, 52)	14.6	13.3	30.4	45.5
Frequency Day 10 (n = 49, 45, 47, 55, 52)	14.3	13.3	36.2	45.5
Frequency Day 11 (n = 50, 45, 47, 55, 52)	20.0	15.6	36.2	45.5
Frequency Day 12 (n = 50, 45, 47, 55, 51)	18.0	17.8	38.3	50.9
Frequency Day 13 (n = 50, 45, 46, 52, 50)	20.0	20.0	30.4	51.9

Frequency Day 14 (n = 49, 42, 45, 52, 49)	24.5	23.8	33.3	48.1
Frequency Day 15 (n = 40, 39, 39, 44, 40)	30.0	20.5	38.5	52.3
Frequency Day 29 (n = 52, 45, 45, 55, 51)	28.8	28.9	40.0	60.0
Frequency Day 43 (n = 51, 48, 47, 54, 52)	23.5	35.4	38.3	57.4
Frequency Day 57 (n = 52, 47, 47, 55, 50)	26.9	29.8	38.3	54.5
Frequency Day 85 (n = 52, 47, 46, 54, 50)	25.0	25.5	34.8	53.7
Frequency Day 99 (n = 30, 27, 27, 40, 41)	30.0	22.2	37.0	47.5
Frequency Day 113 (n = 23, 24, 25, 36, 34)	47.8	25.0	20.0	47.2

Notes:

[6] - "n" represents the number of evaluable subjects at each visit.

End point values	PF-04965842 200mg QD			
Subject group type	Reporting group			
Number of subjects analysed	55			
Units: percentage of subjects				
number (not applicable)				
Itching due to AD Day 2 (n = 50, 45, 47, 54, 53)	17.0			
Itching due to AD Day 3 (n = 50, 45, 47, 54, 53)	28.3			
Itching due to AD Day 4 (n = 50, 45, 47, 54, 52)	34.6			
Itching due to AD Day 5 (n = 50, 45, 47, 54, 52)	36.5			
Itching due to AD Day 6 (n = 50, 45, 47, 54, 52)	40.4			
Itching due to AD Day 7 (n = 51, 45, 47, 53, 52)	42.3			
Itching due to AD Day 8 (n = 50, 45, 48, 55, 51)	51.0			
Itching due to AD Day 9 (n = 48, 45, 46, 55, 52)	50.0			
Itching due to AD Day 10 (n = 49, 45, 47, 55, 52)	55.8			
Itching due to AD Day 11 (n = 50, 45, 47, 55, 52)	57.7			
Itching due to AD Day 12 (n = 50, 45, 47, 55, 51)	60.8			
Itching due to AD Day 13 (n = 50, 45, 46, 52, 50)	66.0			
Itching due to AD Day 14 (n = 49, 42, 45, 52, 49)	67.3			
Itching due to AD Day 15 (n = 40, 39, 39, 44, 40)	72.5			
Itching due to AD Day 29 (n = 52, 45, 45, 55, 51)	74.5			
Itching due to AD Day 43 (n = 51, 48, 47, 54, 52)	73.1			
Itching due to AD Day 57 (n = 52, 47, 47, 55, 50)	72.0			

Itching due to AD Day 85 (n = 52, 47, 46, 54, 50)	64.0			
Itching due to AD Day 99 (n = 30, 27, 27, 40, 41)	41.5			
Itching due to AD Day 113 (n = 23, 24, 25, 36, 34)	35.3			
Frequency Day 2 (n = 50, 45, 47, 54, 53)	26.4			
Frequency Day 3 (n = 50, 45, 47, 54, 53)	34.0			
Frequency Day 4 (n = 50, 45, 47, 54, 52)	48.1			
Frequency Day 5 (n = 50, 45, 47, 54, 52)	46.2			
Frequency Day 6 (n = 50, 45, 47, 54, 52)	57.7			
Frequency Day 7 (n = 51, 45, 47, 53, 52)	55.8			
Frequency Day 8 (n = 50, 45, 48, 55, 51)	60.8			
Frequency Day 9 (n = 48, 45, 46, 55, 52)	55.8			
Frequency Day 10 (n = 49, 45, 47, 55, 52)	65.4			
Frequency Day 11 (n = 50, 45, 47, 55, 52)	63.5			
Frequency Day 12 (n = 50, 45, 47, 55, 51)	60.8			
Frequency Day 13 (n = 50, 45, 46, 52, 50)	70.0			
Frequency Day 14 (n = 49, 42, 45, 52, 49)	71.4			
Frequency Day 15 (n = 40, 39, 39, 44, 40)	72.5			
Frequency Day 29 (n = 52, 45, 45, 55, 51)	74.5			
Frequency Day 43 (n = 51, 48, 47, 54, 52)	75.0			
Frequency Day 57 (n = 52, 47, 47, 55, 50)	74.0			
Frequency Day 85 (n = 52, 47, 46, 54, 50)	70.0			
Frequency Day 99 (n = 30, 27, 27, 40, 41)	39.0			
Frequency Day 113 (n = 23, 24, 25, 36, 34)	38.2			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects achieving ≥ 4 points improvement in the pruritus NRS from baseline at all scheduled time points

End point title	Percentage of subjects achieving ≥ 4 points improvement in the pruritus NRS from baseline at all scheduled time points
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End point description:

The severity of itch (pruritus) due to AD was assessed using a horizontal NRS. Subjects were asked to assess their "worst itching due to AD over the past 24 hours" on a NRS anchored by the terms "no

itching" (0) and "worst possible itching" (10).

The frequency of itch (pruritus) due to AD was assessed using a horizontal NRS. Subjects were asked to assess "frequency of itching due to AD over the past 24 hours" on a NRS anchored by the terms "never/no itching" (0) and "always/constant itching" (10).

End point type	Secondary
End point timeframe:	
Baseline and all scheduled time points, including Days 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 29, 43, 57, 85, 99, 113	

End point values	Placebo	PF-04965842 10mg QD	PF-04965842 30mg QD	PF-04965842 100mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56 ^[7]	49	51	56
Units: percentage of subjects				
number (not applicable)				
Itching due to AD Day 2 (n = 49, 45, 46, 50, 46)	2.0	2.2	6.5	10.0
Itching due to AD Day 3 (n = 49, 45, 46, 50, 46)	0.0	2.2	13.0	14.0
Itching due to AD Day 4 (n = 49, 45, 46, 50, 45)	0.0	0.0	17.4	14.0
Itching due to AD Day 5 (n = 49, 45, 46, 50, 45)	2.0	2.2	19.6	20.0
Itching due to AD Day 6 (n = 49, 45, 46, 50, 45)	6.1	2.2	17.4	24.0
Itching due to AD Day 7 (n = 50, 45, 46, 49, 45)	8.0	8.9	19.6	20.4
Itching due to AD Day 8 (n = 49, 45, 47, 51, 44)	6.1	4.4	14.9	29.4
Itching due to AD Day 9 (n = 47, 45, 45, 51, 45)	2.1	6.7	20.0	27.5
Itching due to AD Day 10 (n = 48, 45, 46, 51, 45)	4.2	6.7	21.7	29.4
Itching due to AD Day 11 (n = 49, 45, 46, 51, 45)	8.2	13.3	19.6	29.4
Itching due to AD Day 12 (n = 49, 45, 46, 51, 45)	10.2	11.1	23.9	35.3
Itching due to AD Day 13 (n = 49, 45, 45, 49, 44)	14.3	6.7	20.0	38.8
Itching due to AD Day 14 (n = 48, 42, 44, 48, 44)	10.4	14.3	25.0	41.7
Itching due to AD Day 15 (n = 40, 38, 38, 43, 37)	15.0	7.9	31.6	41.9
Itching due to AD Day 29 (n = 51, 44, 44, 51, 45)	17.6	13.6	25.0	52.9
Itching due to AD Day 43 (n = 50, 45, 46, 50, 46)	20.0	22.2	23.9	50.0
Itching due to AD Day 57 (n = 51, 44, 46, 51, 44)	17.6	22.7	26.1	52.9
Itching due to AD Day 85 (n = 51, 44, 45, 50, 44)	25.5	22.7	33.3	50.0
Itching due to AD Day 99 (n = 29, 27, 26, 39, 35)	27.6	25.9	23.1	38.5
Itching due to AD Day 113 (n = 23, 24, 24, 35, 29)	43.5	20.8	16.7	34.3
Frequency Day 2 (n = 47, 45, 42, 52, 48)	2.1	0.0	7.1	11.5

Frequency Day 3 (n = 47, 45, 42, 52, 48)	6.4	2.2	11.9	13.5
Frequency Day 4 (n = 47, 45, 42, 52, 47)	2.1	0.0	19.0	21.2
Frequency Day 5 (n = 47, 45, 42, 52, 47)	4.3	4.4	23.8	25.0
Frequency Day 6 (n = 47, 45, 42, 52, 47)	10.6	6.7	26.2	25.0
Frequency Day 7 (n = 48, 45, 42, 50, 47)	10.4	4.4	19.0	30.0
Frequency Day 8 (n = 47, 45, 43, 52, 46)	8.5	2.2	23.3	36.5
Frequency Day 9 (n = 45, 45, 41, 52, 47)	6.7	6.7	26.8	36.5
Frequency Day 10 (n = 46, 45, 42, 52, 47)	6.5	8.9	31.0	28.8
Frequency Day 11 (n = 47, 45, 42, 52, 47)	10.6	15.6	23.8	32.7
Frequency Day 12 (n = 47, 45, 42, 52, 46)	12.8	13.3	26.2	34.6
Frequency Day 13 (n = 47, 45, 41, 50, 45)	17.0	15.6	29.3	32.0
Frequency Day 14 (n = 46, 42, 40, 49, 45)	19.6	16.7	30.0	34.7
Frequency Day 15 (n = 40, 38, 34, 44, 38)	20.0	15.8	35.3	36.4
Frequency Day 29 (n = 49, 44, 40, 52, 47)	16.3	15.9	35.0	51.9
Frequency Day 43 (n = 48, 45, 42, 51, 48)	12.5	24.4	28.6	58.8
Frequency Day 57 (n = 49, 44, 42, 52, 46)	16.3	20.5	33.3	53.8
Frequency Day 85 (n = 49, 44, 42, 51, 46)	24.5	25.0	28.6	47.1
Frequency Day 99 (n = 29, 27, 24, 38, 37)	20.7	18.5	16.7	39.5
Frequency Day 113 (n = 23, 24, 22, 34, 30)	34.8	20.8	22.7	29.4

Notes:

[7] - "n" represents the number of evaluable subjects at each visit.

End point values	PF-04965842 200mg QD			
Subject group type	Reporting group			
Number of subjects analysed	55			
Units: percentage of subjects				
number (not applicable)				
Itching due to AD Day 2 (n = 49, 45, 46, 50, 46)	15.2			
Itching due to AD Day 3 (n = 49, 45, 46, 50, 46)	21.7			
Itching due to AD Day 4 (n = 49, 45, 46, 50, 45)	28.9			
Itching due to AD Day 5 (n = 49, 45, 46, 50, 45)	26.7			
Itching due to AD Day 6 (n = 49, 45, 46, 50, 45)	35.6			
Itching due to AD Day 7 (n = 50, 45, 46, 49, 45)	37.8			

Itching due to AD Day 8 (n = 49, 45, 47, 51, 44)	52.3			
Itching due to AD Day 9 (n = 47, 45, 45, 51, 45)	51.1			
Itching due to AD Day 10 (n = 48, 45, 46, 51, 45)	44.4			
Itching due to AD Day 11 (n = 49, 45, 46, 51, 45)	44.4			
Itching due to AD Day 12 (n = 49, 45, 46, 51, 45)	51.1			
Itching due to AD Day 13 (n = 49, 45, 45, 49, 44)	61.4			
Itching due to AD Day 14 (n = 48, 42, 44, 48, 44)	59.1			
Itching due to AD Day 15 (n = 40, 38, 38, 43, 37)	70.3			
Itching due to AD Day 29 (n = 51, 44, 44, 51, 45)	68.9			
Itching due to AD Day 43 (n = 50, 45, 46, 50, 46)	71.7			
Itching due to AD Day 57 (n = 51, 44, 46, 51, 44)	72.7			
Itching due to AD Day 85 (n = 51, 44, 45, 50, 44)	63.6			
Itching due to AD Day 99 (n = 29, 27, 26, 39, 35)	37.1			
Itching due to AD Day 113 (n = 23, 24, 24, 35, 29)	31.0			
Frequency Day 2 (n = 47, 45, 42, 52, 48)	18.8			
Frequency Day 3 (n = 47, 45, 42, 52, 48)	22.9			
Frequency Day 4 (n = 47, 45, 42, 52, 47)	36.2			
Frequency Day 5 (n = 47, 45, 42, 52, 47)	38.3			
Frequency Day 6 (n = 47, 45, 42, 52, 47)	44.7			
Frequency Day 7 (n = 48, 45, 42, 50, 47)	51.1			
Frequency Day 8 (n = 47, 45, 43, 52, 46)	54.3			
Frequency Day 9 (n = 45, 45, 41, 52, 47)	48.9			
Frequency Day 10 (n = 46, 45, 42, 52, 47)	51.1			
Frequency Day 11 (n = 47, 45, 42, 52, 47)	55.3			
Frequency Day 12 (n = 47, 45, 42, 52, 46)	54.3			
Frequency Day 13 (n = 47, 45, 41, 50, 45)	66.7			
Frequency Day 14 (n = 46, 42, 40, 49, 45)	66.7			
Frequency Day 15 (n = 40, 38, 34, 44, 38)	71.1			
Frequency Day 29 (n = 49, 44, 40, 52, 47)	66.0			
Frequency Day 43 (n = 48, 45, 42, 51, 48)	72.9			
Frequency Day 57 (n = 49, 44, 42, 52, 46)	73.9			

Frequency Day 85 (n = 49, 44, 42, 51, 46)	69.6			
Frequency Day 99 (n = 29, 27, 24, 38, 37)	32.4			
Frequency Day 113 (n = 23, 24, 22, 34, 30)	26.7			

Statistical analyses

No statistical analyses for this end point

Secondary: Time to achieving ≥ 3 points improvement in NRS

End point title	Time to achieving ≥ 3 points improvement in NRS
End point description:	
The severity of itch (pruritus) due to AD was assessed using a horizontal NRS. Subjects were asked to assess their "worst itching due to AD over the past 24 hours" on a NRS anchored by the terms "no itching" (0) and "worst possible itching" (10).	
The frequency of itch (pruritus) due to AD was assessed using a horizontal NRS. Subjects were asked to assess "frequency of itching due to AD over the past 24 hours" on a NRS anchored by the terms "never/no itching" (0) and "always/constant itching" (10).	
End point type	Secondary
End point timeframe:	
Baseline till Week 16	

End point values	Placebo	PF-04965842 10mg QD	PF-04965842 30mg QD	PF-04965842 100mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	55	49	50	55
Units: day				
median (confidence interval 90%)				
Itching due to atopic dermatitis	30.0 (15.0 to 56.0)	43.0 (29.0 to 57.0)	12.0 (8.0 to 30.0)	9.0 (7.0 to 14.0)
Frequency of itching due to atopic dermatitis	29.0 (13.0 to 57.0)	43.0 (29.0 to 85.0)	13.0 (7.0 to 43.0)	8.0 (4.0 to 10.0)

End point values	PF-04965842 200mg QD			
Subject group type	Reporting group			
Number of subjects analysed	54			
Units: day				
median (confidence interval 90%)				
Itching due to atopic dermatitis	7.0 (5.0 to 11.0)			
Frequency of itching due to atopic dermatitis	4.0 (4.0 to 6.0)			

Statistical analyses

No statistical analyses for this end point

Secondary: Time to achieving ≥ 4 points improvement in NRS

End point title	Time to achieving ≥ 4 points improvement in NRS
End point description: The severity of itch (pruritus) due to AD was assessed using a horizontal NRS. Subjects were asked to assess their "worst itching due to AD over the past 24 hours" on a NRS anchored by the terms "no itching" (0) and "worst possible itching" (10). The frequency of itch (pruritus) due to AD was assessed using a horizontal NRS. Subjects were asked to assess "frequency of itching due to AD over the past 24 hours" on a NRS anchored by the terms "never/no itching" (0) and "always/constant itching" (10).	
End point type	Secondary
End point timeframe: Baseline till Week 16	

End point values	Placebo	PF-04965842 10mg QD	PF-04965842 30mg QD	PF-04965842 100mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	55 ^[8]	49 ^[9]	50	55
Units: day				
median (confidence interval 90%)				
Itching due to atopic dermatitis	78.0 (56.0 to 99999)	99999 (47.0 to 99999)	43.0 (15.0 to 85.0)	14.0 (10.0 to 29.0)
Frequency of itching due to atopic dermatitis	59.0 (30.0 to 99999)	99999 (56.0 to 99999)	29.0 (12.0 to 98.0)	14.0 (8.0 to 29.0)

Notes:

[8] - 99999 indicates not estimable.

[9] - 99999 indicates not estimable.

End point values	PF-04965842 200mg QD			
Subject group type	Reporting group			
Number of subjects analysed	54			
Units: day				
median (confidence interval 90%)				
Itching due to atopic dermatitis	10.0 (7.0 to 13.0)			
Frequency of itching due to atopic dermatitis	7.0 (5.0 to 9.0)			

Statistical analyses

Secondary: Percent change from baseline in the pruritus NRS from baseline at all scheduled time points

End point title	Percent change from baseline in the pruritus NRS from baseline at all scheduled time points
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End point description:

The severity of itch (pruritus) due to AD was assessed using a horizontal NRS. Subjects were asked to assess their "worst itching due to AD over the past 24 hours" on a NRS anchored by the terms "no itching" (0) and "worst possible itching" (10).

The frequency of itch (pruritus) due to AD was assessed using a horizontal NRS. Subjects were asked to assess "frequency of itching due to AD over the past 24 hours" on a NRS anchored by the terms "never/no itching" (0) and "always/constant itching" (10).

End point type	Secondary
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End point timeframe:

Baseline and all scheduled time points, including Days 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 29, 43, 57, 85, 99, 113

End point values	Placebo	PF-04965842 10mg QD	PF-04965842 30mg QD	PF-04965842 100mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56 ^[10]	49	51	56
Units: percent change				
arithmetic mean (standard deviation)				
Itching due to AD Day 2 (n = 50, 45, 47, 53, 51)	0.56 (± 19.298)	-1.51 (± 19.857)	-9.39 (± 23.528)	-10.06 (± 25.930)
Itching due to AD Day 3 (n = 50, 45, 47, 52, 51)	-1.32 (± 22.630)	2.48 (± 21.994)	-8.22 (± 33.257)	-15.32 (± 27.874)
Itching due to AD Day 4 (n = 50, 44, 47, 52, 50)	-1.98 (± 22.326)	0.23 (± 17.314)	-12.18 (± 33.385)	-17.62 (± 25.747)
Itching due to AD Day 5 (n = 50, 44, 47, 52, 50)	-2.98 (± 22.385)	-2.37 (± 20.174)	-18.92 (± 31.846)	-20.48 (± 27.983)
Itching due to AD Day 6 (n = 50, 44, 47, 52, 50)	-1.52 (± 25.690)	-5.70 (± 23.478)	-16.70 (± 33.407)	-21.58 (± 27.842)
Itching due to AD Day 7 (n = 51, 44, 47, 51, 50)	-4.18 (± 30.531)	-4.59 (± 28.248)	-18.07 (± 33.640)	-23.02 (± 33.524)
Itching due to AD Day 8 (n = 50, 44, 46, 53, 49)	-0.35 (± 34.144)	-5.69 (± 25.576)	-17.87 (± 34.789)	-32.36 (± 30.610)
Itching due to AD Day 9 (n = 48, 44, 42, 51, 49)	-2.56 (± 30.688)	-8.61 (± 27.803)	-22.74 (± 33.667)	-31.82 (± 30.951)
Itching due to AD Day 10 (n = 49, 44, 43, 51, 49)	-3.32 (± 29.885)	-5.97 (± 29.093)	-22.90 (± 41.573)	-31.93 (± 27.094)
Itching due to AD Day 11 (n = 49, 44, 43, 51, 49)	-7.81 (± 30.201)	-5.94 (± 31.028)	-16.76 (± 49.412)	-33.13 (± 27.902)
Itching due to AD Day 12 (n = 49, 44, 43, 51, 48)	-11.12 (± 30.087)	-6.65 (± 32.617)	-27.84 (± 33.416)	-33.30 (± 34.252)
Itching due to AD Day 13 (n = 48, 44, 42, 49, 47)	-15.16 (± 29.759)	-7.43 (± 27.374)	-24.56 (± 30.086)	-35.89 (± 35.651)
Itching due to AD Day 14 (n = 47, 41, 41, 48, 46)	-13.61 (± 30.153)	-8.84 (± 29.474)	-26.70 (± 29.805)	-36.57 (± 27.552)
Itching due to AD Day 15 (n = 38, 35, 35, 42, 38)	-17.24 (± 30.755)	-7.28 (± 28.058)	-25.09 (± 37.815)	-35.41 (± 29.140)
Itching due to AD Day 29 (n = 46, 41, 41, 51, 49)	-19.43 (± 35.575)	-16.63 (± 34.554)	-28.41 (± 36.183)	-46.62 (± 40.090)
Itching due to AD Day 43 (n = 40, 37, 40, 46, 50)	-26.55 (± 36.418)	-27.15 (± 39.550)	-31.14 (± 39.090)	-49.49 (± 46.279)

Itching due to AD Day 57 (n = 38, 34, 40, 46, 46)	-25.54 (± 39.577)	-21.60 (± 44.446)	-29.60 (± 39.606)	-54.11 (± 36.374)
Itching due to AD Day 85 (n = 35, 30, 31, 42, 44)	-30.10 (± 42.697)	-22.47 (± 48.291)	-30.39 (± 47.772)	-56.51 (± 41.955)
Itching due to AD Day 99 (n = 30, 27, 27, 39, 41)	-19.24 (± 43.251)	-15.94 (± 42.332)	-11.46 (± 39.959)	-32.68 (± 34.789)
Itching due to AD Day 113 (n = 23, 24, 25, 35, 34)	-31.99 (± 45.929)	-14.07 (± 47.186)	-14.34 (± 29.756)	-28.47 (± 41.027)
Frequency Day 2 (n = 50, 45, 47, 53, 52)	6.72 (± 45.759)	-6.67 (± 19.016)	-10.14 (± 28.184)	-17.93 (± 20.967)
Frequency Day 3 (n = 50, 45, 47, 52, 52)	2.59 (± 45.541)	0.30 (± 24.330)	-3.96 (± 49.425)	-19.98 (± 22.910)
Frequency Day 4 (n = 50, 44, 47, 52, 51)	3.73 (± 37.683)	-3.25 (± 15.230)	-9.39 (± 39.225)	-20.71 (± 24.391)
Frequency Day 5 (n = 50, 44, 47, 52, 51)	-0.70 (± 34.834)	-3.73 (± 23.125)	-17.72 (± 38.967)	-23.69 (± 24.954)
Frequency Day 6 (n = 50, 44, 47, 52, 51)	4.04 (± 52.799)	-5.76 (± 24.623)	-14.84 (± 38.256)	-26.47 (± 27.218)
Frequency Day 7 (n = 51, 44, 47, 51, 51)	-2.25 (± 37.193)	-3.56 (± 25.414)	-17.05 (± 40.108)	-27.80 (± 32.466)
Frequency Day 8 (n = 50, 44, 46, 53, 50)	1.22 (± 38.544)	-3.90 (± 25.515)	-19.05 (± 36.488)	-35.44 (± 29.791)
Frequency Day 9 (n = 48, 44, 42, 51, 50)	1.08 (± 58.633)	-8.79 (± 26.589)	-17.58 (± 42.054)	-35.17 (± 29.637)
Frequency Day 10 (n = 49, 44, 43, 51, 50)	-3.47 (± 53.518)	-5.41 (± 32.491)	-19.84 (± 47.884)	-33.23 (± 26.950)
Frequency Day 11 (n = 49, 44, 43, 51, 50)	-6.24 (± 49.163)	-5.88 (± 32.750)	-18.73 (± 42.599)	-34.93 (± 27.181)
Frequency Day 12 (n = 49, 44, 43, 51, 49)	-8.41 (± 49.918)	-5.65 (± 36.637)	-25.00 (± 31.695)	-36.55 (± 27.281)
Frequency Day 13 (n = 48, 44, 42, 49, 48)	-13.45 (± 40.159)	-10.46 (± 31.103)	-24.73 (± 31.960)	-35.75 (± 32.757)
Frequency Day 14 (n = 47, 41, 41, 48, 47)	-10.26 (± 46.126)	-13.86 (± 32.390)	-27.70 (± 30.476)	-38.28 (± 27.724)
Frequency Day 15 (n = 38, 35, 35, 42, 38)	-18.78 (± 34.923)	-11.34 (± 28.494)	-26.88 (± 38.846)	-38.87 (± 29.184)
Frequency Day 29 (n = 46, 41, 41, 51, 49)	-16.05 (± 39.630)	-17.15 (± 33.432)	-28.55 (± 43.421)	-49.94 (± 36.649)
Frequency Day 43 (n = 40, 37, 40, 46, 50)	-24.51 (± 30.798)	-32.19 (± 37.806)	-26.48 (± 46.793)	-53.95 (± 41.772)
Frequency Day 57 (n = 38, 34, 40, 46, 46)	-24.94 (± 35.662)	-23.28 (± 44.257)	-27.91 (± 39.142)	-55.39 (± 35.447)
Frequency Day 85 (n = 35, 30, 31, 42, 44)	-29.81 (± 44.035)	-25.76 (± 43.273)	-32.28 (± 38.817)	-54.51 (± 43.354)
Frequency Day 99 (n = 30, 27, 27, 39, 41)	-17.46 (± 43.552)	-20.21 (± 36.947)	-3.36 (± 52.153)	-13.57 (± 123.800)
Frequency Day 113 (n = 23, 24, 25, 35, 34)	-28.95 (± 46.896)	-16.22 (± 38.055)	-5.65 (± 51.132)	-12.62 (± 113.423)

Notes:

[10] - "n" represents the number of evaluable subjects at each visit.

End point values	PF-04965842 200mg QD			
Subject group type	Reporting group			
Number of subjects analysed	55			
Units: percent change				
arithmetic mean (standard deviation)				
Itching due to AD Day 2 (n = 50, 45, 47, 53, 51)	-6.79 (± 47.751)			

Itching due to AD Day 3 (n = 50, 45, 47, 52, 51)	-16.72 (± 40.055)			
Itching due to AD Day 4 (n = 50, 44, 47, 52, 50)	-25.80 (± 38.557)			
Itching due to AD Day 5 (n = 50, 44, 47, 52, 50)	-30.91 (± 34.215)			
Itching due to AD Day 6 (n = 50, 44, 47, 52, 50)	-34.02 (± 35.532)			
Itching due to AD Day 7 (n = 51, 44, 47, 51, 50)	-38.17 (± 35.428)			
Itching due to AD Day 8 (n = 50, 44, 46, 53, 49)	-43.13 (± 38.684)			
Itching due to AD Day 9 (n = 48, 44, 42, 51, 49)	-39.37 (± 41.055)			
Itching due to AD Day 10 (n = 49, 44, 43, 51, 49)	-39.60 (± 56.607)			
Itching due to AD Day 11 (n = 49, 44, 43, 51, 49)	-42.50 (± 51.621)			
Itching due to AD Day 12 (n = 49, 44, 43, 51, 48)	-46.40 (± 46.241)			
Itching due to AD Day 13 (n = 48, 44, 42, 49, 47)	-49.77 (± 48.426)			
Itching due to AD Day 14 (n = 47, 41, 41, 48, 46)	-55.45 (± 34.331)			
Itching due to AD Day 15 (n = 38, 35, 35, 42, 38)	-59.00 (± 39.804)			
Itching due to AD Day 29 (n = 46, 41, 41, 51, 49)	-68.09 (± 31.214)			
Itching due to AD Day 43 (n = 40, 37, 40, 46, 50)	-67.80 (± 36.372)			
Itching due to AD Day 57 (n = 38, 34, 40, 46, 46)	-70.13 (± 36.338)			
Itching due to AD Day 85 (n = 35, 30, 31, 42, 44)	-53.66 (± 109.454)			
Itching due to AD Day 99 (n = 30, 27, 27, 39, 41)	5.61 (± 139.223)			
Itching due to AD Day 113 (n = 23, 24, 25, 35, 34)	24.61 (± 190.848)			
Frequency Day 2 (n = 50, 45, 47, 53, 52)	-10.52 (± 79.180)			
Frequency Day 3 (n = 50, 45, 47, 52, 52)	-16.46 (± 67.794)			
Frequency Day 4 (n = 50, 44, 47, 52, 51)	-28.27 (± 47.925)			
Frequency Day 5 (n = 50, 44, 47, 52, 51)	-35.45 (± 37.436)			
Frequency Day 6 (n = 50, 44, 47, 52, 51)	-44.31 (± 36.476)			
Frequency Day 7 (n = 51, 44, 47, 51, 51)	-40.19 (± 39.702)			
Frequency Day 8 (n = 50, 44, 46, 53, 50)	-46.26 (± 43.491)			
Frequency Day 9 (n = 48, 44, 42, 51, 50)	-44.29 (± 43.238)			
Frequency Day 10 (n = 49, 44, 43, 51, 50)	-49.78 (± 37.349)			
Frequency Day 11 (n = 49, 44, 43, 51, 50)	-51.62 (± 37.385)			
Frequency Day 12 (n = 49, 44, 43, 51, 49)	-51.92 (± 40.010)			
Frequency Day 13 (n = 48, 44, 42, 49, 48)	-53.17 (± 40.695)			

Frequency Day 14 (n = 47, 41, 41, 48, 47)	-57.50 (± 39.073)			
Frequency Day 15 (n = 38, 35, 35, 42, 38)	-60.99 (± 32.840)			
Frequency Day 29 (n = 46, 41, 41, 51, 49)	-67.84 (± 29.918)			
Frequency Day 43 (n = 40, 37, 40, 46, 50)	-69.24 (± 38.370)			
Frequency Day 57 (n = 38, 34, 40, 46, 46)	-73.50 (± 30.583)			
Frequency Day 85 (n = 35, 30, 31, 42, 44)	-54.54 (± 120.723)			
Frequency Day 99 (n = 30, 27, 27, 39, 41)	2.12 (± 144.572)			
Frequency Day 113 (n = 23, 24, 25, 35, 34)	27.77 (± 203.937)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in pruritus NRS score at all scheduled time points

End point title	Change from baseline in pruritus NRS score at all scheduled time points
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End point description:

The severity of itch (pruritus) due to AD was assessed using a horizontal NRS. Subjects were asked to assess their "worst itching due to AD over the past 24 hours" on a NRS anchored by the terms "no itching" (0) and "worst possible itching" (10).

The frequency of itch (pruritus) due to AD was assessed using a horizontal NRS. Subjects were asked to assess "frequency of itching due to AD over the past 24 hours" on a NRS anchored by the terms "never/no itching" (0) and "always/constant itching" (10).

End point type	Secondary
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End point timeframe:

Baseline and all scheduled time points, including Days 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 29, 43, 57, 85, 99, 113

End point values	Placebo	PF-04965842 10mg QD	PF-04965842 30mg QD	PF-04965842 100mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56 ^[11]	49	51	56
Units: units on a scale				
arithmetic mean (standard deviation)				
Itching due to AD Day 2 (n = 50, 45, 47, 54, 52)	-0.08 (± 1.307)	-0.20 (± 1.217)	-0.83 (± 1.672)	-0.85 (± 1.607)
Itching due to AD Day 3 (n = 50, 45, 47, 53, 52)	-0.22 (± 1.418)	0.02 (± 1.357)	-0.85 (± 2.095)	-1.21 (± 1.702)
Itching due to AD Day 4 (n = 50, 44, 47, 53, 51)	-0.22 (± 1.389)	-0.09 (± 1.117)	-1.09 (± 2.263)	-1.26 (± 1.862)
Itching due to AD Day 5 (n = 50, 44, 47, 53, 51)	-0.32 (± 1.406)	-0.27 (± 1.264)	-1.55 (± 2.348)	-1.58 (± 1.865)
Itching due to AD Day 6 (n = 50, 44, 47, 53, 51)	-0.28 (± 1.727)	-0.55 (± 1.405)	-1.47 (± 2.492)	-1.49 (± 2.317)

Itching due to AD Day 7 (n = 51, 44, 47, 52, 51)	-0.53 (± 2.023)	-0.52 (± 1.745)	-1.51 (± 2.422)	-1.75 (± 2.159)
Itching due to AD Day 8 (n = 50, 44, 46, 54, 50)	-0.30 (± 2.215)	-0.56 (± 1.560)	-1.65 (± 2.514)	-2.39 (± 2.294)
Itching due to AD Day 9 (n = 48, 44, 42, 52, 50)	-0.38 (± 2.080)	-0.75 (± 1.844)	-1.95 (± 2.527)	-2.40 (± 2.154)
Itching due to AD Day 10 (n = 49, 44, 43, 52, 50)	-0.43 (± 1.947)	-0.61 (± 1.967)	-2.09 (± 2.698)	-2.21 (± 2.412)
Itching due to AD Day 11 (n = 49, 44, 43, 52, 50)	-0.73 (± 1.955)	-0.61 (± 2.148)	-1.72 (± 2.462)	-2.33 (± 2.415)
Itching due to AD Day 12 (n = 49, 44, 43, 52, 49)	-0.92 (± 1.988)	-0.73 (± 2.245)	-2.28 (± 2.271)	-2.46 (± 2.578)
Itching due to AD Day 13 (n = 48, 44, 42, 49, 48)	-1.21 (± 1.989)	-0.68 (± 1.801)	-1.98 (± 2.268)	-2.84 (± 2.164)
Itching due to AD Day 14 (n = 47, 41, 41, 49, 47)	-1.11 (± 2.003)	-0.78 (± 2.104)	-2.10 (± 2.211)	-2.53 (± 2.567)
Itching due to AD Day 15 (n = 38, 35, 35, 42, 38)	-1.39 (± 2.034)	-0.69 (± 1.937)	-2.06 (± 2.508)	-2.79 (± 2.290)
Itching due to AD Day 29 (n = 46, 41, 41, 52, 49)	-1.63 (± 2.453)	-1.34 (± 2.383)	-2.17 (± 2.519)	-3.58 (± 3.322)
Itching due to AD Day 43 (n = 40, 37, 40, 47, 50)	-1.93 (± 2.325)	-2.24 (± 2.929)	-2.50 (± 2.562)	-3.77 (± 3.778)
Itching due to AD Day 57 (n = 38, 34, 40, 47, 46)	-1.84 (± 2.594)	-1.97 (± 3.398)	-2.55 (± 2.943)	-4.00 (± 3.336)
Itching due to AD Day 85 (n = 35, 30, 31, 43, 44)	-2.26 (± 3.081)	-2.13 (± 3.711)	-2.68 (± 2.749)	-4.21 (± 3.529)
Itching due to AD Day 99 (n = 30, 27, 27, 40, 41)	-1.57 (± 3.025)	-1.48 (± 2.992)	-1.37 (± 2.452)	-2.28 (± 2.900)
Itching due to AD Day 113 (n = 23, 24, 25, 36, 34)	-2.43 (± 3.259)	-1.38 (± 3.201)	-1.32 (± 2.410)	-2.03 (± 3.185)
Frequency Day 2 (n = 50, 45, 47, 54, 52)	-0.06 (± 1.754)	-0.44 (± 1.198)	-0.94 (± 1.737)	-1.35 (± 1.556)
Frequency Day 3 (n = 50, 45, 47, 53, 52)	-0.38 (± 1.894)	-0.16 (± 1.461)	-0.79 (± 2.331)	-1.49 (± 1.694)
Frequency Day 4 (n = 50, 44, 47, 53, 51)	-0.20 (± 1.738)	-0.32 (± 1.073)	-1.02 (± 2.162)	-1.40 (± 2.069)
Frequency Day 5 (n = 50, 44, 47, 53, 51)	-0.42 (± 1.727)	-0.43 (± 1.516)	-1.49 (± 2.349)	-1.75 (± 1.828)
Frequency Day 6 (n = 50, 44, 47, 53, 51)	-0.40 (± 2.250)	-0.55 (± 1.606)	-1.40 (± 2.402)	-1.77 (± 2.326)
Frequency Day 7 (n = 51, 44, 47, 52, 51)	-0.63 (± 2.181)	-0.43 (± 1.676)	-1.53 (± 2.466)	-2.04 (± 2.214)
Frequency Day 8 (n = 50, 44, 46, 54, 50)	-0.42 (± 2.205)	-0.40 (± 1.679)	-1.74 (± 2.542)	-2.59 (± 2.278)
Frequency Day 9 (n = 48, 44, 42, 52, 50)	-0.54 (± 2.240)	-0.75 (± 2.036)	-1.74 (± 2.567)	-2.62 (± 2.268)
Frequency Day 10 (n = 49, 44, 43, 52, 50)	-0.80 (± 2.198)	-0.64 (± 2.200)	-1.84 (± 2.760)	-2.33 (± 2.565)
Frequency Day 11 (n = 49, 44, 43, 52, 50)	-0.96 (± 2.336)	-0.68 (± 2.380)	-1.79 (± 2.541)	-2.46 (± 2.540)
Frequency Day 12 (n = 49, 44, 43, 52, 49)	-1.06 (± 2.322)	-0.66 (± 2.411)	-2.00 (± 2.182)	-2.54 (± 2.509)
Frequency Day 13 (n = 48, 44, 42, 49, 48)	-1.33 (± 2.337)	-0.91 (± 2.133)	-1.90 (± 2.195)	-2.78 (± 2.275)
Frequency Day 14 (n = 47, 41, 41, 49, 47)	-1.17 (± 2.417)	-1.10 (± 2.417)	-2.00 (± 2.225)	-2.63 (± 2.620)
Frequency Day 15 (n = 38, 35, 35, 42, 38)	-1.50 (± 2.322)	-0.97 (± 2.135)	-2.17 (± 2.407)	-3.02 (± 2.464)
Frequency Day 29 (n = 46, 41, 41, 52, 49)	-1.46 (± 2.518)	-1.34 (± 2.425)	-2.22 (± 2.761)	-3.77 (± 3.317)
Frequency Day 43 (n = 40, 37, 40, 47, 50)	-1.70 (± 1.990)	-2.51 (± 3.061)	-2.28 (± 2.953)	-4.02 (± 3.796)

Frequency Day 57 (n = 38, 34, 40, 47, 46)	-1.74 (± 2.298)	-2.00 (± 3.499)	-2.45 (± 2.943)	-4.02 (± 3.467)
Frequency Day 85 (n = 35, 30, 31, 43, 44)	-2.23 (± 3.209)	-2.33 (± 3.575)	-2.61 (± 2.692)	-4.09 (± 3.663)
Frequency Day 99 (n = 30, 27, 27, 40, 41)	-1.30 (± 2.781)	-1.56 (± 2.736)	-0.93 (± 2.526)	-2.03 (± 3.378)
Frequency Day 113 (n = 23, 24, 25, 36, 34)	-2.00 (± 2.970)	-1.42 (± 3.035)	-1.04 (± 2.557)	-1.81 (± 3.188)

Notes:

[11] - "n" represents the number of evaluable subjects at each visit.

End point values	PF-04965842 200mg QD			
Subject group type	Reporting group			
Number of subjects analysed	55			
Units: units on a scale				
arithmetic mean (standard deviation)				
Itching due to AD Day 2 (n = 50, 45, 47, 54, 52)	-1.00 (± 2.433)			
Itching due to AD Day 3 (n = 50, 45, 47, 53, 52)	-1.48 (± 2.493)			
Itching due to AD Day 4 (n = 50, 44, 47, 53, 51)	-2.12 (± 2.590)			
Itching due to AD Day 5 (n = 50, 44, 47, 53, 51)	-2.35 (± 2.583)			
Itching due to AD Day 6 (n = 50, 44, 47, 53, 51)	-2.53 (± 2.648)			
Itching due to AD Day 7 (n = 51, 44, 47, 52, 51)	-2.77 (± 2.795)			
Itching due to AD Day 8 (n = 50, 44, 46, 54, 50)	-3.22 (± 3.039)			
Itching due to AD Day 9 (n = 48, 44, 42, 52, 50)	-3.18 (± 2.988)			
Itching due to AD Day 10 (n = 49, 44, 43, 52, 50)	-3.38 (± 2.975)			
Itching due to AD Day 11 (n = 49, 44, 43, 52, 50)	-3.40 (± 3.071)			
Itching due to AD Day 12 (n = 49, 44, 43, 52, 49)	-3.63 (± 3.154)			
Itching due to AD Day 13 (n = 48, 44, 42, 49, 48)	-3.88 (± 3.085)			
Itching due to AD Day 14 (n = 47, 41, 41, 49, 47)	-4.06 (± 2.793)			
Itching due to AD Day 15 (n = 38, 35, 35, 42, 38)	-4.37 (± 2.696)			
Itching due to AD Day 29 (n = 46, 41, 41, 52, 49)	-5.00 (± 2.880)			
Itching due to AD Day 43 (n = 40, 37, 40, 47, 50)	-5.02 (± 3.172)			
Itching due to AD Day 57 (n = 38, 34, 40, 47, 46)	-5.26 (± 3.130)			
Itching due to AD Day 85 (n = 35, 30, 31, 43, 44)	-4.84 (± 3.785)			
Itching due to AD Day 99 (n = 30, 27, 27, 40, 41)	-1.90 (± 3.767)			
Itching due to AD Day 113 (n = 23, 24, 25, 36, 34)	-1.50 (± 3.736)			
Frequency Day 2 (n = 50, 45, 47, 54, 52)	-1.60 (± 2.345)			

Frequency Day 3 (n = 50, 45, 47, 53, 52)	-1.92 (± 2.300)			
Frequency Day 4 (n = 50, 44, 47, 53, 51)	-2.47 (± 2.533)			
Frequency Day 5 (n = 50, 44, 47, 53, 51)	-2.73 (± 2.515)			
Frequency Day 6 (n = 50, 44, 47, 53, 51)	-3.24 (± 2.446)			
Frequency Day 7 (n = 51, 44, 47, 52, 51)	-3.15 (± 2.739)			
Frequency Day 8 (n = 50, 44, 46, 54, 50)	-3.69 (± 2.808)			
Frequency Day 9 (n = 48, 44, 42, 52, 50)	-3.54 (± 3.018)			
Frequency Day 10 (n = 49, 44, 43, 52, 50)	-3.68 (± 2.591)			
Frequency Day 11 (n = 49, 44, 43, 52, 50)	-3.74 (± 2.633)			
Frequency Day 12 (n = 49, 44, 43, 52, 49)	-3.84 (± 2.932)			
Frequency Day 13 (n = 48, 44, 42, 49, 48)	-4.08 (± 2.952)			
Frequency Day 14 (n = 47, 41, 41, 49, 47)	-4.28 (± 2.841)			
Frequency Day 15 (n = 38, 35, 35, 42, 38)	-4.50 (± 2.648)			
Frequency Day 29 (n = 46, 41, 41, 52, 49)	-5.06 (± 2.817)			
Frequency Day 43 (n = 40, 37, 40, 47, 50)	-5.30 (± 2.957)			
Frequency Day 57 (n = 38, 34, 40, 47, 46)	-5.59 (± 3.037)			
Frequency Day 85 (n = 35, 30, 31, 43, 44)	-5.14 (± 3.645)			
Frequency Day 99 (n = 30, 27, 27, 40, 41)	-2.15 (± 3.909)			
Frequency Day 113 (n = 23, 24, 25, 36, 34)	-1.50 (± 3.816)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects achieving a $\geq 50\%$ improvement in the EASI Total Score (EASI50) at all scheduled time points

End point title	Percentage of subjects achieving a $\geq 50\%$ improvement in the EASI Total Score (EASI50) at all scheduled time points
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End point description:

The EASI quantifies the severity of subjects' AD based on both severity of lesion clinical signs and the percent of body surface area (BSA) affected. EASI is a composite scoring by the AD clinical evaluator of the degree of erythema, induration/population, excoriation, and lichenification (each scored separately) for each of 4 regions, with adjustment for the percent of BSA involved for each body region and for the proportion of the body region to the whole body. The EASI score can vary in increments of 0.1 and range from 0.0 to 72.0, with higher scores representing greater severity of AD.

End point type	Secondary
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End point timeframe:

All scheduled time points, including Weeks 1, 2, 4, 6, 8, 12, 13, 14, 16

End point values	Placebo	PF-04965842 10mg QD	PF-04965842 30mg QD	PF-04965842 100mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56 ^[12]	49	51	56
Units: percentage of subjects				
number (not applicable)				
Week 1 (n = 54, 48, 50, 55, 54)	9.3	8.3	14.0	12.7
Week 2 (n = 55, 49, 50, 55, 52)	27.3	16.3	24.0	36.4
Week 4 (n = 55, 49, 50, 55, 54)	27.3	30.6	36.0	58.2
Week 6 (n = 55, 49, 50, 55, 54)	36.4	30.6	40.0	60.0
Week 8 (n = 55, 49, 50, 55, 53)	30.9	36.7	40.0	60.0
Week 12 (n = 52, 46, 45, 54, 48)	26.9	26.1	33.3	55.6
Week 13 (n = 30, 29, 31, 38, 45)	43.3	41.4	45.2	55.3
Week 14 (n = 32, 28, 29, 40, 44)	37.5	42.9	37.9	50.0
Week 16 (n = 28, 26, 27, 36, 38)	42.9	42.3	33.3	41.7

Notes:

[12] - "n" represents the number of evaluable subjects at each visit.

End point values	PF-04965842 200mg QD			
Subject group type	Reporting group			
Number of subjects analysed	55			
Units: percentage of subjects				
number (not applicable)				
Week 1 (n = 54, 48, 50, 55, 54)	40.7			
Week 2 (n = 55, 49, 50, 55, 52)	65.4			
Week 4 (n = 55, 49, 50, 55, 54)	85.2			
Week 6 (n = 55, 49, 50, 55, 54)	90.7			
Week 8 (n = 55, 49, 50, 55, 53)	90.6			
Week 12 (n = 52, 46, 45, 54, 48)	79.2			
Week 13 (n = 30, 29, 31, 38, 45)	75.6			
Week 14 (n = 32, 28, 29, 40, 44)	65.9			
Week 16 (n = 28, 26, 27, 36, 38)	68.4			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects achieving a $\geq 75\%$ improvement in the EASI Total Score (EASI75) at all scheduled time points

End point title	Percentage of subjects achieving a $\geq 75\%$ improvement in the EASI Total Score (EASI75) at all scheduled time points
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End point description:

The EASI quantifies the severity of subjects' AD based on both severity of lesion clinical signs and the percent of body surface area (BSA) affected. EASI is a composite scoring by the AD clinical evaluator of the degree of erythema, induration/population, excoriation, and lichenification (each scored separately) for each of four regions, with adjustment for the percent of BSA involved for each body region and for

the proportion of the body region to the whole body. The EASI score can vary in increments of 0.1 and range from 0.0 to 72.0, with higher scores representing greater severity of AD.

End point type	Secondary
End point timeframe:	
All scheduled time points, including Weeks 1, 2, 4, 6, 8, 12, 13, 14, 16	

End point values	Placebo	PF-04965842 10mg QD	PF-04965842 30mg QD	PF-04965842 100mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56 ^[13]	49	51	56
Units: percentage of subjects				
number (not applicable)				
Week 1 (n = 54, 48, 50, 55, 54)	3.7	2.1	6.0	3.6
Week 2 (n = 55, 49, 50, 55, 52)	5.5	12.2	6.0	12.7
Week 4 (n = 55, 49, 50, 55, 54)	10.9	18.4	20.0	27.3
Week 6 (n = 55, 49, 50, 55, 54)	16.4	18.4	18.0	38.2
Week 8 (n = 55, 49, 50, 55, 53)	20.0	22.4	22.0	40.0
Week 12 (n = 52, 46, 45, 54, 48)	15.4	17.4	13.3	40.7
Week 13 (n = 30, 29, 31, 38, 45)	26.7	27.6	12.9	36.8
Week 14 (n = 32, 28, 29, 40, 44)	31.3	25.0	6.9	35.0
Week 16 (n = 28, 26, 27, 36, 38)	32.1	38.5	3.7	25.0

Notes:

[13] - "n" represents the number of evaluable subjects at each visit.

End point values	PF-04965842 200mg QD			
Subject group type	Reporting group			
Number of subjects analysed	55			
Units: percentage of subjects				
number (not applicable)				
Week 1 (n = 54, 48, 50, 55, 54)	16.7			
Week 2 (n = 55, 49, 50, 55, 52)	36.5			
Week 4 (n = 55, 49, 50, 55, 54)	57.4			
Week 6 (n = 55, 49, 50, 55, 54)	68.5			
Week 8 (n = 55, 49, 50, 55, 53)	73.6			
Week 12 (n = 52, 46, 45, 54, 48)	64.6			
Week 13 (n = 30, 29, 31, 38, 45)	55.6			
Week 14 (n = 32, 28, 29, 40, 44)	45.5			
Week 16 (n = 28, 26, 27, 36, 38)	36.8			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects achieving a $\geq 90\%$ improvement in the EASI Total Score (EASI90) at all scheduled time points

End point title	Percentage of subjects achieving a $\geq 90\%$ improvement in the
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End point description:

The EASI quantifies the severity of participants' AD based on both severity of lesion clinical signs and the percent of body surface area (BSA) affected. EASI is a composite scoring by the AD clinical evaluator of the degree of erythema, induration/population, excoriation, and lichenification (each scored separately) for each of four regions, with adjustment for the percent of BSA involved for each body region and for the proportion of the body region to the whole body. The EASI score can vary in increments of 0.1 and range from 0.0 to 72.0, with higher scores representing greater severity of AD.

End point type

Secondary

End point timeframe:

All scheduled time points, including Weeks 1, 2, 4, 6, 8, 12, 13, 14, 16

End point values	Placebo	PF-04965842 10mg QD	PF-04965842 30mg QD	PF-04965842 100mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56 ^[14]	49	51	56
Units: percentage of subjects				
number (not applicable)				
Week 1 (n = 54, 48, 50, 55, 54)	0.0	2.1	4.0	0.0
Week 2 (n = 55, 49, 50, 55, 52)	0.0	6.1	4.0	5.5
Week 4 (n = 55, 49, 50, 55, 54)	1.8	8.2	8.0	10.9
Week 6 (n = 55, 49, 50, 55, 54)	7.3	14.3	14.0	16.4
Week 8 (n = 55, 49, 50, 55, 53)	5.5	12.2	8.0	23.6
Week 12 (n = 52, 46, 45, 54, 48)	9.6	10.9	0.0	25.9
Week 13 (n = 30, 29, 31, 38, 45)	10.0	13.8	3.2	23.7
Week 14 (n = 32, 28, 29, 40, 44)	15.6	14.3	0.0	17.5
Week 16 (n = 28, 26, 27, 36, 38)	14.3	23.1	3.7	8.3

Notes:

[14] - "n" represents the number of evaluable subjects at each visit.

End point values	PF-04965842 200mg QD			
Subject group type	Reporting group			
Number of subjects analysed	55			
Units: percentage of subjects				
number (not applicable)				
Week 1 (n = 54, 48, 50, 55, 54)	7.4			
Week 2 (n = 55, 49, 50, 55, 52)	19.2			
Week 4 (n = 55, 49, 50, 55, 54)	38.9			
Week 6 (n = 55, 49, 50, 55, 54)	44.4			
Week 8 (n = 55, 49, 50, 55, 53)	43.4			
Week 12 (n = 52, 46, 45, 54, 48)	52.1			
Week 13 (n = 30, 29, 31, 38, 45)	31.1			
Week 14 (n = 32, 28, 29, 40, 44)	18.2			
Week 16 (n = 28, 26, 27, 36, 38)	10.5			

Statistical analyses

Secondary: Change from baseline in affected body surface area (BSA) at all scheduled time points

End point title	Change from baseline in affected body surface area (BSA) at all scheduled time points
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End point description:

BSA Efficacy was derived from the sum of the BSA in handprints across 4 body regions assessed as part of the EASI assessment. Handprint refers to that of each individual subject for their own measurement. The BSA Efficacy ranges from 0 to 100%, with higher values representing greater severity of atopic dermatitis. Since the scalp, palms, and soles were excluded from the BSA (Efficacy) assessment, the maximum possible value was less than 100%.

End point type	Secondary
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End point timeframe:

Baseline and all scheduled time points, including Weeks 1, 2, 4, 6, 8, 12, 13, 14, 16

End point values	Placebo	PF-04965842 10mg QD	PF-04965842 30mg QD	PF-04965842 100mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56 ^[15]	49	51	56
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 1 (n = 54, 48, 49, 55, 53)	-0.06 (± 6.699)	-3.76 (± 13.940)	-2.45 (± 7.017)	-4.63 (± 12.144)
Week 2 (n = 55, 48, 47, 53, 50)	-5.43 (± 10.030)	-4.84 (± 16.179)	-6.51 (± 10.485)	-10.80 (± 16.432)
Week 4 (n = 50, 45, 47, 52, 52)	-6.34 (± 16.138)	-8.93 (± 15.960)	-9.59 (± 14.845)	-17.77 (± 19.956)
Week 6 (n = 44, 38, 43, 48, 52)	-10.79 (± 16.413)	-11.80 (± 22.324)	-10.71 (± 15.007)	-18.80 (± 23.387)
Week 8 (n = 41, 36, 43, 47, 49)	-9.71 (± 17.837)	-12.98 (± 25.552)	-10.79 (± 19.259)	-19.41 (± 23.596)
Week 12 (n = 35, 29, 30, 43, 42)	-13.82 (± 22.348)	-11.59 (± 27.112)	-9.37 (± 18.783)	-22.21 (± 22.199)
Week 13 (n = 30, 29, 31, 38, 45)	-7.90 (± 18.233)	-11.07 (± 25.457)	-7.79 (± 17.469)	-17.88 (± 20.905)
Week 14 (n = 32, 28, 29, 40, 44)	-8.97 (± 16.223)	-10.46 (± 26.130)	-6.33 (± 17.404)	-12.75 (± 22.492)
Week 16 (n = 28, 26, 27, 36, 38)	-8.09 (± 15.797)	-14.64 (± 20.948)	-3.52 (± 20.967)	-5.55 (± 21.079)

Notes:

[15] - "n" represents the number of evaluable subjects at each visit.

End point values	PF-04965842 200mg QD			
Subject group type	Reporting group			
Number of subjects analysed	55			
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 1 (n = 54, 48, 49, 55, 53)	-10.86 (± 15.690)			
Week 2 (n = 55, 48, 47, 53, 50)	-21.30 (± 19.285)			

Week 4 (n = 50, 45, 47, 52, 52)	-28.55 (± 20.447)			
Week 6 (n = 44, 38, 43, 48, 52)	-30.51 (± 20.853)			
Week 8 (n = 41, 36, 43, 47, 49)	-29.98 (± 20.864)			
Week 12 (n = 35, 29, 30, 43, 42)	-27.72 (± 18.361)			
Week 13 (n = 30, 29, 31, 38, 45)	-22.61 (± 22.390)			
Week 14 (n = 32, 28, 29, 40, 44)	-16.35 (± 18.931)			
Week 16 (n = 28, 26, 27, 36, 38)	-17.88 (± 17.059)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in scoring atopic dermatitis (SCORAD) at all scheduled time points

End point title	Change from baseline in scoring atopic dermatitis (SCORAD) at all scheduled time points
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End point description:

SCORAD is a validated scoring index for AD, which combines extent (0-100), severity (0-18), and subjective symptoms (0-20) based on pruritus and sleep loss, each scored (0-10). Extent, denoted as A, is measured by BSA affected by AD as a percentage of the whole BSA. The score for each body region is added up to determine A (maximum of 100%). Severity, denoted as B, consists of the severity of several signs. Each is assessed as none(0), mild(1), moderate(2) or severe(3). The severity scores are added together to give B (maximum of 18). Subjective symptoms, denoted as C, are each scored by the subject or caregiver using a numeric rating scale (NRS) where "0" is no itch (or no sleeplessness) and "10" is the worst imaginable itch (or sleeplessness). These scores are added to give 'C' (maximum of 20). The SCORAD for an individual is calculated by the formula: $A/5 + 7B/2 + C$ (can range from 0 to 103).

End point type	Secondary
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End point timeframe:

Baseline and all scheduled time points, including Weeks 1, 2, 4, 6, 8, 12, 13, 14, 16

End point values	Placebo	PF-04965842 10mg QD	PF-04965842 30mg QD	PF-04965842 100mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56 ^[16]	49	51	56
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 1 (n = 54, 48, 49, 55, 53)	-7.910 (± 12.4625)	-5.000 (± 13.3310)	-8.388 (± 14.6316)	-12.024 (± 12.4053)
Week 2 (n = 55, 48, 47, 53, 50)	-10.905 (± 15.4157)	-8.795 (± 16.3883)	-13.266 (± 14.5268)	-20.286 (± 15.2402)
Week 4 (n = 50, 45, 47, 52, 52)	-14.555 (± 16.6414)	-14.116 (± 19.1643)	-15.496 (± 16.4795)	-28.058 (± 16.6775)
Week 6 (n = 44, 38, 43, 48, 52)	-19.527 (± 16.7869)	-16.667 (± 21.8577)	-19.930 (± 17.5966)	-29.729 (± 21.6156)
Week 8 (n = 41, 36, 43, 47, 49)	-19.052 (± 18.5735)	-18.853 (± 21.7947)	-19.534 (± 18.7098)	-30.148 (± 20.7887)

Week 12 (n = 35, 29, 30, 43, 42)	-18.647 (± 20.0191)	-17.986 (± 23.1948)	-21.211 (± 17.6774)	-33.145 (± 21.4221)
Week 13 (n = 30, 29, 31, 38, 45)	-16.603 (± 21.3850)	-16.895 (± 22.1132)	-15.023 (± 16.1573)	-24.261 (± 19.4912)
Week 14 (n = 32, 28, 29, 40, 44)	-17.987 (± 22.0893)	-15.842 (± 19.5000)	-12.768 (± 13.6914)	-20.211 (± 20.2920)
Week 16 (n = 28, 26, 27, 36, 38)	-19.408 (± 22.1744)	-18.925 (± 21.5459)	-12.716 (± 15.9390)	-17.753 (± 19.1842)

Notes:

[16] - "n" represents the number of evaluable subjects at each visit.

End point values	PF-04965842 200mg QD			
Subject group type	Reporting group			
Number of subjects analysed	55			
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 1 (n = 54, 48, 49, 55, 53)	-21.326 (± 15.8867)			
Week 2 (n = 55, 48, 47, 53, 50)	-32.152 (± 14.4354)			
Week 4 (n = 50, 45, 47, 52, 52)	-39.567 (± 14.7328)			
Week 6 (n = 44, 38, 43, 48, 52)	-41.458 (± 14.3943)			
Week 8 (n = 41, 36, 43, 47, 49)	-42.604 (± 13.9771)			
Week 12 (n = 35, 29, 30, 43, 42)	-41.384 (± 15.4359)			
Week 13 (n = 30, 29, 31, 38, 45)	-29.884 (± 19.1501)			
Week 14 (n = 32, 28, 29, 40, 44)	-21.292 (± 17.7775)			
Week 16 (n = 28, 26, 27, 36, 38)	-21.024 (± 18.1576)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percent change from baseline in SCORAD at all scheduled time points

End point title	Percent change from baseline in SCORAD at all scheduled time points
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End point description:

SCORAD is a validated scoring index for AD, which combines extent (0-100), severity (0-18), and subjective symptoms (0-20) based on pruritus and sleep loss, each scored (0-10). Extent, denoted as A, is measured by BSA affected by AD as a percentage of the whole BSA. The score for each body region is added up to determine A (maximum of 100%). Severity, denoted as B, consists of the severity of several signs. Each is assessed as none(0), mild(1), moderate(2) or severe(3). The severity scores are added together to give B (maximum of 18). Subjective symptoms, denoted as C, are each scored by the subject or caregiver using a numeric rating scale (NRS) where "0" is no itch (or no sleeplessness) and "10" is the worst imaginable itch (or sleeplessness). These scores are added to give 'C' (maximum of 20). The SCORAD for an individual is calculated by the formula: A/5 + 7B/2 + C (can range from 0 to 103).

End point type	Secondary
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End point timeframe:

Baseline and all scheduled time points, including Weeks 1, 2, 4, 6, 8, 12, 13, 14, 16

End point values	Placebo	PF-04965842 10mg QD	PF-04965842 30mg QD	PF-04965842 100mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56 ^[17]	49	51	56
Units: percent change				
arithmetic mean (standard deviation)				
Week 1 (n = 54, 48, 49, 55, 53)	-11.547 (± 19.7128)	-7.287 (± 20.6403)	-13.068 (± 21.0746)	-19.185 (± 20.0094)
Week 2 (n = 55, 48, 47, 53, 50)	-16.488 (± 23.0011)	-12.980 (± 25.5198)	-20.613 (± 21.0283)	-31.025 (± 23.9881)
Week 4 (n = 50, 45, 47, 52, 52)	-22.476 (± 26.5163)	-20.751 (± 29.0846)	-24.866 (± 25.3755)	-43.846 (± 26.2001)
Week 6 (n = 44, 38, 43, 48, 52)	-30.789 (± 27.9424)	-25.851 (± 34.2950)	-31.276 (± 29.6517)	-45.270 (± 34.3893)
Week 8 (n = 41, 36, 43, 47, 49)	-29.624 (± 30.5625)	-28.599 (± 33.1460)	-30.480 (± 29.4742)	-46.187 (± 32.7984)
Week 12 (n = 35, 29, 30, 43, 42)	-29.379 (± 31.9081)	-27.607 (± 36.5015)	-32.535 (± 25.2711)	-51.624 (± 33.0106)
Week 13 (n = 30, 29, 31, 38, 45)	-26.794 (± 34.3384)	-26.905 (± 34.1879)	-24.232 (± 26.2461)	-38.193 (± 32.3458)
Week 14 (n = 32, 28, 29, 40, 44)	-29.393 (± 36.6642)	-25.511 (± 31.1985)	-20.072 (± 21.7399)	-31.521 (± 34.1268)
Week 16 (n = 28, 26, 27, 36, 38)	-31.972 (± 36.5058)	-30.135 (± 34.2361)	-19.794 (± 25.0550)	-29.130 (± 33.1868)

Notes:

[17] - "n" represents the number of evaluable subjects at each visit.

End point values	PF-04965842 200mg QD			
Subject group type	Reporting group			
Number of subjects analysed	55			
Units: percent change				
arithmetic mean (standard deviation)				
Week 1 (n = 54, 48, 49, 55, 53)	-34.660 (± 25.0837)			
Week 2 (n = 55, 48, 47, 53, 50)	-51.384 (± 21.3581)			
Week 4 (n = 50, 45, 47, 52, 52)	-63.970 (± 21.6701)			
Week 6 (n = 44, 38, 43, 48, 52)	-66.971 (± 22.4343)			
Week 8 (n = 41, 36, 43, 47, 49)	-69.736 (± 21.4403)			
Week 12 (n = 35, 29, 30, 43, 42)	-68.537 (± 24.2392)			
Week 13 (n = 30, 29, 31, 38, 45)	-48.428 (± 30.1133)			
Week 14 (n = 32, 28, 29, 40, 44)	-36.519 (± 28.5404)			
Week 16 (n = 28, 26, 27, 36, 38)	-34.995 (± 27.4996)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects achieving a $\geq 50\%$ improvement in SCORAD (SCORAD50) from baseline at all scheduled time points

End point title	Percentage of subjects achieving a $\geq 50\%$ improvement in SCORAD (SCORAD50) from baseline at all scheduled time points
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End point description:

SCORAD is a validated scoring index for AD, which combines extent (0-100), severity (0-18), and subjective symptoms (0-20) based on pruritus and sleep loss, each scored (0-10). Extent, denoted as A, is measured by BSA affected by AD as a percentage of the whole BSA. The score for each body region is added up to determine A (maximum of 100%). Severity, denoted as B, consists of the severity of several signs. Each is assessed as none(0), mild(1), moderate(2) or severe(3). The severity scores are added together to give B (maximum of 18). Subjective symptoms, denoted as C, are each scored by the subject or caregiver using a numeric rating scale (NRS) where "0" is no itch (or no sleeplessness) and "10" is the worst imaginable itch (or sleeplessness). These scores are added to give 'C' (maximum of 20). The SCORAD for an individual is calculated by the formula: $A/5 + 7B/2 + C$ (can range from 0 to 103).

End point type	Secondary
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End point timeframe:

Baseline and all scheduled time points, including Weeks 1, 2, 4, 6, 8, 12, 13, 14, 16

End point values	Placebo	PF-04965842 10mg QD	PF-04965842 30mg QD	PF-04965842 100mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56 ^[18]	49	51	56
Units: percentage of subjects				
number (not applicable)				
Week 1 (n = 54, 48, 50, 55, 54)	3.7	2.1	6.0	7.3
Week 2 (n = 55, 49, 50, 55, 52)	5.5	10.2	10.0	18.2
Week 4 (n = 55, 49, 50, 55, 54)	20.0	12.2	16.0	43.6
Week 6 (n = 55, 49, 50, 55, 54)	21.8	16.3	26.0	45.5
Week 8 (n = 55, 49, 50, 55, 53)	23.6	22.4	30.0	43.6
Week 12 (n = 52, 46, 45, 54, 48)	19.2	13.0	15.6	50.0
Week 13 (n = 30, 29, 31, 38, 45)	26.7	20.7	16.1	34.2
Week 14 (n = 32, 28, 29, 40, 44)	31.3	17.9	3.4	32.5
Week 16 (n = 28, 26, 27, 36, 38)	39.3	30.8	14.8	25.0

Notes:

[18] - "n" represents the number of evaluable subjects at each visit.

End point values	PF-04965842 200mg QD			
Subject group type	Reporting group			
Number of subjects analysed	55			

Units: percentage of subjects				
number (not applicable)				
Week 1 (n = 54, 48, 50, 55, 54)	29.6			
Week 2 (n = 55, 49, 50, 55, 52)	55.8			
Week 4 (n = 55, 49, 50, 55, 54)	75.9			
Week 6 (n = 55, 49, 50, 55, 54)	74.1			
Week 8 (n = 55, 49, 50, 55, 53)	73.6			
Week 12 (n = 52, 46, 45, 54, 48)	72.9			
Week 13 (n = 30, 29, 31, 38, 45)	48.9			
Week 14 (n = 32, 28, 29, 40, 44)	36.4			
Week 16 (n = 28, 26, 27, 36, 38)	34.2			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects achieving a $\geq 75\%$ improvement in SCORAD (SCORAD75) from baseline at all scheduled time points

End point title	Percentage of subjects achieving a $\geq 75\%$ improvement in SCORAD (SCORAD75) from baseline at all scheduled time points
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End point description:

SCORAD is a validated scoring index for AD, which combines extent (0-100), severity (0-18), and subjective symptoms (0-20) based on pruritus and sleep loss, each scored (0-10). Extent, denoted as A, is measured by BSA affected by AD as a percentage of the whole BSA. The score for each body region is added up to determine A (maximum of 100%). Severity, denoted as B, consists of the severity of several signs. Each is assessed as none(0), mild(1), moderate(2) or severe(3). The severity scores are added together to give B (maximum of 18). Subjective symptoms, denoted as C, are each scored by the subject or caregiver using a numeric rating scale (NRS) where "0" is no itch (or no sleeplessness) and "10" is the worst imaginable itch (or sleeplessness). These scores are added to give 'C' (maximum of 20). The SCORAD for an individual is calculated by the formula: $A/5 + 7B/2 + C$ (can range from 0 to 103).

End point type	Secondary
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End point timeframe:

Baseline and all scheduled time points, including Weeks 1, 2, 4, 6, 8, 12, 13, 14, 16

End point values	Placebo	PF-04965842 10mg QD	PF-04965842 30mg QD	PF-04965842 100mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56 ^[19]	49	51	56
Units: percentage of subjects				
number (not applicable)				
Week 1 (n = 54, 48, 50, 55, 54)	0.0	2.1	2.0	1.8
Week 2 (n = 55, 49, 50, 55, 52)	0.0	2.0	2.0	3.6
Week 4 (n = 55, 49, 50, 55, 54)	1.8	4.1	4.0	14.5
Week 6 (n = 55, 49, 50, 55, 54)	5.5	12.2	4.0	20.0
Week 8 (n = 55, 49, 50, 55, 53)	3.6	6.1	2.0	16.4
Week 12 (n = 52, 46, 45, 54, 48)	3.8	10.9	0.0	18.5
Week 13 (n = 30, 29, 31, 38, 45)	13.3	10.3	0.0	18.4
Week 14 (n = 32, 28, 29, 40, 44)	15.6	7.1	0.0	12.5

Week 16 (n = 28, 26, 27, 36, 38)	14.3	11.5	0.0	11.1
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Notes:

[19] - "n" represents the number of evaluable subjects at each visit.

End point values	PF-04965842 200mg QD			
Subject group type	Reporting group			
Number of subjects analysed	55			
Units: percentage of subjects				
number (not applicable)				
Week 1 (n = 54, 48, 50, 55, 54)	3.7			
Week 2 (n = 55, 49, 50, 55, 52)	11.5			
Week 4 (n = 55, 49, 50, 55, 54)	27.8			
Week 6 (n = 55, 49, 50, 55, 54)	37.0			
Week 8 (n = 55, 49, 50, 55, 53)	35.8			
Week 12 (n = 52, 46, 45, 54, 48)	37.5			
Week 13 (n = 30, 29, 31, 38, 45)	15.6			
Week 14 (n = 32, 28, 29, 40, 44)	11.4			
Week 16 (n = 28, 26, 27, 36, 38)	2.6			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with treatment-emergent adverse events (AEs)

End point title	Number of subjects with treatment-emergent adverse events (AEs)
End point description:	
An AE was any untoward medical occurrence in a subject administered a product or medical device; the event need not necessarily have a causal relationship with the treatment or usage. Treatment-emergent AEs were events that occurred between the first dose of study drug and the subject's last visit (Week 16) that were absent before treatment or that worsened relative to pretreatment state.	
End point type	Secondary
End point timeframe:	
Baseline till Week 16	

End point values	Placebo	PF-04965842 10mg QD	PF-04965842 30mg QD	PF-04965842 100mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	49	51	56
Units: subjects	32	34	34	43

End point values	PF-04965842 200mg QD			
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Subject group type	Reporting group			
Number of subjects analysed	55			
Units: subjects	41			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with specific clinical laboratory abnormalities (anemia, neutropenia, thrombocytopenia, lymphopenia, lipid profile, liver function tests (LFTs))

End point title	Number of subjects with specific clinical laboratory abnormalities (anemia, neutropenia, thrombocytopenia, lymphopenia, lipid profile, liver function tests (LFTs))
End point description:	
End point type	Secondary
End point timeframe:	
Baseline up to Week 16	

End point values	Placebo	PF-04965842 10mg QD	PF-04965842 30mg QD	PF-04965842 100mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	49	51	56
Units: subjects				
AEs of anemia	0	0	0	0
AEs of neutropenia	0	0	0	0
AEs of thrombocytopenia	0	0	0	0
AEs of lymphopenia	0	0	0	0
AEs of lipid profile	0	0	0	0
AEs of liver function tests	0	0	0	0

End point values	PF-04965842 200mg QD			
Subject group type	Reporting group			
Number of subjects analysed	55			
Units: subjects				
AEs of anemia	0			
AEs of neutropenia	1			
AEs of thrombocytopenia	1			
AEs of lymphopenia	0			
AEs of lipid profile	0			
AEs of liver function tests	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects with patient global assessment (PtGA) of AD of clear (0) or almost clear (1) and ≥ 2 points improvement from baseline at all scheduled time points

End point title	Percentage of subjects with patient global assessment (PtGA) of AD of clear (0) or almost clear (1) and ≥ 2 points improvement from baseline at all scheduled time points
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End point description:

The PtGA asked the subject to evaluate the overall cutaneous disease at that point in time on a single-item, 5-point scale. The same category labels used in the Physician's Global Assessment was used for the PtGA, ie, "severe (4)", "moderate (3)", "mild (2)", "almost clear (1)", and "clear (0)". The PtGA was completed as per schedule of activities.

End point type	Secondary
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End point timeframe:

Baseline and all scheduled time points, including Weeks 1, 2, 4, 6, 8, 12, 14, 16

End point values	Placebo	PF-04965842 10mg QD	PF-04965842 30mg QD	PF-04965842 100mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56 ^[20]	49	51	56
Units: percentage of subjects				
number (not applicable)				
Week 1 (n = 53, 48, 49, 53, 54)	0.0	2.1	4.1	1.9
Week 2 (n = 54, 49, 49, 54, 52)	5.6	0.0	6.1	16.7
Week 4 (n = 53, 49, 49, 54, 53)	3.8	6.1	8.2	22.2
Week 6 (n = 53, 49, 49, 54, 54)	3.8	10.2	8.2	22.2
Week 8 (n = 54, 49, 49, 54, 53)	1.9	6.1	6.1	24.1
Week 12 (n = 54, 48, 48, 54, 52)	7.4	12.5	0.0	25.9
Week 14 (n = 31, 29, 28, 38, 45)	3.2	10.3	0.0	15.8
Week 16 (n = 27, 26, 26, 34, 38)	11.1	7.7	0.0	11.8

Notes:

[20] - "n" represents the number of evaluable subjects at each visit.

End point values	PF-04965842 200mg QD			
Subject group type	Reporting group			
Number of subjects analysed	55			
Units: percentage of subjects				
number (not applicable)				
Week 1 (n = 53, 48, 49, 53, 54)	16.7			
Week 2 (n = 54, 49, 49, 54, 52)	32.7			

Week 4 (n = 53, 49, 49, 54, 53)	54.7			
Week 6 (n = 53, 49, 49, 54, 54)	51.9			
Week 8 (n = 54, 49, 49, 54, 53)	56.6			
Week 12 (n = 54, 48, 48, 54, 52)	51.9			
Week 14 (n = 31, 29, 28, 38, 45)	15.6			
Week 16 (n = 27, 26, 26, 34, 38)	10.5			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in dermatology life quality index (DLQI) total score at all scheduled time points

End point title	Change from baseline in dermatology life quality index (DLQI) total score at all scheduled time points
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End point description:

The DLQI is a general dermatology questionnaire that consists of 10 items that assess subject health-related quality of life (daily activities, personal relationships, symptoms and feelings, leisure, work and school, and treatment). It has been extensively used in clinical trials for AD. The DLQI is a psychometrically valid and reliable instrument that has been translated into several languages, and the DLQI total scores have been shown to be responsive to change. The minimally important difference for the DLQI has been estimated as a 2-5 point change from baseline.

End point type	Secondary
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End point timeframe:

Baseline and all scheduled time points, including Weeks 1, 2, 4, 6, 8, 12, 14, 16

End point values	Placebo	PF-04965842 10mg QD	PF-04965842 30mg QD	PF-04965842 100mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56 ^[21]	49	51	56
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 1 (n = 53, 48, 48, 54, 53)	-1.4 (± 6.04)	-1.4 (± 5.66)	-3.4 (± 6.28)	-5.1 (± 5.40)
Week 2 (n = 53, 48, 46, 52, 50)	-2.3 (± 5.42)	-1.9 (± 6.58)	-5.0 (± 5.55)	-7.5 (± 6.39)
Week 4 (n = 48, 45, 45, 51, 51)	-2.6 (± 6.77)	-3.7 (± 7.33)	-4.7 (± 5.62)	-8.2 (± 7.48)
Week 6 (n = 42, 38, 42, 47, 52)	-4.2 (± 6.01)	-4.6 (± 7.30)	-4.1 (± 7.75)	-9.1 (± 6.75)
Week 8 (n = 40, 36, 42, 46, 49)	-3.7 (± 7.67)	-5.6 (± 8.44)	-4.8 (± 8.52)	-9.2 (± 7.95)
Week 12 (n = 36, 31, 33, 43, 46)	-4.6 (± 8.49)	-4.5 (± 8.90)	-5.2 (± 7.30)	-9.8 (± 8.18)
Week 14 (n = 31, 29, 28, 39, 45)	-3.1 (± 8.24)	-3.9 (± 7.62)	-3.6 (± 6.60)	-6.2 (± 7.87)
Week 16 (n = 27, 26, 26, 34, 38)	-4.5 (± 7.95)	-4.5 (± 7.14)	-3.5 (± 7.17)	-4.6 (± 7.62)

Notes:

[21] - "n" represents the number of evaluable subjects at each visit.

End point values	PF-04965842 200mg QD			
Subject group type	Reporting group			
Number of subjects analysed	55			
Units: units on a scale				

arithmetic mean (standard deviation)				
Week 1 (n = 53, 48, 48, 54, 53)	-6.3 (± 5.55)			
Week 2 (n = 53, 48, 46, 52, 50)	-8.6 (± 6.46)			
Week 4 (n = 48, 45, 45, 51, 51)	-9.7 (± 6.82)			
Week 6 (n = 42, 38, 42, 47, 52)	-10.2 (± 6.72)			
Week 8 (n = 40, 36, 42, 46, 49)	-9.8 (± 7.10)			
Week 12 (n = 36, 31, 33, 43, 46)	-9.5 (± 7.28)			
Week 14 (n = 31, 29, 28, 39, 45)	-4.4 (± 8.78)			
Week 16 (n = 27, 26, 26, 34, 38)	-3.6 (± 7.39)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in patient oriented eczema measure (POEM) at all scheduled time points

End point title	Change from baseline in patient oriented eczema measure (POEM) at all scheduled time points
End point description:	
The POEM is a 7-item patient reported outcome (PRO) measure used to assess the impact of AD over the past week.	
End point type	Secondary
End point timeframe:	
Baseline and all scheduled time points, including Weeks 1, 2, 4, 6, 8, 12, 14, 16	

End point values	Placebo	PF-04965842 10mg QD	PF-04965842 30mg QD	PF-04965842 100mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56 ^[22]	49	51	56
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 1 (n = 53, 48, 48, 53, 50)	-1.1 (± 3.59)	-0.6 (± 4.17)	-2.1 (± 5.83)	-3.9 (± 4.67)
Week 2 (n = 51, 48, 45, 50, 50)	-2.2 (± 4.20)	-1.9 (± 6.13)	-4.1 (± 6.04)	-7.2 (± 6.79)
Week 4 (n = 48, 45, 44, 50, 50)	-2.2 (± 6.05)	-3.6 (± 6.35)	-4.3 (± 5.69)	-8.7 (± 8.30)
Week 6 (n = 41, 38, 42, 45, 50)	-3.5 (± 5.24)	-4.3 (± 7.63)	-3.9 (± 7.43)	-10.4 (± 8.17)
Week 8 (n = 40, 36, 42, 45, 48)	-2.3 (± 5.91)	-4.3 (± 8.94)	-5.4 (± 8.05)	-10.6 (± 8.47)
Week 12 (n = 36, 31, 33, 41, 45)	-3.8 (± 8.21)	-4.7 (± 8.83)	-5.3 (± 7.60)	-11.4 (± 8.08)
Week 14 (n = 31, 29, 28, 38, 44)	-2.2 (± 6.45)	-3.9 (± 8.04)	-2.7 (± 6.05)	-6.3 (± 7.12)
Week 16 (n = 27, 26, 26, 34, 37)	-3.0 (± 7.76)	-3.0 (± 7.67)	-2.2 (± 6.80)	-4.3 (± 6.20)

Notes:

[22] - "n" represents the number of evaluable subjects at each visit.

End point values	PF-04965842 200mg QD			
Subject group type	Reporting group			
Number of subjects analysed	55			
Units: units on a scale				

arithmetic mean (standard deviation)				
Week 1 (n = 53, 48, 48, 53, 50)	-9.2 (± 5.77)			
Week 2 (n = 51, 48, 45, 50, 50)	-11.9 (± 5.95)			
Week 4 (n = 48, 45, 44, 50, 50)	-14.6 (± 6.20)			
Week 6 (n = 41, 38, 42, 45, 50)	-15.0 (± 5.92)			
Week 8 (n = 40, 36, 42, 45, 48)	-15.2 (± 6.15)			
Week 12 (n = 36, 31, 33, 41, 45)	-15.1 (± 6.99)			
Week 14 (n = 31, 29, 28, 38, 44)	-6.2 (± 6.97)			
Week 16 (n = 27, 26, 26, 34, 37)	-5.9 (± 5.93)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in the hospital and anxiety depression scale (HADS) at all scheduled time points

End point title	Change from baseline in the hospital and anxiety depression scale (HADS) at all scheduled time points
End point description: The HADS is a 14-item PRO measure used to detect states of anxiety and depression over the past week. The HADS was completed as per schedule of activities.	
End point type	Secondary
End point timeframe: Baseline and all scheduled time points, including Weeks 1, 2, 4, 6, 8, 12, 14, 16	

End point values	Placebo	PF-04965842 10mg QD	PF-04965842 30mg QD	PF-04965842 100mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56 ^[23]	49	51	56
Units: units on a scale				
arithmetic mean (standard deviation)				
Depression score Week 1 (n = 53, 48, 48, 54, 53)	-0.5 (± 2.71)	0.0 (± 2.38)	-0.6 (± 2.49)	-0.9 (± 2.94)
Depression score Week 2 (n = 53, 48, 46, 52, 50)	-0.5 (± 2.78)	0.4 (± 2.99)	-1.1 (± 1.85)	-1.2 (± 2.93)
Depression score Week 4 (n = 47, 45, 45, 51, 51)	-0.5 (± 3.00)	-0.4 (± 3.26)	-0.8 (± 2.05)	-1.5 (± 3.35)
Depression score Week 8 (n = 41, 36, 42, 46, 50)	-0.7 (± 3.31)	-1.3 (± 3.76)	-0.9 (± 2.84)	-2.1 (± 3.35)
Depression score Week 12 (n = 36, 31, 33, 43, 46)	-0.9 (± 3.96)	-0.9 (± 3.65)	-0.5 (± 2.83)	-2.4 (± 3.74)
Depression score Week 14 (n = 31, 29, 28, 39, 45)	0.1 (± 3.41)	-1.2 (± 3.50)	-0.9 (± 1.53)	-1.7 (± 4.31)
Depression score Week 16 (n = 27, 26, 26, 34, 38)	-0.7 (± 3.18)	-1.1 (± 3.59)	-1.0 (± 1.85)	-1.4 (± 3.93)
Anxiety score Week 1 (n = 53, 48, 48, 54, 53)	-1.0 (± 2.66)	0.2 (± 2.41)	-0.2 (± 2.49)	-1.1 (± 2.26)
Anxiety score Week 2 (n = 53, 48, 46, 52, 50)	-1.5 (± 2.87)	-0.4 (± 2.56)	-0.9 (± 2.88)	-1.7 (± 2.81)
Anxiety score Week 4 (n = 47, 46, 45, 51, 51)	-1.6 (± 3.18)	-1.0 (± 2.80)	-0.7 (± 2.69)	-1.7 (± 2.95)

Anxiety score Week 8 (n = 41, 36, 42, 46, 50)	-1.7 (± 2.33)	-1.6 (± 2.67)	-1.4 (± 3.21)	-2.7 (± 3.44)
Anxiety score Week 12 (n = 36, 31, 33, 43, 46)	-2.6 (± 3.01)	-1.5 (± 2.85)	-1.0 (± 3.43)	-2.8 (± 3.71)
Anxiety score Week 14 (n = 31, 29, 28, 39, 45)	-2.3 (± 3.43)	-1.5 (± 3.17)	-1.4 (± 2.96)	-2.0 (± 3.49)
Anxiety score Week 16 (n = 27, 26, 26, 34, 38)	-2.9 (± 3.75)	-2.2 (± 3.38)	-0.7 (± 3.27)	-1.4 (± 3.85)

Notes:

[23] - "n" represents the number of evaluable subjects at each visit.

End point values	PF-04965842 200mg QD			
Subject group type	Reporting group			
Number of subjects analysed	55			
Units: units on a scale				
arithmetic mean (standard deviation)				
Depression score Week 1 (n = 53, 48, 48, 54, 53)	-1.0 (± 2.16)			
Depression score Week 2 (n = 53, 48, 46, 52, 50)	-1.8 (± 2.66)			
Depression score Week 4 (n = 47, 45, 45, 51, 51)	-2.1 (± 3.30)			
Depression score Week 8 (n = 41, 36, 42, 46, 50)	-1.7 (± 3.08)			
Depression score Week 12 (n = 36, 31, 33, 43, 46)	-1.8 (± 3.90)			
Depression score Week 14 (n = 31, 29, 28, 39, 45)	-0.1 (± 4.18)			
Depression score Week 16 (n = 27, 26, 26, 34, 38)	-0.1 (± 3.57)			
Anxiety score Week 1 (n = 53, 48, 48, 54, 53)	-1.2 (± 2.71)			
Anxiety score Week 2 (n = 53, 48, 46, 52, 50)	-2.4 (± 3.15)			
Anxiety score Week 4 (n = 47, 46, 45, 51, 51)	-2.4 (± 4.04)			
Anxiety score Week 8 (n = 41, 36, 42, 46, 50)	-2.5 (± 3.31)			
Anxiety score Week 12 (n = 36, 31, 33, 43, 46)	-2.5 (± 3.51)			
Anxiety score Week 14 (n = 31, 29, 28, 39, 45)	-1.5 (± 3.93)			
Anxiety score Week 16 (n = 27, 26, 26, 34, 38)	-1.5 (± 3.10)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Baseline up to Week 16

Adverse event reporting additional description:

The same event may appear as both an adverse event (AE) and a serious adverse event (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
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	20.0
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Reporting groups

Reporting group title	Placebo
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Reporting group description:

Treatment Group Description TBD

Reporting group title	PF-04965842 10mg QD
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Reporting group description:

Treatment Group Description TBD

Reporting group title	PF-04965842 30mg QD
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Reporting group description:

Treatment Group Description TBD

Reporting group title	PF-04965842 100mg QD
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Reporting group description:

Treatment Group Description TBD

Reporting group title	PF-04965842 200mg QD
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Reporting group description:

Treatment Group Description TBD

Serious adverse events	Placebo	PF-04965842 10mg QD	PF-04965842 30mg QD
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 56 (3.57%)	2 / 49 (4.08%)	0 / 51 (0.00%)
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)			
Malignant melanoma			
subjects affected / exposed	0 / 56 (0.00%)	1 / 49 (2.04%)	0 / 51 (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
Respiratory, thoracic and mediastinal disorders			

Asthma			
subjects affected / exposed	0 / 56 (0.00%)	1 / 49 (2.04%)	0 / 51 (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
Pulmonary embolism			
subjects affected / exposed	0 / 56 (0.00%)	0 / 49 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatitis atopic			
subjects affected / exposed	1 / 56 (1.79%)	0 / 49 (0.00%)	0 / 51 (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
Dermatitis exfoliative			
subjects affected / exposed	1 / 56 (1.79%)	0 / 49 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Eczema herpeticum			
subjects affected / exposed	0 / 56 (0.00%)	0 / 49 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 49 (0.00%)	0 / 51 (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-04965842 100mg QD	PF-04965842 200mg QD	
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 56 (5.36%)	2 / 55 (3.64%)	
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)			
Malignant melanoma			

subjects affected / exposed	0 / 56 (0.00%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	1 / 56 (1.79%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	0 / 56 (0.00%)	1 / 55 (1.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Dermatitis atopic			
subjects affected / exposed	1 / 56 (1.79%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis exfoliative			
subjects affected / exposed	0 / 56 (0.00%)	0 / 55 (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			
Eczema herpeticum			
subjects affected / exposed	1 / 56 (1.79%)	0 / 55 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	0 / 56 (0.00%)	1 / 55 (1.82%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Placebo	PF-04965842 10mg QD	PF-04965842 30mg QD
Total subjects affected by non-serious adverse events			
subjects affected / exposed	17 / 56 (30.36%)	18 / 49 (36.73%)	25 / 51 (49.02%)
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 56 (0.00%)	0 / 49 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	2
Headache			
subjects affected / exposed	2 / 56 (3.57%)	2 / 49 (4.08%)	5 / 51 (9.80%)
occurrences (all)	2	2	5
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	1 / 56 (1.79%)	3 / 49 (6.12%)	1 / 51 (1.96%)
occurrences (all)	1	3	1
Nausea			
subjects affected / exposed	1 / 56 (1.79%)	3 / 49 (6.12%)	3 / 51 (5.88%)
occurrences (all)	1	4	5
Skin and subcutaneous tissue disorders			
Dermatitis atopic			
subjects affected / exposed	6 / 56 (10.71%)	8 / 49 (16.33%)	9 / 51 (17.65%)
occurrences (all)	9	9	9
Dermatitis contact			
subjects affected / exposed	0 / 56 (0.00%)	0 / 49 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	5 / 56 (8.93%)	3 / 49 (6.12%)	5 / 51 (9.80%)
occurrences (all)	5	3	5
Viral upper respiratory tract infection			
subjects affected / exposed	5 / 56 (8.93%)	5 / 49 (10.20%)	6 / 51 (11.76%)
occurrences (all)	6	5	7

Non-serious adverse events	PF-04965842 100mg QD	PF-04965842 200mg QD	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	25 / 56 (44.64%)	27 / 55 (49.09%)	
Nervous system disorders			

Dizziness subjects affected / exposed occurrences (all)	0 / 56 (0.00%) 0	3 / 55 (5.45%) 3	
Headache subjects affected / exposed occurrences (all)	5 / 56 (8.93%) 6	4 / 55 (7.27%) 6	
Gastrointestinal disorders			
Diarrhoea subjects affected / exposed occurrences (all)	1 / 56 (1.79%) 1	5 / 55 (9.09%) 5	
Nausea subjects affected / exposed occurrences (all)	1 / 56 (1.79%) 1	8 / 55 (14.55%) 9	
Skin and subcutaneous tissue disorders			
Dermatitis atopic subjects affected / exposed occurrences (all)	7 / 56 (12.50%) 7	7 / 55 (12.73%) 7	
Dermatitis contact subjects affected / exposed occurrences (all)	3 / 56 (5.36%) 3	0 / 55 (0.00%) 0	
Infections and infestations			
Upper respiratory tract infection subjects affected / exposed occurrences (all)	3 / 56 (5.36%) 4	5 / 55 (9.09%) 5	
Viral upper respiratory tract infection subjects affected / exposed occurrences (all)	10 / 56 (17.86%) 15	7 / 55 (12.73%) 8	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported