# 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 |

**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 |

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 |

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:<br>30 mg | |

| | |
|---|---|
| **Arm title** | PF-04965842 100mg QD |
| Arm description:<br>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:<br>100 mg | |
| **Arm title** | PF-04965842 200mg QD |
| Arm description:<br>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:<br>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<br>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<br>Units: years | | | |
| arithmetic mean | 41.1 | 38.7 | |
| standard deviation | ± 15.6 | ± 17.6 | - |
| Gender, Male/Female<br>Units: Subjects | | | |
| Female | 25 | 27 | 144 |
| Male | 31 | 28 | 123 |
| Race/Ethnicity<br>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 (± 2.55) | 8.2 (± 2.32) | 12.3 (± 2.88) | 27.8 (± 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 (± 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 |

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:

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 |
|---|---|

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 |
|---|---|

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 |
|---|---|

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 |
|---|---|

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. |
|---|---|

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 |
|---|---|

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 |
|---|---|

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[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 |
|---|---|

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

No statistical analyses for this end point

## 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 |
|---|---|

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[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 |
|---|---|

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[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 >=50% improvement in the EASI Total Score (EASI50) at all scheduled time points

| End point title | Percentage of subjects achieving a >=50% improvement in the EASI Total Score (EASI50) at all scheduled time points |
|---|---|

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 |
|---|---|

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 >=75% improvement in the EASI Total Score (EASI75) at all scheduled time points

| End point title | Percentage of subjects achieving a >=75% improvement in the EASI Total Score (EASI75) at all scheduled time points |
|---|---|

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 >=90% improvement in the EASI Total Score (EASI90) at all scheduled time points

| End point title | Percentage of subjects achieving a >=90% improvement in the |
|---|---|

| | EASI Total Score (EASI90) at all scheduled time points |
|---|---|

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

No statistical analyses for this end point

## 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 |
|---|---|

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 |
|---|---|

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 |

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 |

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 |
|---|---|

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 |
|---|---|

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 >=50% improvement in SCORAD (SCORAD50) from baseline at all scheduled time points

| End point title | Percentage of subjects achieving a >=50% improvement in SCORAD (SCORAD50) from baseline at all scheduled time points |
|---|---|

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 |
|---|---|

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 >=75% improvement in SCORAD (SCORAD75) from baseline at all scheduled time points

| End point title | Percentage of subjects achieving a >=75% improvement in SCORAD (SCORAD75) from baseline at all scheduled time points |
|---|---|

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 |
|---|---|

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 |

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 | | | |
|---|---|---|---|---|

| 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 |
|---|---|

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 |
|---|---|

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 |
|---|---|

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 |
|---|---|

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 |

### Dictionary used

| | |
|---|---|
| Dictionary name | MedDRA |
| Dictionary version | 20.0 |

### Reporting groups

| | |
|---|---|
| Reporting group title | Placebo |
| Reporting group description: | |
| Treatment Group Description TBD | |
| Reporting group title | PF-04965842 10mg QD |
| Reporting group description: | |
| Treatment Group Description TBD | |
| Reporting group title | PF-04965842 30mg QD |
| Reporting group description: | |
| Treatment Group Description TBD | |
| Reporting group title | PF-04965842 100mg QD |
| Reporting group description: | |
| Treatment Group Description TBD | |
| Reporting group title | PF-04965842 200mg QD |
| 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 | 0 / 56 (0.00%) | 3 / 55 (5.45%) | |
| occurrences (all) | 0 | 3 | |
| Headache | | | |
| subjects affected / exposed | 5 / 56 (8.93%) | 4 / 55 (7.27%) | |
| occurrences (all) | 6 | 6 | |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed | 1 / 56 (1.79%) | 5 / 55 (9.09%) | |
| occurrences (all) | 1 | 5 | |
| Nausea | | | |
| subjects affected / exposed | 1 / 56 (1.79%) | 8 / 55 (14.55%) | |
| occurrences (all) | 1 | 9 | |
| Skin and subcutaneous tissue disorders | | | |
| Dermatitis atopic | | | |
| subjects affected / exposed | 7 / 56 (12.50%) | 7 / 55 (12.73%) | |
| occurrences (all) | 7 | 7 | |
| Dermatitis contact | | | |
| subjects affected / exposed | 3 / 56 (5.36%) | 0 / 55 (0.00%) | |
| occurrences (all) | 3 | 0 | |
| Infections and infestations | | | |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 3 / 56 (5.36%) | 5 / 55 (9.09%) | |
| occurrences (all) | 4 | 5 | |
| Viral upper respiratory tract infection | | | |
| subjects affected / exposed | 10 / 56 (17.86%) | 7 / 55 (12.73%) | |
| occurrences (all) | 15 | 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