# Clinical trial results:
# A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Multi-center Study Investigating the Efficacy and Safety of PF-04965842 Co-administered With Background Medicated Topical Therapy in Adolescent Participants 12 to <18 Years of Age With Moderate-to-Severe Atopic Dermatitis

## Summary

| | |
|---|---|
| EudraCT number | 2018-003804-37 |
| Trial protocol | HU CZ LV PL GB DE IT |
| Global end of trial date | 08 April 2020 |

### Results information

| | |
|---|---|
| Result version number | v1 (current) |
| This version publication date | 17 October 2020 |
| First version publication date | 17 October 2020 |

## Trial information

### Trial identification

| | |
|---|---|
| Sponsor protocol code | B7451036 |

### Additional study identifiers

| | |
|---|---|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT03796676 |
| WHO universal trial number (UTN) | - |

Notes:

### Sponsors

| | |
|---|---|
| Sponsor organisation name | Pfizer, Inc. |
| Sponsor organisation address | 235 E 42nd Street, New York, United States, NY 10017 |
| Public contact | Pfizer ClinicalTrials.gov Call Center, Pfizer, Inc., +1 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com |
| Scientific contact | Pfizer ClinicalTrials.gov Call Center, Pfizer, Inc., +1 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com |

Notes:

### Paediatric regulatory details

| | |
|---|---|
| Is trial part of an agreed paediatric investigation plan (PIP) | No |
| Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial? | No |
| Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial? | No |

Notes:

## Results analysis stage

| | |
|---|---|
| Analysis stage | Final |
| Date of interim/final analysis | 10 September 2020 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 08 April 2020 |
| Global end of trial reached? | Yes |
| Global end of trial date | 08 April 2020 |
| Was the trial ended prematurely? | No |

Notes:

## General information about the trial

Main objective of the trial:

The main objective was to assess the efficacy of PF-04965842 compared with placebo when coadministered with background medicated topical therapy in adolescent subjects 12 to <18 years of age with moderate-to-severe atopic dermatitis (AD).

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trial subjects were followed.

Background therapy:

Medicated topical therapy (topical corticosteroid or topical calcineurin inhibitors or phosphodiesterase type 4 [PDE4] inhibitor)

Evidence for comparator: -

| | |
|---|---|
| Actual start date of recruitment | 18 February 2019 |
| Long term follow-up planned | Yes |
| Long term follow-up rationale | Safety |
| Long term follow-up duration | 24 Months |
| Independent data monitoring committee (IDMC) involvement? | Yes |

Notes:

## Population of trial subjects

### Subjects enrolled per country

| | |
|---|---|
| Country: Number of subjects enrolled | Australia: 9 |
| Country: Number of subjects enrolled | China: 52 |
| Country: Number of subjects enrolled | Czech Republic: 4 |
| Country: Number of subjects enrolled | Germany: 6 |
| Country: Number of subjects enrolled | Hungary: 17 |
| Country: Number of subjects enrolled | Italy: 2 |
| Country: Number of subjects enrolled | Japan: 26 |
| Country: Number of subjects enrolled | Latvia: 2 |
| Country: Number of subjects enrolled | Mexico: 23 |
| Country: Number of subjects enrolled | Poland: 43 |
| Country: Number of subjects enrolled | Spain: 13 |
| Country: Number of subjects enrolled | Taiwan: 8 |
| Country: Number of subjects enrolled | United States: 80 |
| Worldwide total number of subjects | 285 |
| EEA total number of subjects | 87 |

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) | 1 |
| Adolescents (12-17 years) | 283 |
| Adults (18-64 years) | 1 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

A total of 408 subjects were screened, 287 subjects were enrolled and assigned to 1 of 3 treatments. Only 285 subjects received the study treatment and 2 subjects withdrew prior to dosing.

### 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** | PF-04965842 100mg QD |

Arm description:

Subjects in this treatment group received PF-04965842 100 mg once daily (QD) for 12 weeks.

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

Dosage and administration details:

Subjects received 1 tablet of PF-04965842 100 mg and 1 tablet of placebo QD.

| | |
|---|---|
| **Arm title** | PF-04965842 200mg QD |

Arm description:

Subjects in this treatment group received PF-04965842 200 mg QD for 12 weeks.

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

Dosage and administration details:

Subjects received 2 tablets of PF-04965842 100 mg QD.

| | |
|---|---|
| **Arm title** | Placebo |

Arm description:

Subjects in this treatment group received PF-04965842-matching placebo QD for 12 weeks.

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

Dosage and administration details:
Subjects received 2 tablets of PF-04965842 matching placebo QD.

| **Number of subjects in period 1** | PF-04965842 100mg QD | PF-04965842 200mg QD | Placebo |
|---|---|---|---|
| Started | 95 | 94 | 96 |
| Completed | 92 | 91 | 90 |
| Not completed | 3 | 3 | 6 |
| Adverse event, non-fatal | 1 | 2 | 2 |
| Withdrawal by Parent/Guardian | 1 | - | 1 |
| Lost to follow-up | 1 | - | 2 |
| COVID-19 impact | - | - | 1 |
| Protocol deviation | - | 1 | - |

## Baseline characteristics

| Reporting groups | |
|---|---|
| Reporting group title | Overall Study |
| Reporting group description: | |
| Subjects received QD PF-04965842 at 200 mg, 100 mg or placebo for 12 weeks. | |

| Reporting group values | Overall Study | Total | |
|---|---|---|---|
| Number of subjects | 285 | 285 | |
| Age Categorical<br>Units: Subjects | | | |
| In utero | 0 | 0 | |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | |
| Newborns (0-27 days) | 0 | 0 | |
| Infants and toddlers (28 days-23 months) | 0 | 0 | |
| Children (2-11 years) | 1 | 1 | |
| Adolescents (12-17 years) | 283 | 283 | |
| Adults (18-64 years) | 1 | 1 | |
| From 65-84 years | 0 | 0 | |
| 85 years and over | 0 | 0 | |
| Age Continuous<br>Units: years | | | |
| median | 15 | | |
| full range (min-max) | 11 to 18 | - | |
| Gender Categorical<br>Units: Subjects | | | |
| Female | 140 | 140 | |
| Male | 145 | 145 | |
| Race<br>Units: Subjects | | | |
| White | 160 | 160 | |
| Black or African American | 17 | 17 | |
| Asian | 94 | 94 | |
| American Indian or Alaska Native | 8 | 8 | |
| Native Hawaiian or Other Pacific Islander | 2 | 2 | |
| Multiracial | 2 | 2 | |
| Not reported | 2 | 2 | |

## End points

### End points reporting groups

| | |
|---|---|
| Reporting group title | PF-04965842 100mg QD |
| Reporting group description: | |
| Subjects in this treatment group received PF-04965842 100 mg once daily (QD) for 12 weeks. | |
| Reporting group title | PF-04965842 200mg QD |
| Reporting group description: | |
| Subjects in this treatment group received PF-04965842 200 mg QD for 12 weeks. | |
| Reporting group title | Placebo |
| Reporting group description: | |
| Subjects in this treatment group received PF-04965842-matching placebo QD for 12 weeks. | |

### Primary: Proportion of Subjects Achieving Investigator's Global Assessment (IGA) Response of "Clear" (0) or "Almost Clear" (1) and >=2 Points Improvement from Baseline at Week 12

| | |
|---|---|
| End point title | Proportion of Subjects Achieving Investigator's Global Assessment (IGA) Response of "Clear" (0) or "Almost Clear" (1) and >=2 Points Improvement from Baseline at Week 12 |
| End point description: | |
| The IGA of AD is scored on a 5-point scale (0-4), reflecting a global consideration of the erythema, induration and scaling. The overall severity of AD were assessed according to a 5-point scale: 0=Clear, 1=Almost Clear, 2=Mild, 3=Moderate, and 4=Severe. Subjects who withdrew from the study were counted as non-responder. The analysis of this endpoint were performed using the full analysis set (FAS) which was defined as all subjects randomly assigned to study intervention and who took at least 1 dose of study intervention. | |
| End point type | Primary |
| End point timeframe: | |
| Baseline to Week 12 | |

| End point values | PF-04965842 100mg QD | PF-04965842 200mg QD | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 89 | 93 | 94 | |
| Units: Percent of total evaluable subjects | | | | |
| number (confidence interval 95%) | 41.6 (31.3 to 51.8) | 46.2 (36.1 to 56.4) | 24.5 (15.8 to 33.2) | |

### Statistical analyses

| | |
|---|---|
| **Statistical analysis title** | PF-04965842 100 mg Versus Placebo |
| Comparison groups | PF-04965842 100mg QD v Placebo |

| | |
|---|---|
| Number of subjects included in analysis | 183 |
| Analysis specification | Pre-specified |
| Analysis type | superiority[1] |
| P-value | = 0.0147 [2] |
| Method | Cochran-Mantel-Haenszel |
| Parameter estimate | Estimate of difference |
| Point estimate | 16.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 3.5 |
| upper limit | 29.9 |

Notes:

[1] - Estimate of the difference in proportions of response was calculated by PF-04965842 100 mg minus placebo
[2] - The significance level is 0.05.

| **Statistical analysis title** | PF-04965842 200 mg Versus Placebo |
|---|---|
| Comparison groups | PF-04965842 200mg QD v Placebo |
| Number of subjects included in analysis | 187 |
| Analysis specification | Pre-specified |
| Analysis type | superiority[3] |
| P-value | = 0.003 [4] |
| Method | Cochran-Mantel-Haenszel |
| Parameter estimate | Estimate of difference |
| Point estimate | 20.6 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 7.3 |
| upper limit | 33.9 |

Notes:

[3] - Estimate of the difference in proportions of response was calculated by PF-04965842 200 mg minus placebo
[4] - The significance level is 0.05.

## Primary: Proportion of Subjects Achieving Eczema Area and Severity Index (EASI) Response >= 75% Improvement from Baseline at Week 12

| | |
|---|---|
| End point title | Proportion of Subjects Achieving Eczema Area and Severity Index (EASI) Response >= 75% Improvement from Baseline at Week 12 |

End point description:

The EASI quantifies the severity of a subject’s AD based on both severity of lesion clinical signs and the percent of body surface area (BSA) affected. 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. Subjects who withdrew from the study were counted as non-responder. The analysis of this endpoint was performed using the FAS which was defined as all subjects randomly assigned to study intervention and who took at least 1 dose of study intervention.

| | |
|---|---|
| End point type | Primary |

End point timeframe:

Baseline to Week 12

| End point values | PF-04965842 100mg QD | PF-04965842 200mg QD | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 89 | 93 | 94 | |
| Units: Percent of total evaluable subjects | | | | |
| number (confidence interval 95%) | 68.5 (58.9 to 78.2) | 72.0 (62.9 to 81.2) | 41.5 (31.5 to 51.4) | |

**Statistical analyses**

| Statistical analysis title | PF-04965842 100 mg Versus Placebo |
|---|---|
| Comparison groups | PF-04965842 100mg QD v Placebo |
| Number of subjects included in analysis | 183 |
| Analysis specification | Pre-specified |
| Analysis type | superiority[5] |
| P-value | = 0.0002 [6] |
| Method | Cochran-Mantel-Haenszel |
| Parameter estimate | Estimate of difference |
| Point estimate | 26.5 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 13.1 |
| upper limit | 39.8 |

Notes:

[5] - Estimate of the difference in proportions of response was calculated by PF-04965842 100 mg minus placebo
[6] - The significance level is 0.05.

| Statistical analysis title | PF-04965842 200 mg Versus Placebo |
|---|---|
| Comparison groups | PF-04965842 200mg QD v Placebo |
| Number of subjects included in analysis | 187 |
| Analysis specification | Pre-specified |
| Analysis type | superiority[7] |
| P-value | < 0.0001 [8] |
| Method | Cochran-Mantel-Haenszel |
| Parameter estimate | Estimate of difference |
| Point estimate | 29.4 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 16.3 |
| upper limit | 42.5 |

Notes:

[7] - Estimate of the difference in proportions of response was calculated by PF-04965842 200 mg minus placebo
[8] - The significance level is 0.05.

## Secondary: Proportion of Subjects Achieving >=4 Points Improvement from Baseline in Peak Pruritis Numeric Rating Scale (PP-NRS) for Severity of Pruritus at Weeks 2, 4 and 12

| End point title | Proportion of Subjects Achieving >=4 Points Improvement from Baseline in Peak Pruritis Numeric Rating Scale (PP-NRS) for Severity of Pruritus at Weeks 2, 4 and 12 |
|---|---|

End point description:

PP-NRS assesses the severity of itch (pruritus) due to AD. Subjects were asked to assess their worst itching due to AD on an NRS anchored by the terms "no itch" (0) and "worst itch imaginable" (10). Subjects who withdrew from the study were counted as non-responder. The analysis of this endpoint was performed using the FAS which was defined as all subjects randomly assigned to study intervention and who took at least 1 dose of study intervention.

| End point type | Secondary |
|---|---|

End point timeframe:

Baseline, Weeks 2, 4, and 12

| **End point values** | PF-04965842 100mg QD | PF-04965842 200mg QD | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 95 | 94 | 96 | |
| Units: Percent of total evaluable subjects | | | | |
| number (confidence interval 95%) | | | | |
| Week 2 | 27.2 (18.1 to 36.3) | 38.6 (28.5 to 48.8) | 12.6 (6.0 to 19.3) | |
| Week 4 | 31.5 (21.8 to 41.1) | 50.0 (39.3 to 60.7) | 20.7 (12.4 to 28.9) | |
| Week 12 | 52.6 (41.4 to 63.9) | 55.4 (44.1 to 66.7) | 29.8 (20.0 to 39.5) | |

**Statistical analyses**

| **Statistical analysis title** | PF-04965842 100 mg Versus Palcebo at Week2 |
|---|---|
| Comparison groups | PF-04965842 100mg QD v Placebo |
| Number of subjects included in analysis | 191 |
| Analysis specification | Pre-specified |
| Analysis type | superiority[9] |
| P-value | = 0.0119 [10] |
| Method | Cochran-Mantel-Haenszel |
| Parameter estimate | Estimate of difference |
| Point estimate | 14.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 3.5 |
| upper limit | 25.9 |

Notes:

[9] - Estimate of the difference in proportions of response was calculated by PF-04965842 100 mg minus placebo
[10] - The significance level is 0.05.

| **Statistical analysis title** | PF-04965842 200 mg Versus Placebo at Week 2 |
|---|---|
| Comparison groups | PF-04965842 200mg QD v Placebo |

| | |
|---|---|
| Number of subjects included in analysis | 190 |
| Analysis specification | Pre-specified |
| Analysis type | superiority[11] |
| P-value | < 0.0001 [12] |
| Method | Cochran-Mantel-Haenszel |
| Parameter estimate | Estimate of difference |
| Point estimate | 26.1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 13.9 |
| upper limit | 38.3 |

Notes:

[11] - Estimate of the difference in proportions of response was calculated by PF-04965842 200 mg minus placebo
[12] - The significance level is 0.05.

| **Statistical analysis title** | PF-04965842 100 mg Versus Placebo at Week 4 |
|---|---|
| Comparison groups | PF-04965842 100mg QD v Placebo |
| Number of subjects included in analysis | 191 |
| Analysis specification | Pre-specified |
| Analysis type | superiority[13] |
| P-value | = 0.0971 [14] |
| Method | Cochran-Mantel-Haenszel |
| Parameter estimate | Estimate of difference |
| Point estimate | 10.9 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -1.8 |
| upper limit | 23.6 |

Notes:

[13] - Estimate of the difference in proportions of response was calculated by PF-04965842 100 mg minus placebo
[14] - The significance level is 0.05.

| **Statistical analysis title** | PF-04965842 200 mg Versus Placebo at Week 4 |
|---|---|
| Comparison groups | PF-04965842 200mg QD v Placebo |
| Number of subjects included in analysis | 190 |
| Analysis specification | Pre-specified |
| Analysis type | superiority[15] |
| P-value | < 0.0001 [16] |
| Method | Cochran-Mantel-Haenszel |
| Parameter estimate | Estimate of difference |
| Point estimate | 29.4 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 16 |
| upper limit | 42.9 |

Notes:

[15] - Estimate of the difference in proportions of response was calculated by PF-04965842 200 mg minus placebo
[16] - The significance level is 0.05.

| **Statistical analysis title** | PF-04965842 100 mg Versus Placebo at Week 12 |
|---|---|
| Comparison groups | PF-04965842 100mg QD v Placebo |
| Number of subjects included in analysis | 191 |
| Analysis specification | Pre-specified |
| Analysis type | superiority[17] |
| P-value | = 0.0035 [18] |
| Method | Cochran-Mantel-Haenszel |
| Parameter estimate | Estimate of difference |
| Point estimate | 22.8 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 8 |
| upper limit | 37.7 |

Notes:

[17] - Estimate of the difference in proportions of response was calculated by PF-04965842 100 mg minus placebo
[18] - It is considered not statistically significant according to the sequential Bonferronibased iterative multiple testing procedure.

| **Statistical analysis title** | PF-04965842 200 mg Versus Placebo at Week 12 |
|---|---|
| Comparison groups | PF-04965842 200mg QD v Placebo |
| Number of subjects included in analysis | 190 |
| Analysis specification | Pre-specified |
| Analysis type | superiority[19] |
| P-value | = 0.0013 [20] |
| Method | Cochran-Mantel-Haenszel |
| Parameter estimate | Estimate of difference |
| Point estimate | 25.6 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 10.6 |
| upper limit | 40.6 |

Notes:

[19] - Estimate of the difference in proportions of response was calculated by PF-04965842 200 mg minus placebo
[20] - The significance level is 0.05.

## Secondary: Change from Baseline in Pruritus and Symptoms Assessment for Atopic Dermatitis (PSAAD) at Week 12

| End point title | Change from Baseline in Pruritus and Symptoms Assessment for Atopic Dermatitis (PSAAD) at Week 12 |
|---|---|

End point description:

The PSAAD is a 15 item questionnaire that includes 11 items developed to measure symptoms of AD based on a 24 hour recall. Four additional items were added for exploratory and psychometric validation purposes (Sleep & Usual Activities Questions and Patient Global Impression of Severity & Patient Global Impression of Change Questions). The analysis of this endpoint were performed using the FAS which was defined as all subjects randomly assigned to study intervention and who took at least 1 dose of study intervention.

| End point type | Secondary |
|---|---|

End point timeframe:
Baseline to Week 12

| End point values | PF-04965842 100mg QD | PF-04965842 200mg QD | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 95 | 93 | 95 | |
| Units: Units on a scale | | | | |
| least squares mean (confidence interval 95%) | -2.5 (-2.9 to -2.1) | -2.7 (-3.1 to -2.3) | -2.0 (-2.4 to -1.6) | |

**Statistical analyses**

| Statistical analysis title | PF-04965842 100 mg Versus Placebo |
|---|---|
| Comparison groups | PF-04965842 100mg QD v Placebo |
| Number of subjects included in analysis | 190 |
| Analysis specification | Pre-specified |
| Analysis type | superiority[21] |
| P-value | = 0.0664 [22] |
| Method | Mixed models analysis |
| Parameter estimate | Mean difference (net) |
| Point estimate | -0.5 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -1.1 |
| upper limit | 0 |

Notes:
[21] - The least squares mean difference was calculated by PF-04965842 100 mg minus placebo.
[22] - The significance level is 0.05.

| Statistical analysis title | PF-04965842 200 mg Versus Placebo |
|---|---|
| Comparison groups | PF-04965842 200mg QD v Placebo |
| Number of subjects included in analysis | 188 |
| Analysis specification | Pre-specified |
| Analysis type | superiority[23] |
| P-value | = 0.0142 [24] |
| Method | Mixed models analysis |
| Parameter estimate | Mean difference (net) |
| Point estimate | -0.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -1.3 |
| upper limit | -0.1 |

Notes:

[23] - The least squares mean difference was calculated by PF-04965842 200 mg minus placebo.

[24] - It is considered not statistically significant according to the sequential Bonferronibased iterative multiple testing procedure.

## Secondary: Proportion of Subjects Achieving IGA Response of 'Clear'(0) or 'Almost Clear'(1) and >=2 Points Improvement from Baseline at All Scheduled Time Points Except Week 12

| End point title | Proportion of Subjects Achieving IGA Response of '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 of AD is scored on a 5-point scale (0-4), reflecting a global consideration of the erythema, induration and scaling. The overall severity of AD were assessed according to a 5-point scale: 0=Clear, 1=Almost Clear, 2=Mild, 3=Moderate, and 4=Severe. Subjects who withdrew from the study were counted as non-responder. The analysis of this endpoint were performed using the FAS which was defined as all subjects randomly assigned to study intervention and who took at least 1 dose of study intervention.

| End point type | Secondary |
|---|---|

End point timeframe:

Baseline, Weeks 2, 4, and 8

| End point values | PF-04965842 100mg QD | PF-04965842 200mg QD | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 95 | 94 | 96 | |
| Units: Percent of total evaluable subjects | | | | |
| number (confidence interval 95%) | | | | |
| Week 2 | 6.5 (1.5 to 11.6) | 12.8 (6.0 to 19.5) | 1.1 (0.0 to 3.2) | |
| Week 4 | 19.6 (11.5 to 27.7) | 38.3 (28.5 to 48.1) | 3.1 (0.0 to 6.6) | |
| Week 8 | 30.8 (21.3 to 40.3) | 48.9 (38.7 to 59.1) | 16.0 (8.6 to 23.4) | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Proportion of Subjects Achieving EASI Response >= 75% Improvement from Baseline at All Scheduled Time Points Except Week 12

| End point title | Proportion of Subjects Achieving EASI Response >= 75% Improvement from Baseline at All Scheduled Time Points Except Week 12 |
|---|---|

End point description:

The EASI quantifies the severity of a subject’s AD based on both severity of lesion clinical signs and the percent of BSA affected. The EASI score can vary in increments of 0.1 and range from 0 to 72.0, with higher scores representing greater severity of AD. Subjects who withdrew from the study were counted as non-responder. The analysis of this endpoint was performed using the FAS which was defined as all subjects randomly assigned to study intervention and who took at least 1 dose of study intervention.

| End point type | Secondary |
|---|---|

End point timeframe:

Baseline, Weeks 2, 4 and 8

| End point values | PF-04965842 100mg QD | PF-04965842 200mg QD | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 95 | 94 | 96 | |
| Units: Percent of total evaluable subjects | | | | |
| number (confidence interval 95%) | | | | |
| Week 2 | 19.6 (11.5 to 27.7) | 25.5 (16.7 to 34.3) | 4.4 (0.2 to 8.6) | |
| Week 4 | 41.3 (31.2 to 51.4) | 63.8 (54.1 to 73.5) | 14.6 (7.5 to 21.6) | |
| Week 8 | 60.4 (50.4 to 70.5) | 68.5 (59.0 to 78.0) | 33.3 (23.8 to 42.9) | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Proportion of Subjects Achieving EASI Response >= 50% Improvement from Baseline

| End point title | Proportion of Subjects Achieving EASI Response >= 50% Improvement from Baseline |
|---|---|

End point description:

The EASI quantifies the severity of a subject’s AD based on both severity of lesion clinical signs and the percent of BSA affected. The EASI score can vary in increments of 0.1 and range from 0 to 72.0, with higher scores representing greater severity of AD. Subjects who withdrew from the study were counted as non-responder. The analysis of this endpoint was performed using the FAS which was defined as all subjects randomly assigned to study intervention and who took at least 1 dose of study intervention.

| End point type | Secondary |
|---|---|

End point timeframe:

Baseline, Weeks 2, 4, 8, and 12

| End point values | PF-04965842 100mg QD | PF-04965842 200mg QD | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 95 | 94 | 96 | |
| Units: Percent of total evaluable subjects | | | | |
| number (confidence interval 95%) | | | | |
| Week 2 | 55.4 (45.3 to 65.6) | 64.9 (55.2 to 74.5) | 24.2 (15.4 to 33.0) | |
| Week 4 | 75.0 (66.2 to 83.8) | 81.9 (74.1 to 89.7) | 51.0 (41.0 to 61.0) | |
| Week 8 | 85.7 (78.5 to 92.9) | 82.6 (74.9 to 90.4) | 65.6 (55.9 to 75.2) | |

| | | | | |
|---|---|---|---|---|
| Week 12 | 87.6 (80.8 to 94.5) | 87.1 (80.3 to 93.9) | 69.1 (59.8 to 78.5) | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Proportion of Subjects Achieving EASI Response >= 90% Improvement from Baseline

| End point title | Proportion of Subjects Achieving EASI Response >= 90% Improvement from Baseline |
|---|---|

End point description:

The EASI quantifies the severity of a subject's AD based on both severity of lesion clinical signs and the percent of BSA affected. The EASI score can vary in increments of 0.1 and range from 0 to 72.0, with higher scores representing greater severity of AD. Subjects who withdrew from the study were counted as non-responder. The analysis of this endpoint was performed using the FAS which was defined as all subjects randomly assigned to study intervention and who took at least 1 dose of study intervention.

| End point type | Secondary |
|---|---|

End point timeframe:

Baseline, Week 2, 4, 8, and 12

| End point values | PF-04965842 100mg QD | PF-04965842 200mg QD | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 95 | 94 | 96 | |
| Units: Percent of total evaluable subjects | | | | |
| number (confidence interval 95%) | | | | |
| Week 2 | 8.7 (2.9 to 14.5) | 10.6 (4.4 to 16.9) | 0 (0.0 to 4.0) | |
| Week 4 | 17.4 (9.6 to 25.1) | 30.9 (21.5 to 40.2) | 2.1 (0.0 to 4.9) | |
| Week 8 | 29.7 (20.3 to 39.1) | 40.2 (30.2 to 50.2) | 14.0 (6.9 to 21.0) | |
| Week 12 | 41.6 (31.3 to 51.8) | 49.5 (39.3 to 59.6) | 18.1 (10.3 to 25.9) | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Proportion of Subjects Achieving EASI Response = 100% Improvement from Baseline

| End point title | Proportion of Subjects Achieving EASI Response = 100% Improvement from Baseline |
|---|---|

End point description:

The EASI quantifies the severity of a subject's AD based on both severity of lesion clinical signs and the

percent of BSA affected. The EASI score can vary in increments of 0.1 and range from 0 to 72.0, with higher scores representing greater severity of AD. Subjects who withdrew from the study were counted as non-responder. The analysis of this endpoint was performed using the FAS which was defined as all subjects randomly assigned to study intervention and who took at least 1 dose of study intervention.

| End point type | Secondary |
|---|---|

End point timeframe:

Baseline, Weeks 2, 4, 8, and 12

| **End point values** | PF-04965842 100mg QD | PF-04965842 200mg QD | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 95 | 94 | 96 | |
| Units: Percent of total evaluable subjects | | | | |
| number (confidence interval 95%) | | | | |
| Week 2 | 1.1 (0.0 to 3.2) | 0 (0.0 to 3.8) | 0 (0.0 to 4.0) | |
| Week 4 | 2.2 (0.0 to 5.2) | 5.3 (0.8 to 9.9) | 0 (0.0 to 3.8) | |
| Week 8 | 3.3 (0.0 to 7.0) | 9.8 (3.7 to 15.9) | 0 (0.0 to 3.9) | |
| Week 12 | 2.2 (0.0 to 5.3) | 8.6 (2.9 to 14.3) | 2.1 (0.0 to 5.0) | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Percent Change from Baseline in EASI Score

| End point title | Percent Change from Baseline in EASI Score |
|---|---|

End point description:

The EASI quantifies the severity of a subject’s AD based on both severity of lesion clinical signs and the percent of BSA affected. 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. The analysis of this endpoint was performed using the FAS which was defined as all subjects randomly assigned to study intervention and who took at least 1 dose of study intervention.

| End point type | Secondary |
|---|---|

End point timeframe:

Baseline, Weeks 2, 4, 8 and 12

| **End point values** | PF-04965842 100mg QD | PF-04965842 200mg QD | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 95 | 94 | 96 | |
| Units: Percent change | | | | |
| least squares mean (confidence interval 95%) | | | | |
| Week 2 | -51.5 (-57.9 to -45.1) | -54.5 (-61.0 to -48.0) | -27.6 (-34.0 to -21.2) | |

| | | | | |
|---|---|---|---|---|
| Week 4 | -66.1 (-72.7 to -59.4) | -74.3 (-81.0 to -67.5) | -41.7 (-48.3 to -35.1) | |
| Week 8 | -72.6 (-78.4 to -66.8) | -77.8 (-83.7 to -71.9) | -57.6 (-63.4 to -51.8) | |
| Week 12 | -77.3 (-83.1 to -71.5) | -80.6 (-86.5 to -74.8) | -63.7 (-69.5 to -57.9) | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Proportion of Subjects Achieving >=4 Points Improvement from Baseline in PP-NRS or Severity of Pruritus at All Scheduled Time Points Other Than Weeks 2, 4 and 12

| | |
|---|---|
| End point title | Proportion of Subjects Achieving >=4 Points Improvement from Baseline in PP-NRS or Severity of Pruritus at All Scheduled Time Points Other Than Weeks 2, 4 and 12 |

End point description:

PP-NRS assesses the severity of itch (pruritus) due to AD. Subjects were asked to assess their worst itching due to AD on an NRS anchored by the terms "no itch" (0) and "worst itch imaginable" (10). Subjects who withdrew from the study were counted as non-responder. The analysis of this endpoint was performed using the FAS which was defined as all subjects randomly assigned to study intervention and who took at least 1 dose of study intervention.

| | |
|---|---|
| End point type | Secondary |

End point timeframe:

Baseline, Days 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, and 15

| End point values | PF-04965842 100mg QD | PF-04965842 200mg QD | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 95 | 94 | 96 | |
| Units: Percent of total evaluable subjects | | | | |
| number (confidence interval 95%) | | | | |
| Day 2 | 2.8 (0.0 to 6.7) | 3.9 (0.0 to 8.2) | 1.2 (0.0 to 3.6) | |
| Day 3 | 5.1 (0.2 to 9.9) | 7.7 (1.8 to 13.6) | 0 (0.0 to 4.6) | |
| Day 4 | 11.5 (4.4 to 18.6) | 14.3 (6.5 to 22.1) | 4.9 (0.2 to 9.7) | |
| Day 5 | 12.2 (5.1 to 19.3) | 18.5 (10.1 to 27.0) | 6.9 (1.1 to 12.8) | |
| Day 6 | 16.0 (8.1 to 24.0) | 21.3 (12.3 to 30.2) | 8.8 (2.6 to 14.9) | |
| Day 7 | 16.0 (8.1 to 24.0) | 21.3 (12.3 to 30.2) | 10.1 (3.5 to 16.8) | |
| Day 8 | 17.3 (8.8 to 25.9) | 25.0 (15.3 to 34.7) | 4.0 (0.0 to 8.4) | |
| Day 9 | 16.0 (7.7 to 24.3) | 25.0 (15.5 to 34.5) | 6.0 (0.9 to 11.1) | |
| Day 10 | 15.6 (7.5 to 23.7) | 28.8 (18.8 to 38.7) | 8.3 (2.4 to 14.2) | |
| Day 11 | 20.8 (11.7 to 29.8) | 27.0 (16.9 to 37.1) | 7.6 (1.8 to 13.4) | |

| | | | | |
|---|---|---|---|---|
| Day 12 | 22.2 (12.6 to 31.8) | 23.6 (13.8 to 33.4) | 10.8 (3.7 to 17.9) | |
| Day 13 | 26.3 (16.6 to 35.9) | 31.2 (20.8 to 41.5) | 10.0 (3.4 to 16.6) | |
| Day 14 | 24.7 (15.3 to 34.1) | 32.4 (21.8 to 43.1) | 9.5 (3.2 to 15.8) | |
| Day 15 | 27.7 (18.1 to 37.3) | 37.8 (27.3 to 48.3) | 14.3 (6.8 to 21.8) | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Time to First Achieve >=4 Points Improvement from Baseline in PP-NRS for Severity of Pruritus

| End point title | Time to First Achieve >=4 Points Improvement from Baseline in PP-NRS for Severity of Pruritus |
|---|---|

End point description:

PP-NRS assesses the severity of itch (pruritus) due to AD. Subjects were asked to assess their worst itching due to AD on an NRS anchored by the terms “no itch” (0) and “worst itch imaginable” (10). Subjects from FAS population with a baseline numeric rating scale score for severity of pruritus >=4 were included in the analysis. "99999" represents "non-evaluable" datum.

| End point type | Secondary |
|---|---|

End point timeframe:

Baseline to Week 16

| End point values | PF-04965842 100mg QD | PF-04965842 200mg QD | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 95 | 94 | 96 | |
| Units: Days | | | | |
| median (confidence interval 95%) | 70.0 (30.0 to 85.0) | 29.0 (15.0 to 61.0) | 90.0 (62.0 to 99999) | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Percent Change from Baseline in PP-NRS for Severity of Pruritus

| End point title | Percent Change from Baseline in PP-NRS for Severity of Pruritus |
|---|---|

End point description:

PP-NRS assesses the severity of itch (pruritus) due to AD. Subjects were asked to assess their worst itching due to AD on an NRS anchored by the terms “no itch” (0) and “worst itch imaginable” (10). The analysis of this endpoint was performed using the FAS which was defined as all subjects randomly assigned to study intervention and who took at least 1 dose of study intervention.

| End point type | Secondary |
|---|---|

End point timeframe:

Baseline, Days 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14 and 15

| End point values | PF-04965842 100mg QD | PF-04965842 200mg QD | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 95 | 94 | 96 | |
| Units: Percent Change | | | | |
| least squares mean (confidence interval 95%) | | | | |
| Day 2 | -9.5 (-14.2 to -4.8) | -5.4 (-10.0 to -0.7) | -0.9 (-5.5 to 3.6) | |
| Day 3 | -11.3 (-16.2 to -6.4) | -10.2 (-15.2 to -5.2) | -1.1 (-6.0 to 3.8) | |
| Day 4 | -14.6 (-20.2 to -9.1) | -14.7 (-20.3 to -9.1) | -5.0 (-10.6 to 0.5) | |
| Day 5 | -16.1 (-22.3 to -9.9) | -17.6 (-23.9 to -11.3) | -9.5 (-15.8 to -3.2) | |
| Day 6 | -18.5 (-25.0 to -12.1) | -18.7 (-25.3 to -12.1) | -8.7 (-15.2 to -2.2) | |
| Day 7 | -20.0 (-27.1 to -12.9) | -18.8 (-26.0 to -11.6) | -12.3 (-19.4 to -5.2) | |
| Day 8 | -21.6 (-28.9 to -14.2) | -22.7 (-30.2 to -15.3) | -10.6 (-17.9 to -3.3) | |
| Day 9 | -20.9 (-28.7 to -13.2) | -21.7 (-29.5 to -13.9) | -9.9 (-17.6 to -2.3) | |
| Day 10 | -26.1 (-33.1 to -19.0) | -28.0 (-35.1 to -20.8) | -10.8 (-17.8 to -3.8) | |
| Day 11 | -26.5 (-33.5 to -19.4) | -26.3 (-33.5 to -19.1) | -10.7 (-17.7 to -3.7) | |
| Day 12 | -27.0 (-34.0 to -20.0) | -28.9 (-36.1 to -21.8) | -11.0 (-18.0 to -4.0) | |
| Day 13 | -25.2 (-31.5 to -18.8) | -32.5 (-39.0 to -26.0) | -14.1 (-20.4 to -7.8) | |
| Day 14 | -29.4 (-35.5 to -23.2) | -35.3 (-41.6 to -29.0) | -12.0 (-18.1 to -5.8) | |
| Day 15 | -30.7 (-37.7 to -23.7) | -33.4 (-40.5 to -26.3) | -15.8 (-22.7 to -8.8) | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Change from Baseline in Percentage Body Surface Area (BSA)

| End point title | Change from Baseline in Percentage Body Surface Area (BSA) |
|---|---|

End point description:

BSA efficacy is 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 AD. Since the scalp, palms, and soles were excluded from the BSA (efficacy) assessment, the maximum possible value was less than 100%. The analysis of this endpoint was performed using the FAS which was defined as all subjects randomly assigned to study intervention and who took at least 1 dose of study intervention.

| End point type | Secondary |
|---|---|

End point timeframe:

Baseline, Weeks 2, 4, 8 and 12

| **End point values** | PF-04965842 100mg QD | PF-04965842 200mg QD | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 95 | 94 | 96 | |
| Units: Units on a scale | | | | |
| least squares mean (confidence interval 95%) | | | | |
| Week 2 | -21.0 (-24.1 to -17.9) | -20.7 (-23.8 to -17.6) | -10.9 (-14.0 to -7.8) | |
| Week 4 | -27.7 (-31.0 to -24.3) | -32.6 (-36.0 to -29.1) | -15.1 (-18.4 to -11.7) | |
| Week 8 | -32.6 (-36.1 to -29.1) | -34.1 (-37.7 to -30.6) | -21.8 (-25.3 to -18.3) | |
| Week 12 | -34.4 (-38.0 to -30.8) | -35.2 (-38.8 to -31.6) | -24.2 (-27.8 to -20.7) | |

**Statistical analyses**

No statistical analyses for this end point

**Secondary: Percent Change from Baseline in Percentage BSA**

| End point title | Percent Change from Baseline in Percentage BSA |
|---|---|

End point description:

BSA efficacy is 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%. The analysis of this endpoint was performed using the FAS which was defined as all subjects randomly assigned to study intervention and who took at least 1 dose of study intervention.

| End point type | Secondary |
|---|---|

End point timeframe:

Baseline, Weeks 2, 4, 8, and 12

| **End point values** | PF-04965842 100mg QD | PF-04965842 200mg QD | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 95 | 94 | 96 | |
| Units: Percent change | | | | |
| least squares mean (confidence interval 95%) | | | | |
| Week 2 | -40.4 (-46.5 to -34.3) | -42.2 (-48.3 to -36.1) | -20.6 (-26.7 to -14.5) | |

| | | | | |
|---|---|---|---|---|
| Week 4 | -55.4 (-62.7 to -48.1) | -66.0 (-73.4 to -58.6) | -29.0 (-36.3 to -21.8) | |
| Week 8 | -65.7 (-72.4 to -59.1) | -69.5 (-76.3 to -62.8) | -46.0 (-52.6 to -39.3) | |
| Week 12 | -71.4 (-78.2 to -64.7) | -72.6 (-79.3 to -65.8) | -53.4 (-60.1 to -46.7) | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Proportion of Subjects Achieving Percentage BSA < 5% at Week 12

| End point title | Proportion of Subjects Achieving Percentage BSA < 5% at Week 12 |
|---|---|

End point description:

BSA efficacy is 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%. Subjects who withdrew from the study were counted as non-responder. The analysis of this endpoint was performed using the FAS which was defined as all subjects randomly assigned to study intervention and who took at least 1 dose of study intervention.

| End point type | Secondary |
|---|---|

End point timeframe:

Baseline to Week 12

| **End point values** | PF-04965842 100mg QD | PF-04965842 200mg QD | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 89 | 93 | 94 | |
| Units: Percent of evaluable subjects | | | | |
| number (confidence interval 95%) | 38.2 (28.1 to 48.3) | 36.6 (26.8 to 46.3) | 24.5 (15.8 to 33.2) | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Proportion of Subjects Achieving Scoring Atopic Dermatitis (SCORAD) Response >= 50% Improvement from Baseline

| End point title | Proportion of Subjects Achieving Scoring Atopic Dermatitis (SCORAD) Response >= 50% Improvement from Baseline |
|---|---|

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 using a 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).Higher values of SCORAD represent worse outcome.

| End point type | Secondary |
|---|---|

End point timeframe:

Baseline, Weeks 2, 4, 8, and 12

| **End point values** | PF-04965842 100mg QD | PF-04965842 200mg QD | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 95 | 94 | 96 | |
| Units: Percent of evaluable subjects | | | | |
| number (confidence interval 95%) | | | | |
| Week 2 | 22.6 (14.1 to 31.1) | 29.0 (19.8 to 38.3) | 8.6 (2.9 to 14.3) | |
| Week 4 | 44.1 (34.0 to 54.2) | 64.1 (54.3 to 73.9) | 24.0 (15.4 to 32.5) | |
| Week 8 | 65.6 (55.9 to 75.2) | 75.0 (66.2 to 83.8) | 34.0 (24.5 to 43.6) | |
| Week 12 | 75.6 (66.7 to 84.4) | 73.9 (64.9 to 82.9) | 37.6 (27.8 to 47.5) | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Proportion of Subjects Achieving SCORAD Response >= 75% Improvement from Baseline

| End point title | Proportion of Subjects Achieving SCORAD Response >= 75% Improvement from Baseline |
|---|---|

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 using a 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). Higher values of SCORAD represent worse outcome.

| End point type | Secondary |
|---|---|

End point timeframe:

Baseline, Weeks 2, 4, 8, and 12

| End point values | PF-04965842 100mg QD | PF-04965842 200mg QD | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 95 | 94 | 96 | |
| Units: Percent of evaluable subjects | | | | |
| number (confidence interval 95%) | | | | |
| Week 2 | 5.4 (0.8 to 10.0) | 7.5 (2.2 to 12.9) | 0 (0.0 to 3.9) | |
| Week 4 | 11.8 (5.3 to 18.4) | 21.7 (13.3 to 30.2) | 0 (0.0 to 3.8) | |
| Week 8 | 17.2 (9.5 to 24.9) | 33.7 (24.0 to 43.4) | 8.5 (2.9 to 14.2) | |
| Week 12 | 36.7 (26.7 to 46.6) | 34.8 (25.1 to 44.5) | 12.9 (6.1 to 19.7) | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Change from Baseline in SCORAD Total Score

| End point title | Change from Baseline in SCORAD Total Score |
|---|---|

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 using a 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). Higher values of SCORAD represent worse outcome.

| End point type | Secondary |
|---|---|

End point timeframe:

Baseline, Weeks 2, 4, 8, and 12

| End point values | PF-04965842 100mg QD | PF-04965842 200mg QD | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 95 | 93 | 96 | |
| Units: Units on a scale | | | | |
| least squares mean (confidence interval 95%) | | | | |
| Week 2 | -24.6 (-27.7 to -21.6) | -25.8 (-28.9 to -22.7) | -12.3 (-15.4 to -9.2) | |
| Week 4 | -32.4 (-35.5 to -29.2) | -38.0 (-41.2 to -34.8) | -20.2 (-23.3 to -17.0) | |
| Week 8 | -37.3 (-40.7 to -33.9) | -41.5 (-45.0 to -38.0) | -26.6 (-30.0 to -23.2) | |
| Week 12 | -40.9 (-44.7 to -37.2) | -42.9 (-46.7 to -39.1) | -30.2 (-33.9 to -26.4) | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Percent Change from Baseline in SCORAD Total Score

| End point title | Percent Change from Baseline in SCORAD Total Score |
|---|---|

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 using a 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). Higher values of SCORAD represent worse outcome.

| End point type | Secondary |
|---|---|

End point timeframe:

Baseline, Weeks 2, 4, 8, and 12

| End point values | PF-04965842 100mg QD | PF-04965842 200mg QD | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 95 | 93 | 96 | |
| Units: Percent change | | | | |
| least squares mean (confidence interval 95%) | | | | |
| Week 2 | -36.1 (-40.6 to -31.7) | -38.7 (-43.2 to -34.2) | -18.7 (-23.1 to -14.2) | |
| Week 4 | -47.4 (-52.0 to -42.9) | -56.9 (-61.6 to -52.3) | -30.0 (-34.5 to -25.5) | |
| Week 8 | -54.0 (-59.0 to -48.9) | -62.0 (-67.2 to -56.9) | -39.9 (-44.9 to -34.8) | |
| Week 12 | -59.2 (-64.9 to -53.6) | -64.3 (-70.1 to -58.6) | -44.4 (-50.1 to -38.8) | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Change from Baseline in SCORAD Subjective Visual Analogue Scale (VAS) of Sleep Loss and Itch

| End point title | Change from Baseline in SCORAD Subjective Visual Analogue Scale (VAS) of Sleep Loss and Itch |
|---|---|

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). The SCORAD for an individual is calculated by the formula: A/5 + 7B/2 + C (can range from 0 to 103). Subjective symptoms (ie, itch and sleep loss) are each scored by the subject using a VAS where "0" is no itch (or no sleep loss) and "10" is the worst imaginable itch (or sleep loss). The value for each should reflect the average on a 10 point scale for the last 3 days/nights. Change from baseline in SCORAD subjective assessments of itch was not evaluated. Only change from baseline in SCORAD subjective assessments of sleep loss is present below.

| End point type | Secondary |
|---|---|

End point timeframe:

Baseline, Weeks 2, 4, 8, and 12

| **End point values** | PF-04965842 100mg QD | PF-04965842 200mg QD | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 95 | 93 | 96 | |
| Units: Units on a scale | | | | |
| least squares mean (confidence interval 95%) | | | | |
| Sleep loss, Week 2 | -2.1 (-2.6 to -1.6) | -2.6 (-3.1 to -2.1) | -0.9 (-1.4 to -0.4) | |
| Sleep loss, Week 4 | -2.9 (-3.3 to -2.4) | -3.4 (-3.9 to -2.9) | -1.8 (-2.3 to -1.3) | |
| Sleep loss, Week 8 | -3.3 (-3.8 to -2.9) | -3.7 (-4.2 to -3.2) | -2.2 (-2.7 to -1.7) | |
| Sleep loss, Week 12 | -3.5 (-3.9 to -3.0) | -3.9 (-4.4 to -3.4) | -2.7 (-3.2 to -2.2) | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Percent Change from Baseline in SCORAD Subjective VAS of Sleep Loss and Itch

| End point title | Percent Change from Baseline in SCORAD Subjective VAS of Sleep Loss and Itch |
|---|---|

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). The SCORAD for an individual is calculated by the formula: A/5 + 7B/2 + C (can range from 0 to 103). Subjective symptoms (ie, itch and sleep loss) are each scored by the subject using a VAS where "0" is no itch (or no sleep loss) and "10" is the worst imaginable itch (or sleep loss). The value for each should reflect the average on a 10 point scale for the last 3 days/nights. Change from baseline in SCORAD subjective assessments of itch was not evaluated. Only change from baseline in SCORAD subjective assessments of sleep loss is present below.

| End point type | Secondary |
|---|---|

End point timeframe:

Baseline, Weeks 2, 4, 8, and 12

| End point values | PF-04965842 100mg QD | PF-04965842 200mg QD | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 95 | 93 | 96 | |
| Units: Percent change | | | | |
| least squares mean (confidence interval 95%) | | | | |
| Sleep loss, Week 2 | 65.1 (-39.2 to 169.4) | -36.5 (-140.7 to 67.8) | 2.6 (-101.2 to 106.3) | |
| Sleep loss, Week 4 | -35.2 (-50.7 to -19.8) | -53.4 (-69.1 to -37.8) | -20.0 (-35.2 to -4.9) | |
| Sleep loss, Week 8 | -44.2 (-79.9 to -8.5) | -30.6 (-66.7 to 5.5) | -24.7 (-60.1 to 10.8) | |
| Sleep loss, Week 12 | -49.8 (-88.3 to -11.3) | -35.2 (-74.1 to 3.7) | -39.5 (-77.7 to -1.3) | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Number of Days When a Corticosteroid Not Used up to Day 88

| End point title | Number of Days When a Corticosteroid Not Used up to Day 88 |
|---|---|

End point description:

The analysis include all randomized subjects who received at least one dose of study medication and had used corticosteroid during treatment period

| End point type | Secondary |
|---|---|

End point timeframe:

Baseline to Day 88

| End point values | PF-04965842 100mg QD | PF-04965842 200mg QD | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 89 | 82 | 83 | |
| Units: Days | | | | |
| least squares mean (confidence interval 95%) | 10.9 (6.2 to 15.5) | 15.1 (10.2 to 19.9) | 6.8 (2.0 to 11.6) | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Change from Baseline in Children's Dermatology Life Quality Index (DLQI)

| End point title | Change from Baseline in Children's Dermatology Life Quality Index (DLQI) |
|---|---|

End point description:

The DLQI is a general dermatology questionnaire that consists of 10 items to assess subject-reported health-related quality of life (daily activities, personal relationships, symptoms and feelings, leisure,

work and school, and treatment).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 3-5 point change from baseline. Each item is scored as "very much (3)", "a lot (2)", "a little (1)" and "not at all (0)". The score can range from 0 to 30. The higher values represent the worse dermatology life quality. Subjects who were withdrew from the study were counted as non-responder. This endpoint's analysis included all randomized subjects who took at least 1 dose of study intervention.

| End point type | Secondary |
|---|---|

End point timeframe:

Baseline, Weeks 2, 4, 8, and 12

| **End point values** | PF-04965842 100mg QD | PF-04965842 200mg QD | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 95 | 94 | 96 | |
| Units: Units on a scale | | | | |
| least squares mean (confidence interval 95%) | | | | |
| Week 2 | -6.1 (-7.1 to -5.2) | -6.3 (-7.2 to -5.3) | -4.2 (-5.1 to -3.3) | |
| Week 4 | -7.3 (-8.2 to -6.4) | -7.6 (-8.6 to -6.7) | -5.4 (-6.3 to -4.5) | |
| Week 8 | -8.1 (-9.1 to -7.1) | -8.2 (-9.2 to -7.2) | -6.1 (-7.0 to -5.1) | |
| Week 12 | -8.6 (-9.6 to -7.5) | -8.7 (-9.7 to -7.6) | -6.3 (-7.4 to -5.3) | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Proportion of Subjects with >=2.5 Points at Baseline and Achieving >=2.5 Points Improvement from Baseline in Children's DLQI

| End point title | Proportion of Subjects with >=2.5 Points at Baseline and Achieving >=2.5 Points Improvement from Baseline in Children's DLQI |
|---|---|

End point description:

The DLQI is a general dermatology questionnaire that consists of 10 items to assess subject-reported 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 3-5 point change from baseline. Each item is scored as "very much (3)", "a lot (2)", "a little (1)" and "not at all (0)". The score can range from 0 to 30. The higher values represent the worse dermatology life quality. Subjects who were withdrew from the study were counted as non-responder. The analysis of this endpoint was performed using the FAS which was defined as all randomized subjects who took at least 1 dose of study intervention.

| End point type | Secondary |
|---|---|

End point timeframe:

Baseline, Weeks 2, 4, 8, and 12

| End point values | PF-04965842 100mg QD | PF-04965842 200mg QD | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 95 | 94 | 96 | |
| Units: Percent of evaluable subjects | | | | |
| number (confidence interval 95%) | | | | |
| Week 2 | 73.6 (64.6 to 82.7) | 71.3 (62.1 to 80.4) | 61.5 (51.5 to 71.5) | |
| Week 4 | 82.4 (74.6 to 90.2) | 73.4 (64.5 to 82.3) | 73.7 (64.8 to 82.5) | |
| Week 8 | 85.9 (78.8 to 93.0) | 79.6 (71.4 to 87.8) | 71.0 (61.7 to 80.2) | |
| Week 12 | 80.9 (72.7 to 89.1) | 78.5 (70.1 to 86.8) | 67.7 (58.2 to 77.2) | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Change from Baseline in Anxiety of Hospital Anxiety and Depression Scale (HADS)

| End point title | Change from Baseline in Anxiety of Hospital Anxiety and Depression Scale (HADS) |
|---|---|

End point description:

The HADS is a 14-item patient reported outcome (PRO) measure used to detect states of anxiety and depression over the past week. Seven of the items relate to anxiety and seven relate to depression. Each item is scored from 0 to 3 which means a person can score between 0 to 21 for either anxiety or depression. Higher values represent worse outcome. The analysis of this endpoint was performed using the FAS which was defined as all randomized subjects who took at least 1 dose of study intervention.

| End point type | Secondary |
|---|---|

End point timeframe:

Baseline, Weeks 2, 4, 8, and 12

| End point values | PF-04965842 100mg QD | PF-04965842 200mg QD | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 95 | 94 | 96 | |
| Units: Units on a scale | | | | |
| least squares mean (confidence interval 95%) | | | | |
| Week 2 | -1.6 (-2.1 to -1.1) | -1.3 (-1.8 to -0.8) | -1.2 (-1.7 to -0.7) | |
| Week 4 | -1.6 (-2.2 to -1.1) | -1.9 (-2.5 to -1.3) | -1.5 (-2.1 to -1.0) | |
| Week 8 | -2.1 (-2.7 to -1.5) | -2.2 (-2.8 to -1.5) | -1.7 (-2.3 to -1.1) | |
| Week 12 | -2.0 (-2.6 to -1.4) | -2.4 (-3.0 to -1.8) | -2.1 (-2.7 to -1.5) | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change from Baseline in Depression of HADS

| End point title | Change from Baseline in Depression of HADS |
|---|---|

End point description:

The HADS is a 14-item PRO measure used to detect states of anxiety and depression over the past week. Seven of the items relate to anxiety and seven relate to depression. Each item is scored from 0 to 3 which means a person can score between 0 to 21 for either anxiety or depression. Higher values represent worse outcome. The analysis of this endpoint was performed using the FAS which was defined as all randomized subjects who took at least 1 dose of study intervention.

| End point type | Secondary |
|---|---|

End point timeframe:

Baseline, Weeks 2, 4, 8, and 12

| End point values | PF-04965842 100mg QD | PF-04965842 200mg QD | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 95 | 94 | 96 | |
| Units: Units on a scale | | | | |
| least squares mean (confidence interval 95%) | | | | |
| Week 2 | -1.2 (-1.7 to -0.8) | -0.8 (-1.3 to -0.3) | -0.8 (-1.3 to -0.3) | |
| Week 4 | -1.3 (-1.8 to -0.8) | -1.3 (-1.8 to -0.8) | -0.8 (-1.3 to -0.3) | |
| Week 8 | -1.4 (-1.9 to -0.9) | -1.2 (-1.7 to -0.7) | -1.1 (-1.6 to -0.6) | |
| Week 12 | -1.4 (-1.9 to -0.8) | -1.2 (-1.7 to -0.6) | -1.0 (-1.5 to -0.5) | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change from Baseline in Patient-Oriented Eczema Measure (POEM)

| End point title | Change from Baseline in Patient-Oriented Eczema Measure (POEM) |
|---|---|

End point description:

The POEM is a 7-item PRO measure used to assess the impact of AD over the past week. Each item is scored as "no days (0)", "1-2 days (1)", "3-4 days (2)", "5-6 days (3)" and "every day (4)". The score ranges from 0 to 28. The higher values represent more severe AD. The analysis of this endpoint was performed using the FAS which was defined as all randomized subjects who took at least 1 dose of study

intervention.

| End point type | Secondary |
|---|---|

End point timeframe:

Baseline, Weeks 2, 4, 8, and 12

| End point values | PF-04965842 100mg QD | PF-04965842 200mg QD | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 95 | 94 | 95 | |
| Units: Units on a scale | | | | |
| least squares mean (confidence interval 95%) | | | | |
| Week 2 | -6.9 (-8.2 to -5.6) | -8.2 (-9.5 to -6.9) | -3.4 (-4.7 to -2.1) | |
| Week 4 | -9.5 (-10.7 to -8.3) | -10.6 (-11.9 to -9.4) | -4.8 (-6.0 to -3.6) | |
| Week 8 | -10.0 (-11.4 to -8.7) | -10.6 (-12.0 to -9.3) | -5.4 (-6.7 to -4.0) | |
| Week 12 | -11.1 (-12.5 to -9.7) | -10.9 (-12.2 to -9.5) | -6.9 (-8.3 to -5.6) | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Change from Baseline in Dermatitis Family Impact (DFI) at Week 12

| End point title | Change from Baseline in Dermatitis Family Impact (DFI) at Week 12 |
|---|---|

End point description:

The DFI is a validated 10-item measure filled out by the parent/caregiver of the patient used to assess the impact of the patient’s eczema on the family. The instrument has a recall period of 7 days. Each item is scored as "very much (3)", "a lot (2)", "a little (1)" and "not at all (0)". The score can range from 0 to 30. The higher values represent the worse impact. The analysis of this endpoint was performed using the FAS which was defined as all randomized subjects who took at least 1 dose of study intervention.

| End point type | Secondary |
|---|---|

End point timeframe:

Baseline, Weeks 2, 4, 8, and 12

| End point values | PF-04965842 100mg QD | PF-04965842 200mg QD | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 95 | 93 | 92 | |
| Units: Units on a scale | | | | |
| least squares mean (confidence interval 95%) | | | | |
| Week 2 | -4.2 (-5.2 to -3.1) | -5.2 (-6.2 to -4.1) | -2.7 (-3.7 to -1.6) | |

| | | | | |
|---|---|---|---|---|
| Week 4 | -5.7 (-6.7 to -4.6) | -5.9 (-7.0 to -4.9) | -4.8 (-5.8 to -3.7) | |
| Week 8 | -6.8 (-7.9 to -5.7) | -7.3 (-8.5 to -6.2) | -5.1 (-6.3 to -4.0) | |
| Week 12 | -6.7 (-7.9 to -5.4) | -7.3 (-8.6 to -6.0) | -5.2 (-6.5 to -3.9) | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Change from Baseline in Patient Global Assessment (PtGA)

| End point title | Change from Baseline in Patient Global Assessment (PtGA) |
|---|---|

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. The analysis of this endpoint was performed using the FAS which was defined as all randomized subjects who took at least 1 dose of study intervention.

| End point type | Secondary |
|---|---|

End point timeframe:

Baseline, Weeks 2, 4, 8, and 12

| End point values | PF-04965842 100mg QD | PF-04965842 200mg QD | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 95 | 94 | 96 | |
| Units: Units on a scale | | | | |
| least squares mean (confidence interval 95%) | | | | |
| Week 2 | -0.7 (-0.9 to -0.6) | -1.0 (-1.1 to -0.8) | -0.4 (-0.6 to -0.3) | |
| Week 4 | -0.9 (-1.1 to -0.8) | -1.2 (-1.4 to -1.1) | -0.7 (-0.8 to -0.5) | |
| Week 8 | -1.2 (-1.3 to -1.0) | -1.4 (-1.6 to -1.2) | -0.8 (-1.0 to -0.6) | |
| Week 12 | -1.4 (-1.6 to -1.2) | -1.6 (-1.8 to -1.4) | -0.9 (-1.1 to -0.7) | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Proportion of Subjects with >=2 Points at Baseline and Achieving 'Clear' or 'Almost Clear' and >=2 Points Improvement from Baseline in PtGA

| End point title | Proportion of Subjects with >=2 Points at Baseline and Achieving 'Clear' or 'Almost Clear' and >=2 Points Improvement from Baseline in PtGA |
|---|---|

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. Subjects who were withdrew from the study were counted as non-responder. The analysis of this endpoint was performed using the FAS which was defined as all randomized subjects who took at least 1 dose of study intervention.

| End point type | Secondary |
|---|---|

End point timeframe:

Baseline, Weeks 2, 4, 8, and 12

| **End point values** | PF-04965842 100mg QD | PF-04965842 200mg QD | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 95 | 94 | 96 | |
| Units: Percent of evaluable subjects | | | | |
| number (confidence interval 95%) | | | | |
| Week 2 | 5.4 (0.8 to 10.1) | 5.3 (0.8 to 9.9) | 1.1 (0.0 to 3.2) | |
| Week 4 | 14.1 (7.0 to 21.2) | 20.2 (12.1 to 28.3) | 4.2 (0.2 to 8.2) | |
| Week 8 | 22.6 (14.1 to 31.1) | 26.9 (17.9 to 35.9) | 6.4 (1.4 to 11.3) | |
| Week 12 | 30.0 (20.5 to 39.5) | 36.6 (26.8 to 46.3) | 10.6 (4.4 to 16.9) | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change from Baseline in EuroQol Quality of Life 5-Dimension Youth Scale (EQ-5D-Y) VAS Score

| End point title | Change from Baseline in EuroQol Quality of Life 5-Dimension Youth Scale (EQ-5D-Y) VAS Score |
|---|---|

End point description:

The EQ-5D is a validated, standardized, generic instrument that is the most widely used preference based health related quality of life questionnaire in cost effectiveness and health technologies assessment. The EQ-5D-Y is a version of the instrument specifically developed and validated for use by youths aged 12 through 17 years. Components assess level of current health for 5 domains: mobility, self-care, usual activities, pain and discomfort, anxiety and depression. Score scale ranges from 1 (minimum) to 3 (maximum). Higher scores indicates worse health condition. The analysis of this endpoint was performed using the FAS which was defined as all randomized subjects who took at least 1 dose of study intervention.

| End point type | Secondary |
|---|---|

End point timeframe:

Baseline, Weeks 2, 4, 8, and 12

| End point values | PF-04965842 100mg QD | PF-04965842 200mg QD | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 95 | 94 | 96 | |
| Units: Units on a scale | | | | |
| least squares mean (confidence interval 95%) | | | | |
| Week 2 | 11.241 (7.882 to 14.601) | 12.141 (8.763 to 15.520) | 7.140 (3.787 to 10.492) | |
| Week 4 | 13.222 (10.020 to 16.423) | 14.677 (11.438 to 17.917) | 8.784 (5.625 to 11.943) | |
| Week 8 | 14.502 (10.977 to 18.028) | 14.653 (11.076 to 18.231) | 8.415 (4.888 to 11.941) | |
| Week 12 | 14.226 (10.624 to 17.828) | 15.756 (12.153 to 19.360) | 9.944 (6.373 to 13.515) | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Change from Baseline in Pediatric Functional Assessment of Chronic Illness Therapy Fatigue Scale (Peds-FACIT-F)

| End point title | Change from Baseline in Pediatric Functional Assessment of Chronic Illness Therapy Fatigue Scale (Peds-FACIT-F) |
|---|---|

End point description:

The Functional Assessment of Chronic Illness Therapy Fatigue Scale (FACIT–F) is a 13-item questionnaire. Participants scored each item on a 5-point scale: 0 (none of the time) to 4 (all of the time). Larger the participant's response to the questions (with the exception of 2 negatively stated), greater was the participant's fatigue. For all questions, except for the 2 negatively stated ones, the code was reversed and a new score was calculated as (4 minus the participant's response). The sum of all responses resulted in the FACIT-F score for a total possible score of 0 (worse score) to 52 (better score), with higher scores representing better overall health status (less fatigue). The analysis of this endpoint was performed using the FAS which was defined as all randomized subjects who took at least 1 dose of study intervention. Change from baseline at Week 12 is present below. Change from baseline at other scheduled time points were not evaluated.

| End point type | Secondary |
|---|---|

End point timeframe:

Baseline to Week 12

| End point values | PF-04965842 100mg QD | PF-04965842 200mg QD | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 95 | 94 | 96 | |
| Units: Units on a scale | | | | |
| least squares mean (confidence interval 95%) | 4.5 (3.0 to 5.9) | 4.3 (2.9 to 5.7) | 2.5 (1.1 to 3.9) | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Number of Subjects With Treatment Emergent Adverse Events (TEAEs)

| End point title | Number of Subjects With Treatment Emergent Adverse Events (TEAEs) |
|---|---|

End point description:

An adverse event (AE) was any untoward medical occurrence in a clinical investigation subject administered a product; the event did not need to have a causal relationship with the treatment. TEAEs were AEs occurred following the start of treatment or AEs increasing in severity during treatment. Treatment-related TEAEs were determined by the investigator. The safety analysis population included all subjects who received at least 1 dose of study medication.

| End point type | Secondary |
|---|---|

End point timeframe:

16 Weeks

| End point values | PF-04965842 100mg QD | PF-04965842 200mg QD | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 95 | 94 | 96 | |
| Units: Subjects | | | | |
| All-causality AEs | 54 | 59 | 50 | |
| Treatment-related AEs | 20 | 31 | 16 | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Number of Subjects With Serious Adverse Events (SAEs)

| End point title | Number of Subjects With Serious Adverse Events (SAEs) |
|---|---|

End point description:

A serious adverse event (SAE) was any untoward medical occurrence at any dose that resulted in death; was life threatening; required inpatient hospitalization or prolongation of existing hospitalization; resulted in persistent or significant disability/incapacity; resulted in congenital anomaly/birth defect.Treatment-related SAEs were determined by the investigator. The safety analysis population included all subjects who received at least 1 dose of study medication.

| End point type | Secondary |
|---|---|

End point timeframe:

16 weeks

| End point values | PF-04965842 100mg QD | PF-04965842 200mg QD | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 95 | 94 | 96 | |
| Units: Subjects | | | | |
| All-causality SAEs | 0 | 1 | 2 | |
| Treatment-related SAEs | 0 | 0 | 0 | |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of Subjects Who Discontinued From the Study Due to TEAEs

| End point title | Number of Subjects Who Discontinued From the Study Due to TEAEs |
|---|---|

End point description:

An AE was any untoward medical occurrence in a clinical investigation participant administered a product; the event did not need to have a causal relationship with the treatment. TEAEs were AEs occurred following the start of treatment or AEs increasing in severity during treatment. Treatment-related TEAEs were determined by the investigator. The safety analysis population included all subjects who received at least 1 dose of study medication.

| End point type | Secondary |
|---|---|

End point timeframe:

16 Weeks

| End point values | PF-04965842 100mg QD | PF-04965842 200mg QD | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 95 | 94 | 96 | |
| Units: Subjects | | | | |
| All-causality TEAEs | 1 | 2 | 2 | |
| Treatment-related TEAEs | 0 | 2 | 0 | |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of Subjects With Laboratory Test Abnormalities (Without Regard to Baseline)

| End point title | Number of Subjects With Laboratory Test Abnormalities (Without Regard to Baseline) |
|---|---|

End point description:

Laboratory tests included hematology (including coagulation panel), chemistry, lipid profiles, and urinalysis. The safety analysis population included all subjects who received at least 1 dose of study medication. LLN is lower limit of normal, ULN is upper limit of normal..

| End point type | Secondary |
|---|---|

End point timeframe:
16 weeks

| End point values | PF-04965842 100mg QD | PF-04965842 200mg QD | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 95 | 93 | 96 | |
| Units: Subjects | | | | |
| Hb (g/dL) <0.8*LLN | 0 | 0 | 0 | |
| Hematocrit (%) <0.8*LLN | 0 | 0 | 0 | |
| Erythrocytes (10^6/mm^3) <0.8*LLN | 0 | 0 | 0 | |
| Reticulocytes (10^3/mm^3) <0.5*LLN | 0 | 0 | 0 | |
| Reticulocytes (10^3/mm^3) >1.5*ULN | 0 | 0 | 0 | |
| Ery. Mean Corpuscular Volume (10^-15L) <0.9*LLN | 1 | 0 | 1 | |
| Ery. Mean Corpuscular Volume (10^-15L) >1.1*ULN | 0 | 0 | 0 | |
| Ery. Mean Corpuscular Hb (pg/cell) <0.9*LLN | 1 | 0 | 1 | |
| Ery. Mean Corpuscular Hb (pg/cell) >1.1*ULN | 0 | 0 | 0 | |
| Ery. Mean Corpuscular Hb Conc. (g/dL) <0.9*LLN | 0 | 0 | 0 | |
| Ery. Mean Corpuscular Hb Conc. (g/dL)>1.1*ULN | 0 | 0 | 0 | |
| Platelets (10^3/mm^3) <0.5*LLN | 0 | 0 | 1 | |
| Platelets (10^3/mm^3) >1.75*ULN | 0 | 0 | 0 | |
| Reticulocytes/Erythrocytes (%) <0.5*LLN | 0 | 0 | 0 | |
| Reticulocytes/Erythrocytes (%) >1.5*ULN | 0 | 1 | 0 | |
| Leukocytes (10^3/mm^3) <0.6*LLN | 0 | 0 | 0 | |
| Leukocytes (10^3/mm^3) >1.5*ULN | 0 | 0 | 1 | |
| Lymphocytes (10^3/mm^3) <0.8*LLN | 0 | 1 | 0 | |
| Lymphocytes (10^3/mm^3) >1.2*ULN | 0 | 1 | 0 | |
| Lymphocytes/Leukocytes (%) <0.8*LLN | 4 | 6 | 6 | |
| Lymphocytes/Leukocytes (%)>1.2*ULN | 1 | 4 | 1 | |
| Neutrophils (10^3/mm^3) <0.8*LLN | 2 | 1 | 1 | |
| Neutrophils (10^3/mm^3) >1.2*ULN | 5 | 3 | 6 | |
| Neutrophils/Leukocytes (%) <0.8*LLN | 3 | 7 | 5 | |
| Neutrophils/Leukocytes (%) >1.2*ULN | 0 | 0 | 0 | |
| Basophils (10^3/mm^3) >1.2*ULN | 0 | 0 | 3 | |
| Basophils/Leukocytes (%) >1.2*ULN | 24 | 27 | 35 | |
| Eosinophils (10^3/mm^3) >1.2*ULN | 55 | 39 | 63 | |
| Eosinophils/Leukocytes (%) >1.2*ULN | 62 | 47 | 61 | |
| Monocytes (10^3/mm^3)>1.2*ULN | 0 | 0 | 1 | |
| Monocytes/Leukocytes (%) >1.2*ULN | 11 | 6 | 7 | |
| Partial Thromboplastin Time (sec) >1.1*ULN | 4 | 4 | 2 | |
| Prothrombin Time (sec) >1.1*ULN | 6 | 8 | 4 | |
| Prothrombin Intl. Normalized Ratio >1.1*ULN | 0 | 0 | 0 | |
| Bilirubin (mg/dL) >1.5*ULN | 4 | 0 | 1 | |

| | | | | |
|---|---|---|---|---|
| Direct Bilirubin (mg/dL) >1.5*ULN | 0 | 0 | 0 | |
| Indirect Bilirubin (mg/dL) >1.5*ULN | 2 | 0 | 1 | |
| Aspartate Aminotransferase (U/L) >3.0*ULN | 1 | 3 | 1 | |
| Alanine Aminotransferase (U/L) >3.0*ULN | 3 | 1 | 0 | |
| Gamma Glutamyl Transferase(U/L) >3.0*ULN | 0 | 0 | 1 | |
| Lactate Dehydrogenase (U/L) >3.0*ULN | 1 | 2 | 0 | |
| Alkaline Phosphatase (U/L) >3.0*ULN | 0 | 1 | 0 | |
| Protein (g/dL) <0.8*LLN | 0 | 0 | 0 | |
| Protein (g/dL) >1.2*ULN | 0 | 1 | 0 | |
| Albumin (g/dL) <0.8*LLN | 0 | 0 | 0 | |
| Albumin (g/dL) >1.2*ULN | 0 | 3 | 0 | |
| Urea Nitrogen (mg/dL) >1.3*ULN | 0 | 0 | 0 | |
| Creatine (mg/dL) >1.3*ULN | 2 | 0 | 3 | |
| Urate (mg/dL) >1.2*ULN | 4 | 1 | 2 | |
| LDL Cholesterol (mg/dL) >1.2*ULN | 2 | 3 | 2 | |
| Triglycerides (mg/dL) >1.3*ULN | 11 | 13 | 17 | |
| Sodium (mEq/L) <0.95*LLN | 0 | 0 | 0 | |
| Sodium (mEq/L) >1.05*ULN | 0 | 0 | 0 | |
| Potassium (mEq/L) <0.9*LLN | 0 | 0 | 0 | |
| Potassium (mEq/L)>1.1*ULN | 0 | 0 | 1 | |
| Chloride (mEq/L) <0.9*LLN | 0 | 0 | 0 | |
| Chloride (mEq/L) >1.1*ULN | 0 | 0 | 0 | |
| Calcium (mEq/L) <0.9*LLN | 0 | 0 | 0 | |
| Calcium (mEq/L) >1.1*ULN | 0 | 0 | 0 | |
| Bicarbonate (mEq/L) <0.9*LLN | 1 | 0 | 1 | |
| Bicarbonate (mEq/L) >1.1*ULN | 0 | 0 | 0 | |
| Glucose (mg/dL) <0.6*LLN | 0 | 0 | 0 | |
| Glucose (mg/dL) >1.5*ULN | 2 | 3 | 0 | |
| Creatine Kinase (U/L) >2.0*ULN | 7 | 12 | 5 | |
| Cholesterol (mg/dL) >1.3*ULN | 2 | 2 | 2 | |
| HDL Cholesterol (mg/dL) <0.8*LLN | 0 | 0 | 0 | |
| Urine Specific Gravity (scalar) <1.003 | 0 | 0 | 0 | |
| Urine Specific Gravity (scalar) >1.030 | 1 | 0 | 0 | |
| Urine pH (scalar) <4.5 | 0 | 0 | 0 | |
| Urine pH (scalar) >8 | 1 | 0 | 0 | |
| Urine Glucose >=1 | 0 | 0 | 1 | |
| Urine Ketones >=1 | 0 | 1 | 8 | |
| Urine Protein >=1 | 5 | 0 | 4 | |
| Urine Hemoglobin >=1 | 19 | 15 | 20 | |
| Urine Nitrite >=1 | 1 | 0 | 0 | |
| Urine Leukocyte Esterase >=1 | 14 | 17 | 7 | |
| Urine Erythrocytes (/HPF) >=20 | 7 | 5 | 8 | |
| Urine Leukocytes (/HPF) >=20 | 2 | 1 | 0 | |
| Granular Casts (/LPF) >1 | 0 | 0 | 1 | |
| Hyaline Casts (/LPF) >1 | 1 | 1 | 2 | |
| Urine Bacteria >20 | 0 | 0 | 0 | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Number of Subject with Electrocardiogram (ECG) Data Meeting Pre-specified Criteria

| End point title | Number of Subject with Electrocardiogram (ECG) Data Meeting Pre-specified Criteria |
|---|---|

End point description:

A 12-lead ECG was obtained using an ECG machine that automatically calculates the heart rate and measures PR, QRS, QT, and corrected QT intervals. All scheduled ECGs were performed after the subject had rested quietly for at least 10 minutes in a supine position. The endpoint's analysis included all subjects who received at least 1 dose of study medication.

| End point type | Secondary |
|---|---|

End point timeframe:

16 Weeks

| End point values | PF-04965842 100mg QD | PF-04965842 200mg QD | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 95 | 93 | 96 | |
| Units: Subjects | | | | |
| QTcF interval>500 msec | 0 | 0 | 0 | |
| Change from Screening in QTcF >60 msec | 0 | 0 | 0 | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Categoriztion of Vital Signs Data Meeting Prespecified Criteria

| End point title | Categoriztion of Vital Signs Data Meeting Prespecified Criteria |
|---|---|

End point description:

Vital signs (pulse rate, systolic and diastolic blood pressure [BP]) were obtained with subject in the seated position, after having sat calmly for at least 5 minutes. The endpoint's analysis included all subjects who received at least 1 dose of study medication.

| End point type | Secondary |
|---|---|

End point timeframe:

16 weeks

| End point values | PF-04965842 100mg QD | PF-04965842 200mg QD | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 95 | 93 | 96 | |
| Units: Subjects | | | | |
| Diastolic BP <50 mmHg | 1 | 9 | 3 | |
| Diastolic BR increase from baseline >= 20 mmHg | 6 | 6 | 3 | |
| Diastolic BR decrease from baseline >= 20 mmHg | 4 | 8 | 3 | |
| Pulse Rate <40 bpm | 0 | 0 | 0 | |
| Pulse Rate >120 bpm | 0 | 0 | 0 | |
| Systolic BP <90 mmHg | 7 | 4 | 4 | |
| Systolic BR increase from baseline >= 30 mmHg | 1 | 2 | 2 | |
| Systolic BR decrease from baseline >= 30 mmHg | 1 | 2 | 2 | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Fold Increase of Immunoglobulin G (IgG) Concentrations against Specific Vaccine Antigens at 4 Weeks Post-Vaccination

| End point title | Fold Increase of Immunoglobulin G (IgG) Concentrations against Specific Vaccine Antigens at 4 Weeks Post-Vaccination |
|---|---|

End point description:

The immunogenicity analysis was to evaluate the effect of abrocitinib on immunogenicity to a tetanus, diphtheria and pertussis combination vaccine (Tdap) vaccine in adolescent subjects 12 to <18 years of age with moderate to severe AD. Subjects who completed 8 weeks of treatment with study intervention received Tdap at Week 8, and had blood samples collected for the evaluation of immunogenicity to the vaccine at Weeks 8 and 12. Immunogenicity analysis set was defined as subjects who had completed 8 weeks of treatment and after Tdap vaccination. The fold increase was defined as the ratio (post-vaccination: pre-vaccination) of concentration values. The geometric mean fold rise (GMFR) is presented below and it was calculated by first arithmetically averaging the logarithmically transformed ratio (post-vaccination: pre-vaccination) values, and then back transformation.

| End point type | Secondary |
|---|---|

End point timeframe:

4 weeks

| End point values | PF-04965842 100mg QD | PF-04965842 200mg QD | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 9 | 6 | 10 | |
| Units: Ratio | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Diphtheria IgG Antibody | 6.51 (2.31 to 18.34) | 34.61 (6.96 to 172.06) | 14.00 (6.32 to 30.99) | |
| Filamentous Hemagglutinin IgG | 11.48 (2.65 to 49.69) | 22.77 (7.26 to 71.45) | 15.19 (4.89 to 47.16) | |

| | | | | |
|---|---|---|---|---|
| Fimbriae 2/3 IgG | 1.11 (0.85 to 1.46) | 1.47 (0.61 to 3.50) | 1.93 (0.79 to 4.73) | |
| Pertactin IgG | 15.60 (5.77 to 42.14) | 60.18 (12.79 to 283.08) | 54.03 (14.67 to 199.03) | |
| Pertussis Toxin IgG | 10.17 (4.71 to 21.94) | 33.16 (5.04 to 218.38) | 6.94 (1.95 to 24.71) | |
| Tetanus Toxoid IgG Antibody | 16.26 (3.52 to 75.11) | 48.41 (9.01 to 260.09) | 8.36 (1.62 to 43.18) | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Plasma PF-04965842 Concentration at Week 8

| End point title | Plasma PF-04965842 Concentration at Week 8[25] |
|---|---|

End point description:

| End point type | Secondary |
|---|---|

End point timeframe:

2 hours before Week 8 visit dose

Notes:

[25] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: No statistical analysis was planned for this endpoint

| End point values | PF-04965842 100mg QD | PF-04965842 200mg QD | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 72 | 62 | | |
| Units: ng/mL | | | | |
| arithmetic mean (standard deviation) | 7.882 (± 26.350) | 32.33 (± 76.506) | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Plasma PF-04965842 Concentration at Week 12

| End point title | Plasma PF-04965842 Concentration at Week 12[26] |
|---|---|

End point description:

| End point type | Secondary |
|---|---|

End point timeframe:

2 hours post Week 12 visit dosing

Notes:

[26] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: No statistical analysis was planned for this endpoint

| End point values | PF-04965842 100mg QD | PF-04965842 200mg QD | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 59 | 50 | | |
| Units: ng/mL | | | | |
| arithmetic mean (standard deviation) | 486.6 (± 403.69) | 1271 (± 1000.4) | | |

## Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

16 weeks

Adverse event reporting additional description:

The same event may appear as both an AE and an SAE. 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. Total number at risk below refers to the number of subjects evaluable for SAEs or AEs.

| | |
|---|---|
| Assessment type | Non-systematic |

### Dictionary used

| | |
|---|---|
| Dictionary name | MedDRA |
| Dictionary version | 23.0 |

### Reporting groups

| | |
|---|---|
| Reporting group title | PF-04965842 100 mg QD |
| Reporting group description: - | |
| Reporting group title | PF-04965842 200 mg QD |
| Reporting group description: - | |
| Reporting group title | Placebo |

Reporting group description: -

| Serious adverse events | PF-04965842 100 mg QD | PF-04965842 200 mg QD | Placebo |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 95 (0.00%) | 1 / 94 (1.06%) | 2 / 96 (2.08%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Skin and subcutaneous tissue disorders | | | |
| Angioedema | | | |
| subjects affected / exposed | 0 / 95 (0.00%) | 0 / 94 (0.00%) | 1 / 96 (1.04%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Dermatitis atopic | | | |
| subjects affected / exposed | 0 / 95 (0.00%) | 0 / 94 (0.00%) | 1 / 96 (1.04%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Psychiatric disorders | | | |
| Anxiety | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 95 (0.00%) | 1 / 94 (1.06%) | 0 / 96 (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 |

Frequency threshold for reporting non-serious adverse events: 2 %

| **Non-serious adverse events** | PF-04965842 100 mg QD | PF-04965842 200 mg QD | Placebo |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 54 / 95 (56.84%) | 59 / 94 (62.77%) | 49 / 96 (51.04%) |
| Investigations | | | |
| Blood creatine phosphokinase increased | | | |
| subjects affected / exposed | 4 / 95 (4.21%) | 4 / 94 (4.26%) | 0 / 96 (0.00%) |
| occurrences (all) | 5 | 4 | 0 |
| Blood lactate dehydrogenase increased | | | |
| subjects affected / exposed | 1 / 95 (1.05%) | 2 / 94 (2.13%) | 0 / 96 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| Blood uric acid increased | | | |
| subjects affected / exposed | 1 / 95 (1.05%) | 0 / 94 (0.00%) | 2 / 96 (2.08%) |
| occurrences (all) | 1 | 0 | 2 |
| Haemoglobin increased | | | |
| subjects affected / exposed | 0 / 95 (0.00%) | 2 / 94 (2.13%) | 0 / 96 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Protein urine | | | |
| subjects affected / exposed | 1 / 95 (1.05%) | 0 / 94 (0.00%) | 2 / 96 (2.08%) |
| occurrences (all) | 1 | 0 | 2 |
| Injury, poisoning and procedural complications | | | |
| Contusion | | | |
| subjects affected / exposed | 2 / 95 (2.11%) | 0 / 94 (0.00%) | 0 / 96 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Nervous system disorders | | | |
| Dizziness | | | |
| subjects affected / exposed | 0 / 95 (0.00%) | 6 / 94 (6.38%) | 1 / 96 (1.04%) |
| occurrences (all) | 0 | 9 | 2 |
| Headache | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 5 / 95 (5.26%) | 8 / 94 (8.51%) | 7 / 96 (7.29%) |
| occurrences (all) | 7 | 12 | 8 |
| Somnolence | | | |
| subjects affected / exposed | 0 / 95 (0.00%) | 2 / 94 (2.13%) | 2 / 96 (2.08%) |
| occurrences (all) | 0 | 2 | 2 |
| General disorders and administration site conditions | | | |
| Fatigue | | | |
| subjects affected / exposed | 2 / 95 (2.11%) | 0 / 94 (0.00%) | 1 / 96 (1.04%) |
| occurrences (all) | 2 | 0 | 1 |
| Pyrexia | | | |
| subjects affected / exposed | 3 / 95 (3.16%) | 1 / 94 (1.06%) | 4 / 96 (4.17%) |
| occurrences (all) | 3 | 1 | 4 |
| Blood and lymphatic system disorders | | | |
| Eosinophilia | | | |
| subjects affected / exposed | 0 / 95 (0.00%) | 0 / 94 (0.00%) | 2 / 96 (2.08%) |
| occurrences (all) | 0 | 0 | 2 |
| Gastrointestinal disorders | | | |
| Abdominal pain | | | |
| subjects affected / exposed | 1 / 95 (1.05%) | 3 / 94 (3.19%) | 1 / 96 (1.04%) |
| occurrences (all) | 1 | 3 | 1 |
| Diarrhoea | | | |
| subjects affected / exposed | 2 / 95 (2.11%) | 1 / 94 (1.06%) | 0 / 96 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| Lip swelling | | | |
| subjects affected / exposed | 0 / 95 (0.00%) | 0 / 94 (0.00%) | 2 / 96 (2.08%) |
| occurrences (all) | 0 | 0 | 2 |
| Nausea | | | |
| subjects affected / exposed | 7 / 95 (7.37%) | 17 / 94 (18.09%) | 1 / 96 (1.04%) |
| occurrences (all) | 7 | 27 | 2 |
| Abdominal pain upper | | | |
| subjects affected / exposed | 0 / 95 (0.00%) | 4 / 94 (4.26%) | 0 / 96 (0.00%) |
| occurrences (all) | 0 | 5 | 0 |
| Vomiting | | | |
| subjects affected / exposed | 4 / 95 (4.21%) | 5 / 94 (5.32%) | 0 / 96 (0.00%) |
| occurrences (all) | 4 | 7 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |

| | | | |
|---|---|---|---|
| Asthma | | | |
| subjects affected / exposed | 1 / 95 (1.05%) | 1 / 94 (1.06%) | 2 / 96 (2.08%) |
| occurrences (all) | 1 | 3 | 2 |
| Cough | | | |
| subjects affected / exposed | 4 / 95 (4.21%) | 1 / 94 (1.06%) | 2 / 96 (2.08%) |
| occurrences (all) | 6 | 1 | 2 |
| Rhinorrhoea | | | |
| subjects affected / exposed | 1 / 95 (1.05%) | 0 / 94 (0.00%) | 3 / 96 (3.13%) |
| occurrences (all) | 1 | 0 | 4 |
| Skin and subcutaneous tissue disorders | | | |
| Acne | | | |
| subjects affected / exposed | 3 / 95 (3.16%) | 5 / 94 (5.32%) | 1 / 96 (1.04%) |
| occurrences (all) | 3 | 5 | 2 |
| Dermatitis atopic | | | |
| subjects affected / exposed | 2 / 95 (2.11%) | 1 / 94 (1.06%) | 2 / 96 (2.08%) |
| occurrences (all) | 2 | 2 | 2 |
| Infections and infestations | | | |
| Folliculitis | | | |
| subjects affected / exposed | 7 / 95 (7.37%) | 2 / 94 (2.13%) | 1 / 96 (1.04%) |
| occurrences (all) | 7 | 2 | 1 |
| Gastroenteritis | | | |
| subjects affected / exposed | 2 / 95 (2.11%) | 2 / 94 (2.13%) | 1 / 96 (1.04%) |
| occurrences (all) | 2 | 2 | 1 |
| Hordeolum | | | |
| subjects affected / exposed | 2 / 95 (2.11%) | 0 / 94 (0.00%) | 0 / 96 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Influenza | | | |
| subjects affected / exposed | 4 / 95 (4.21%) | 2 / 94 (2.13%) | 1 / 96 (1.04%) |
| occurrences (all) | 4 | 2 | 1 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 8 / 95 (8.42%) | 8 / 94 (8.51%) | 9 / 96 (9.38%) |
| occurrences (all) | 10 | 9 | 11 |
| Oral herpes | | | |
| subjects affected / exposed | 1 / 95 (1.05%) | 2 / 94 (2.13%) | 0 / 96 (0.00%) |
| occurrences (all) | 2 | 2 | 0 |
| Pharyngitis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 5 / 95 (5.26%) | 3 / 94 (3.19%) | 3 / 96 (3.13%) |
| occurrences (all) | 5 | 3 | 3 |
| Pharyngitis streptococcal | | | |
| subjects affected / exposed | 0 / 95 (0.00%) | 0 / 94 (0.00%) | 2 / 96 (2.08%) |
| occurrences (all) | 0 | 0 | 2 |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 95 (0.00%) | 3 / 94 (3.19%) | 0 / 96 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 9 / 95 (9.47%) | 10 / 94 (10.64%) | 10 / 96 (10.42%) |
| occurrences (all) | 11 | 14 | 12 |

## 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