



## Clinical trial results:

### A Phase 2b, DoubleBlind, Randomized, PlaceboControlled, Parallel Group, Dose Ranging Study of Oral PF06651600 and PF06700841 as Induction and Chronic Therapy in Subjects With Moderate to Severe Ulcerative Colitis

#### Summary

|                          |                                  |
|--------------------------|----------------------------------|
| EudraCT number           | 2016-003708-29                   |
| Trial protocol           | SK LT DK DE AT PL HU ES NL BG IT |
| Global end of trial date | 10 May 2021                      |

#### Results information

|                                |              |
|--------------------------------|--------------|
| Result version number          | v2 (current) |
| This version publication date  | 27 July 2022 |
| First version publication date | 25 May 2022  |
| Version creation reason        |              |

#### Trial information

##### Trial identification

|                       |          |
|-----------------------|----------|
| Sponsor protocol code | B7981005 |
|-----------------------|----------|

##### Additional study identifiers

|                                    |             |
|------------------------------------|-------------|
| ISRCTN number                      | -           |
| ClinicalTrials.gov id (NCT number) | NCT02958865 |
| 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 May 2021 |
| Is this the analysis of the primary completion data? | No          |
| Global end of trial reached?                         | Yes         |
| Global end of trial date                             | 10 May 2021 |
| Was the trial ended prematurely?                     | No          |

Notes:

## General information about the trial

Main objective of the trial:

This multicenter, multiple arm, dose ranging, placebo controlled (in the induction period only) study was to evaluate the efficacy (based on total Mayo score), safety, tolerability, PK, and PD of multiple doses of PF-06651600 (20, 70, and 200 mg doses) and PF-06700841 (10, 30, and 60 mg doses) during an 8-week induction period, followed by a chronic dosing period at doses of 50 mg and 30 mg of PF-06651600 and PF-06700841, respectively, for 24 weeks.

Protection of trial subjects:

This study was conducted in compliance with the ethical principles originating in or derived from the Declaration of Helsinki and in compliance with all International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Good Clinical Practice (GCP) Guidelines. In addition, all local regulatory requirements were followed, in particular, those affording greater protection to the safety of trial subjects.

Background therapy: -

Evidence for comparator: -

|                                                           |                  |
|-----------------------------------------------------------|------------------|
| Actual start date of recruitment                          | 03 February 2017 |
| Long term follow-up planned                               | No               |
| Independent data monitoring committee (IDMC) involvement? | Yes              |

Notes:

## Population of trial subjects

### Subjects enrolled per country

|                                      |                        |
|--------------------------------------|------------------------|
| Country: Number of subjects enrolled | Bulgaria: 8            |
| Country: Number of subjects enrolled | Czechia: 5             |
| Country: Number of subjects enrolled | Denmark: 12            |
| Country: Number of subjects enrolled | Georgia: 2             |
| Country: Number of subjects enrolled | Germany: 23            |
| Country: Number of subjects enrolled | Hungary: 20            |
| Country: Number of subjects enrolled | Israel: 3              |
| Country: Number of subjects enrolled | Italy: 29              |
| Country: Number of subjects enrolled | Korea, Republic of: 8  |
| Country: Number of subjects enrolled | Poland: 77             |
| Country: Number of subjects enrolled | Romania: 1             |
| Country: Number of subjects enrolled | Russian Federation: 31 |
| Country: Number of subjects enrolled | Serbia: 8              |
| Country: Number of subjects enrolled | Slovakia: 6            |
| Country: Number of subjects enrolled | Spain: 10              |
| Country: Number of subjects enrolled | Turkey: 18             |
| Country: Number of subjects enrolled | Ukraine: 23            |

|                                      |                   |
|--------------------------------------|-------------------|
| Country: Number of subjects enrolled | United States: 33 |
| Worldwide total number of subjects   | 317               |
| EEA total number of subjects         | 191               |

Notes:

| <b>Subjects enrolled per age group</b>    |     |
|-------------------------------------------|-----|
| In utero                                  | 0   |
| Preterm newborn - gestational age < 37 wk | 0   |
| Newborns (0-27 days)                      | 0   |
| Infants and toddlers (28 days-23 months)  | 0   |
| Children (2-11 years)                     | 0   |
| Adolescents (12-17 years)                 | 0   |
| Adults (18-64 years)                      | 304 |
| From 65 to 84 years                       | 13  |
| 85 years and over                         | 0   |

## Subject disposition

### Recruitment

Recruitment details:

The study consisted of a screening period of up to 6 weeks, an 8 week double blind induction period, an additional 24 week open label active chronic dosing period followed by a 4 week follow up period after the last dose of investigational product for a total of 36 weeks.

### Pre-assignment

Screening details:

A total of 319 subjects were randomized and 317 subjects were treated.

### Period 1

|                              |                         |
|------------------------------|-------------------------|
| Period 1 title               | Induction 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 |
|------------------------------|-----|

|                  |                                   |
|------------------|-----------------------------------|
| <b>Arm title</b> | Placebo (Induction: 0 to 8 weeks) |
|------------------|-----------------------------------|

Arm description:

The placebo was administered orally once daily (QD) from Day 1 to Week 8.

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

Dosage and administration details:

Subjects received Placebo QD from Day 1 to Week 8.

|                  |                               |
|------------------|-------------------------------|
| <b>Arm title</b> | PF-06651600 20 mg (Induction) |
|------------------|-------------------------------|

Arm description:

PF-06651600 tablet was administered orally at 20 mg QD from Day 1 to Week 8.

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

Dosage and administration details:

Subjects received PF-06651600 20 mg QD from Day 1 to Week 8.

|                  |                               |
|------------------|-------------------------------|
| <b>Arm title</b> | PF-06651600 70 mg (Induction) |
|------------------|-------------------------------|

Arm description:

PF-06651600 tablet was administered orally at 70 mg QD from Day 1 to Week 8.

|          |              |
|----------|--------------|
| Arm type | Experimental |
|----------|--------------|

|                                                                               |                                |
|-------------------------------------------------------------------------------|--------------------------------|
| Investigational medicinal product name                                        | PF-06651600                    |
| Investigational medicinal product code                                        |                                |
| Other name                                                                    | Ritlecitinib                   |
| Pharmaceutical forms                                                          | Tablet                         |
| Routes of administration                                                      | Oral use                       |
| Dosage and administration details:                                            |                                |
| Subjects received PF-06651600 70 mg QD from Day 1 to Week 8.                  |                                |
| <b>Arm title</b>                                                              | PF-06651600 200 mg (Induction) |
| Arm description:                                                              |                                |
| PF-06651600 tablet was administered orally at 200 mg QD from Day 1 to Week 8. |                                |
| Arm type                                                                      | Experimental                   |
| Investigational medicinal product name                                        | PF-06651600                    |
| Investigational medicinal product code                                        |                                |
| Other name                                                                    | Ritlecitinib                   |
| Pharmaceutical forms                                                          | Tablet                         |
| Routes of administration                                                      | Oral use                       |
| Dosage and administration details:                                            |                                |
| Subjects received PF-06651600 200 mg QD from Day 1 to Week 8.                 |                                |
| <b>Arm title</b>                                                              | PF-06700841 10 mg (Induction)  |
| Arm description:                                                              |                                |
| PF-06700841 tablet was administered orally at 10 mg QD from Day 1 to Week 8.  |                                |
| Arm type                                                                      | Experimental                   |
| Investigational medicinal product name                                        | PF-06700841                    |
| Investigational medicinal product code                                        |                                |
| Other name                                                                    | Brepocitinib                   |
| Pharmaceutical forms                                                          | Tablet                         |
| Routes of administration                                                      | Oral use                       |
| Dosage and administration details:                                            |                                |
| Subjects received PF-06700841 10 mg QD from Day 1 to Week 8.                  |                                |
| <b>Arm title</b>                                                              | PF-06700841 30 mg (Induction)  |
| Arm description:                                                              |                                |
| PF-06700841 tablet was administered orally at 30 mg QD from Day 1 to Week 8.  |                                |
| Arm type                                                                      | Experimental                   |
| Investigational medicinal product name                                        | PF-06700841                    |
| Investigational medicinal product code                                        |                                |
| Other name                                                                    | Brepocitinib                   |
| Pharmaceutical forms                                                          | Tablet                         |
| Routes of administration                                                      | Oral use                       |
| Dosage and administration details:                                            |                                |
| Subjects received PF-06700841 30 mg QD from Day 1 to Week 8.                  |                                |
| <b>Arm title</b>                                                              | PF-06700841 60 mg (Induction)  |
| Arm description:                                                              |                                |
| PF-06700841 tablet was administered orally at 60 mg QD from Day 1 to Week 8.  |                                |
| Arm type                                                                      | Experimental                   |
| Investigational medicinal product name                                        | PF-06700841                    |
| Investigational medicinal product code                                        |                                |
| Other name                                                                    | Brepocitinib                   |
| Pharmaceutical forms                                                          | Tablet                         |
| Routes of administration                                                      | Oral use                       |

Dosage and administration details:

Subjects received PF-06700841 60 mg QD from Day 1 to Week 8.

| <b>Number of subjects in period 1</b> | Placebo (Induction:<br>0 to 8 weeks) | PF-06651600 20 mg<br>(Induction) | PF-06651600 70 mg<br>(Induction) |
|---------------------------------------|--------------------------------------|----------------------------------|----------------------------------|
| Started                               | 25                                   | 51                               | 49                               |
| Completed                             | 21                                   | 44                               | 43                               |
| Not completed                         | 4                                    | 7                                | 6                                |
| Consent withdrawn by subject          | 2                                    | -                                | 3                                |
| Physician decision                    | 1                                    | 1                                | -                                |
| Adverse event, non-fatal              | -                                    | 2                                | -                                |
| ADVERSE EVENT, serious non-fatal      | -                                    | 2                                | -                                |
| No longer meets eligibility criteria  | -                                    | -                                | -                                |
| Death                                 | -                                    | 1                                | -                                |
| other                                 | -                                    | -                                | 1                                |
| Lost to follow-up                     | -                                    | -                                | -                                |
| Lack of efficacy                      | 1                                    | 1                                | 1                                |
| Protocol deviation                    | -                                    | -                                | 1                                |

| <b>Number of subjects in period 1</b> | PF-06651600 200<br>mg (Induction) | PF-06700841 10 mg<br>(Induction) | PF-06700841 30 mg<br>(Induction) |
|---------------------------------------|-----------------------------------|----------------------------------|----------------------------------|
| Started                               | 50                                | 48                               | 47                               |
| Completed                             | 41                                | 45                               | 43                               |
| Not completed                         | 9                                 | 3                                | 4                                |
| Consent withdrawn by subject          | 1                                 | 1                                | 1                                |
| Physician decision                    | -                                 | -                                | -                                |
| Adverse event, non-fatal              | 3                                 | -                                | 1                                |
| ADVERSE EVENT, serious non-fatal      | 2                                 | 1                                | 1                                |
| No longer meets eligibility criteria  | 1                                 | -                                | -                                |
| Death                                 | -                                 | -                                | -                                |
| other                                 | 2                                 | -                                | 1                                |
| Lost to follow-up                     | -                                 | 1                                | -                                |
| Lack of efficacy                      | -                                 | -                                | -                                |
| Protocol deviation                    | -                                 | -                                | -                                |

| <b>Number of subjects in period 1</b> | PF-06700841 60 mg<br>(Induction) |
|---------------------------------------|----------------------------------|
| Started                               | 47                               |

|                                      |    |
|--------------------------------------|----|
| Completed                            | 44 |
| Not completed                        | 3  |
| Consent withdrawn by subject         | 1  |
| Physician decision                   | -  |
| Adverse event, non-fatal             | -  |
| ADVERSE EVENT, serious non-fatal     | 1  |
| No longer meets eligibility criteria | 1  |
| Death                                | -  |
| other                                | -  |
| Lost to follow-up                    | -  |
| Lack of efficacy                     | -  |
| Protocol deviation                   | -  |

## Period 2

|                              |                         |
|------------------------------|-------------------------|
| Period 2 title               | Chronic Period          |
| Is this the baseline period? | No                      |
| Allocation method            | Randomised - controlled |
| Blinding used                | Not blinded             |

## Arms

|                              |                                         |
|------------------------------|-----------------------------------------|
| Are arms mutually exclusive? | Yes                                     |
| <b>Arm title</b>             | PF-06651600 200 mg -> PF-06651600 50 mg |

Arm description:

PF-06651600 tablet was administered orally at 200 mg QD from Day 1 to Week 8 and at 50 mg QD from Week 9 to Week 32.

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

Dosage and administration details:

Subjects received PF-06651600 50 mg QD from Week 9 to Week 32.

|                  |                                        |
|------------------|----------------------------------------|
| <b>Arm title</b> | PF-06651600 70 mg -> PF-06651600 50 mg |
|------------------|----------------------------------------|

Arm description:

PF-06651600 tablet was administered orally at 70 mg QD from Day 1 to Week 8 and at 50 mg QD from Week 9 to Week 32.

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

Dosage and administration details:

Subjects received PF-06651600 50 mg QD from Week 9 to Week 32.

|                                                                                                                                                      |                                        |
|------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|
| <b>Arm title</b>                                                                                                                                     | PF-06651600 20 mg -> PF-06651600 50 mg |
| Arm description:<br>PF-06651600 tablet was administered orally at 20 mg QD from Day 1 to Week 8 and at 50 mg QD from Week 9 to Week 32.              |                                        |
| Arm type                                                                                                                                             | Experimental                           |
| Investigational medicinal product name                                                                                                               | PF-06651600                            |
| Investigational medicinal product code                                                                                                               |                                        |
| Other name                                                                                                                                           | Ritlecitinib                           |
| Pharmaceutical forms                                                                                                                                 | Tablet                                 |
| Routes of administration                                                                                                                             | Oral use                               |
| Dosage and administration details:<br>Subjects received PF-06651600 50 mg QD from Week 9 to Week 32.                                                 |                                        |
| <b>Arm title</b>                                                                                                                                     | Placebo -> PF-06651600 50 mg           |
| Arm description:<br>The placebo was administered orally QD from Day 1 to Week 8 and PF-06651600 was administered at 50 mg QD from Week 9 to Week 32. |                                        |
| Arm type                                                                                                                                             | Placebo                                |
| Investigational medicinal product name                                                                                                               | PF-06651600                            |
| Investigational medicinal product code                                                                                                               |                                        |
| Other name                                                                                                                                           | Ritlecitinib                           |
| Pharmaceutical forms                                                                                                                                 | Tablet                                 |
| Routes of administration                                                                                                                             | Oral use                               |
| Dosage and administration details:<br>Subjects received PF-06651600 50 mg QD from Week 9 to Week 32.                                                 |                                        |
| <b>Arm title</b>                                                                                                                                     | PF-06700841 60 mg -> PF-06700841 30 mg |
| Arm description:<br>PF-06700841 tablet was administered orally at 60 mg QD from Day 1 to Week 8 and at 30 mg QD from Week 9 to Week 32.              |                                        |
| Arm type                                                                                                                                             | Experimental                           |
| Investigational medicinal product name                                                                                                               | PF-06700841                            |
| Investigational medicinal product code                                                                                                               |                                        |
| Other name                                                                                                                                           | Brepocitinib                           |
| Pharmaceutical forms                                                                                                                                 | Tablet                                 |
| Routes of administration                                                                                                                             | Oral use                               |
| Dosage and administration details:<br>Subjects received PF-06700841 30 mg QD from Week 9 to Week 32.                                                 |                                        |
| <b>Arm title</b>                                                                                                                                     | PF-06700841 30 mg -> PF-06700841 30 mg |
| Arm description:<br>PF-06700841 tablet was administered orally at 30 mg QD from Day 1 to Week 8 and at 30 mg QD from Week 9 to Week 32.              |                                        |
| Arm type                                                                                                                                             | Experimental                           |
| Investigational medicinal product name                                                                                                               | PF-06700841                            |
| Investigational medicinal product code                                                                                                               |                                        |
| Other name                                                                                                                                           | Brepocitinib                           |
| Pharmaceutical forms                                                                                                                                 | Tablet                                 |
| Routes of administration                                                                                                                             | Oral use                               |
| Dosage and administration details:<br>Subjects received PF-06700841 30 mg QD from Week 9 to Week 32.                                                 |                                        |
| <b>Arm title</b>                                                                                                                                     | PF-06700841 10 mg -> PF-06700841 30 mg |
| Arm description:<br>PF-06700841 tablet was administered orally at 10 mg QD from Day 1 to Week 8 and at 30 mg QD from Week 9 to Week 32.              |                                        |



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

Dosage and administration details:

Subjects received PF-06700841 30 mg QD from Week 9 to Week 32.

|                  |                              |
|------------------|------------------------------|
| <b>Arm title</b> | Placebo -> PF-06700841 30 mg |
|------------------|------------------------------|

Arm description:

The placebo was administered orally from Day 1 to Week 8 and PF-06700841 was administered orally at 30 mg QD from Week 9 to Week 32.

|                                        |              |
|----------------------------------------|--------------|
| Arm type                               | Placebo      |
| Investigational medicinal product name | PF-06700841  |
| Investigational medicinal product code |              |
| Other name                             | Brepocitinib |
| Pharmaceutical forms                   | Tablet       |
| Routes of administration               | Oral use     |

Dosage and administration details:

Subjects received PF-06700841 30 mg QD from Week 9 to Week 32.

|                  |                                |
|------------------|--------------------------------|
| <b>Arm title</b> | Pooling Placebo During Chronic |
|------------------|--------------------------------|

Arm description:

The placebo was administered orally QD from Week 9 to Week 32 regardless of what was administered from Day 1 to Week 8.

|                                        |          |
|----------------------------------------|----------|
| 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 Placebo QD from Week 9 to Week 32.

| <b>Number of subjects in period 2<sup>[1]</sup></b> | PF-06651600 200 mg -> PF-06651600 50 mg | PF-06651600 70 mg -> PF-06651600 50 mg | PF-06651600 20 mg -> PF-06651600 50 mg |
|-----------------------------------------------------|-----------------------------------------|----------------------------------------|----------------------------------------|
| Started                                             | 35                                      | 36                                     | 39                                     |
| Completed                                           | 33                                      | 33                                     | 33                                     |
| Not completed                                       | 2                                       | 3                                      | 6                                      |
| Consent withdrawn by subject                        | -                                       | -                                      | -                                      |
| ADVERSE EVENT, serious non-fatal                    | 1                                       | 1                                      | 1                                      |
| Adverse event, non-fatal                            | -                                       | -                                      | 1                                      |
| No longer meets eligibility criteria                | -                                       | -                                      | 1                                      |
| Pregnancy                                           | -                                       | -                                      | 1                                      |
| Non-compliance with study drug                      | -                                       | -                                      | -                                      |
| other                                               | 1                                       | -                                      | 1                                      |

|                    |   |   |   |
|--------------------|---|---|---|
| Lack of efficacy   | - | 2 | 1 |
| Protocol deviation | - | - | - |

| Number of subjects in period 2 <sup>[1]</sup> | Placebo -> PF-06651600 50 mg | PF-06700841 60 mg -> PF-06700841 30 mg | PF-06700841 30 mg -> PF-06700841 30 mg |
|-----------------------------------------------|------------------------------|----------------------------------------|----------------------------------------|
|                                               |                              |                                        |                                        |
| Started                                       | 10                           | 38                                     | 37                                     |
| Completed                                     | 10                           | 31                                     | 26                                     |
| Not completed                                 | 0                            | 7                                      | 11                                     |
| Consent withdrawn by subject                  | -                            | 1                                      | 6                                      |
| ADVERSE EVENT, serious non-fatal              | -                            | 1                                      | 3                                      |
| Adverse event, non-fatal                      | -                            | -                                      | 1                                      |
| No longer meets eligibility criteria          | -                            | -                                      | -                                      |
| Pregnancy                                     | -                            | -                                      | -                                      |
| Non-compliance with study drug                | -                            | -                                      | -                                      |
| other                                         | -                            | -                                      | 1                                      |
| Lack of efficacy                              | -                            | 5                                      | -                                      |
| Protocol deviation                            | -                            | -                                      | -                                      |

| Number of subjects in period 2 <sup>[1]</sup> | PF-06700841 10 mg -> PF-06700841 30 mg | Placebo -> PF-06700841 30 mg | Pooling Placebo During Chronic |
|-----------------------------------------------|----------------------------------------|------------------------------|--------------------------------|
|                                               |                                        |                              |                                |
| Started                                       | 39                                     | 9                            | 37                             |
| Completed                                     | 31                                     | 5                            | 20                             |
| Not completed                                 | 8                                      | 4                            | 17                             |
| Consent withdrawn by subject                  | 3                                      | 3                            | 2                              |
| ADVERSE EVENT, serious non-fatal              | -                                      | -                            | -                              |
| Adverse event, non-fatal                      | 1                                      | 1                            | 5                              |
| No longer meets eligibility criteria          | -                                      | -                            | -                              |
| Pregnancy                                     | -                                      | -                            | 1                              |
| Non-compliance with study drug                | 1                                      | -                            | -                              |
| other                                         | -                                      | -                            | 1                              |
| Lack of efficacy                              | 2                                      | -                            | 8                              |
| Protocol deviation                            | 1                                      | -                            | -                              |

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: One subject who was re-randomized but not treated during chronic period was not included.

## Baseline characteristics

### Reporting groups

|                                                                               |                                   |
|-------------------------------------------------------------------------------|-----------------------------------|
| Reporting group title                                                         | Placebo (Induction: 0 to 8 weeks) |
| Reporting group description:                                                  |                                   |
| The placebo was administered orally once daily (QD) from Day 1 to Week 8.     |                                   |
| Reporting group title                                                         | PF-06651600 20 mg (Induction)     |
| Reporting group description:                                                  |                                   |
| PF-06651600 tablet was administered orally at 20 mg QD from Day 1 to Week 8.  |                                   |
| Reporting group title                                                         | PF-06651600 70 mg (Induction)     |
| Reporting group description:                                                  |                                   |
| PF-06651600 tablet was administered orally at 70 mg QD from Day 1 to Week 8.  |                                   |
| Reporting group title                                                         | PF-06651600 200 mg (Induction)    |
| Reporting group description:                                                  |                                   |
| PF-06651600 tablet was administered orally at 200 mg QD from Day 1 to Week 8. |                                   |
| Reporting group title                                                         | PF-06700841 10 mg (Induction)     |
| Reporting group description:                                                  |                                   |
| PF-06700841 tablet was administered orally at 10 mg QD from Day 1 to Week 8.  |                                   |
| Reporting group title                                                         | PF-06700841 30 mg (Induction)     |
| Reporting group description:                                                  |                                   |
| PF-06700841 tablet was administered orally at 30 mg QD from Day 1 to Week 8.  |                                   |
| Reporting group title                                                         | PF-06700841 60 mg (Induction)     |
| Reporting group description:                                                  |                                   |
| PF-06700841 tablet was administered orally at 60 mg QD from Day 1 to Week 8.  |                                   |

| Reporting group values                             | Placebo (Induction: 0 to 8 weeks) | PF-06651600 20 mg (Induction) | PF-06651600 70 mg (Induction) |
|----------------------------------------------------|-----------------------------------|-------------------------------|-------------------------------|
| Number of subjects                                 | 25                                | 51                            | 49                            |
| Age Categorical<br>Units: Subjects                 |                                   |                               |                               |
| In utero                                           | 0                                 | 0                             | 0                             |
| Preterm newborn infants (gestational age < 37 wks) | 0                                 | 0                             | 0                             |
| Newborns (0-27 days)                               | 0                                 | 0                             | 0                             |
| Infants and toddlers (28 days-23 months)           | 0                                 | 0                             | 0                             |
| Children (2-11 years)                              | 0                                 | 0                             | 0                             |
| Adolescents (12-17 years)                          | 0                                 | 0                             | 0                             |
| Adults (18-64 years)                               | 23                                | 47                            | 48                            |
| From 65-84 years                                   | 2                                 | 4                             | 1                             |
| 85 years and over                                  | 0                                 | 0                             | 0                             |
| Age Continuous<br>Units: years                     |                                   |                               |                               |
| arithmetic mean                                    | 42.8                              | 41.3                          | 40.2                          |
| standard deviation                                 | ± 15.45                           | ± 14.03                       | ± 13.31                       |
| Gender Categorical<br>Units: Subjects              |                                   |                               |                               |
| Male                                               | 14                                | 34                            | 24                            |
| Female                                             | 11                                | 17                            | 25                            |

|                           |    |    |    |
|---------------------------|----|----|----|
| Race                      |    |    |    |
| Units: Subjects           |    |    |    |
| White                     | 22 | 46 | 46 |
| Black or African American | 1  | 1  | 2  |
| Asian                     | 1  | 3  | 1  |
| Other                     | 1  | 1  | 0  |
| Ethnicity                 |    |    |    |
| Units: Subjects           |    |    |    |
| Hispanic or Latino        | 0  | 2  | 0  |
| Not Hispanic or Latino    | 25 | 49 | 49 |

| Reporting group values                             | PF-06651600 200 mg (Induction) | PF-06700841 10 mg (Induction) | PF-06700841 30 mg (Induction) |
|----------------------------------------------------|--------------------------------|-------------------------------|-------------------------------|
| Number of subjects                                 | 50                             | 48                            | 47                            |
| Age Categorical                                    |                                |                               |                               |
| Units: Subjects                                    |                                |                               |                               |
| In utero                                           | 0                              | 0                             | 0                             |
| Preterm newborn infants (gestational age < 37 wks) | 0                              | 0                             | 0                             |
| Newborns (0-27 days)                               | 0                              | 0                             | 0                             |
| Infants and toddlers (28 days-23 months)           | 0                              | 0                             | 0                             |
| Children (2-11 years)                              | 0                              | 0                             | 0                             |
| Adolescents (12-17 years)                          | 0                              | 0                             | 0                             |
| Adults (18-64 years)                               | 46                             | 47                            | 47                            |
| From 65-84 years                                   | 4                              | 1                             | 0                             |
| 85 years and over                                  | 0                              | 0                             | 0                             |
| Age Continuous                                     |                                |                               |                               |
| Units: years                                       |                                |                               |                               |
| arithmetic mean                                    | 37.3                           | 40.8                          | 40.9                          |
| standard deviation                                 | ± 15.67                        | ± 13.04                       | ± 13.03                       |
| Gender Categorical                                 |                                |                               |                               |
| Units: Subjects                                    |                                |                               |                               |
| Male                                               | 32                             | 30                            | 23                            |
| Female                                             | 18                             | 18                            | 24                            |
| Race                                               |                                |                               |                               |
| Units: Subjects                                    |                                |                               |                               |
| White                                              | 48                             | 44                            | 44                            |
| Black or African American                          | 1                              | 0                             | 0                             |
| Asian                                              | 0                              | 3                             | 3                             |
| Other                                              | 1                              | 1                             | 0                             |
| Ethnicity                                          |                                |                               |                               |
| Units: Subjects                                    |                                |                               |                               |
| Hispanic or Latino                                 | 0                              | 0                             | 2                             |
| Not Hispanic or Latino                             | 50                             | 48                            | 45                            |

| Reporting group values | PF-06700841 60 mg (Induction) | Total |  |
|------------------------|-------------------------------|-------|--|
| Number of subjects     | 47                            | 317   |  |
| Age Categorical        |                               |       |  |
| Units: Subjects        |                               |       |  |
| In utero               | 0                             | 0     |  |

|                                                       |         |     |  |
|-------------------------------------------------------|---------|-----|--|
| Preterm newborn infants<br>(gestational age < 37 wks) | 0       | 0   |  |
| Newborns (0-27 days)                                  | 0       | 0   |  |
| Infants and toddlers (28 days-23<br>months)           | 0       | 0   |  |
| Children (2-11 years)                                 | 0       | 0   |  |
| Adolescents (12-17 years)                             | 0       | 0   |  |
| Adults (18-64 years)                                  | 46      | 304 |  |
| From 65-84 years                                      | 1       | 13  |  |
| 85 years and over                                     | 0       | 0   |  |
| Age Continuous                                        |         |     |  |
| Units: years                                          |         |     |  |
| arithmetic mean                                       | 40.3    |     |  |
| standard deviation                                    | ± 12.80 | -   |  |
| Gender Categorical                                    |         |     |  |
| Units: Subjects                                       |         |     |  |
| Male                                                  | 25      | 182 |  |
| Female                                                | 22      | 135 |  |
| Race                                                  |         |     |  |
| Units: Subjects                                       |         |     |  |
| White                                                 | 45      | 295 |  |
| Black or African American                             | 1       | 6   |  |
| Asian                                                 | 0       | 11  |  |
| Other                                                 | 1       | 5   |  |
| Ethnicity                                             |         |     |  |
| Units: Subjects                                       |         |     |  |
| Hispanic or Latino                                    | 2       | 6   |  |
| Not Hispanic or Latino                                | 45      | 311 |  |

## End points

### End points reporting groups

|                                                                                                                                                                  |                                         |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|
| Reporting group title                                                                                                                                            | Placebo (Induction: 0 to 8 weeks)       |
| Reporting group description:<br>The placebo was administered orally once daily (QD) from Day 1 to Week 8.                                                        |                                         |
| Reporting group title                                                                                                                                            | PF-06651600 20 mg (Induction)           |
| Reporting group description:<br>PF-06651600 tablet was administered orally at 20 mg QD from Day 1 to Week 8.                                                     |                                         |
| Reporting group title                                                                                                                                            | PF-06651600 70 mg (Induction)           |
| Reporting group description:<br>PF-06651600 tablet was administered orally at 70 mg QD from Day 1 to Week 8.                                                     |                                         |
| Reporting group title                                                                                                                                            | PF-06651600 200 mg (Induction)          |
| Reporting group description:<br>PF-06651600 tablet was administered orally at 200 mg QD from Day 1 to Week 8.                                                    |                                         |
| Reporting group title                                                                                                                                            | PF-06700841 10 mg (Induction)           |
| Reporting group description:<br>PF-06700841 tablet was administered orally at 10 mg QD from Day 1 to Week 8.                                                     |                                         |
| Reporting group title                                                                                                                                            | PF-06700841 30 mg (Induction)           |
| Reporting group description:<br>PF-06700841 tablet was administered orally at 30 mg QD from Day 1 to Week 8.                                                     |                                         |
| Reporting group title                                                                                                                                            | PF-06700841 60 mg (Induction)           |
| Reporting group description:<br>PF-06700841 tablet was administered orally at 60 mg QD from Day 1 to Week 8.                                                     |                                         |
| Reporting group title                                                                                                                                            | PF-06651600 200 mg -> PF-06651600 50 mg |
| Reporting group description:<br>PF-06651600 tablet was administered orally at 200 mg QD from Day 1 to Week 8 and at 50 mg QD from Week 9 to Week 32.             |                                         |
| Reporting group title                                                                                                                                            | PF-06651600 70 mg -> PF-06651600 50 mg  |
| Reporting group description:<br>PF-06651600 tablet was administered orally at 70 mg QD from Day 1 to Week 8 and at 50 mg QD from Week 9 to Week 32.              |                                         |
| Reporting group title                                                                                                                                            | PF-06651600 20 mg -> PF-06651600 50 mg  |
| Reporting group description:<br>PF-06651600 tablet was administered orally at 20 mg QD from Day 1 to Week 8 and at 50 mg QD from Week 9 to Week 32.              |                                         |
| Reporting group title                                                                                                                                            | Placebo -> PF-06651600 50 mg            |
| Reporting group description:<br>The placebo was administered orally QD from Day 1 to Week 8 and PF-06651600 was administered at 50 mg QD from Week 9 to Week 32. |                                         |
| Reporting group title                                                                                                                                            | PF-06700841 60 mg -> PF-06700841 30 mg  |
| Reporting group description:<br>PF-06700841 tablet was administered orally at 60 mg QD from Day 1 to Week 8 and at 30 mg QD from Week 9 to Week 32.              |                                         |
| Reporting group title                                                                                                                                            | PF-06700841 30 mg -> PF-06700841 30 mg  |
| Reporting group description:<br>PF-06700841 tablet was administered orally at 30 mg QD from Day 1 to Week 8 and at 30 mg QD from Week 9 to Week 32.              |                                         |
| Reporting group title                                                                                                                                            | PF-06700841 10 mg -> PF-06700841 30 mg  |
| Reporting group description:<br>PF-06700841 tablet was administered orally at 10 mg QD from Day 1 to Week 8 and at 30 mg QD from Week 9 to Week 32.              |                                         |
| Reporting group title                                                                                                                                            | Placebo -> PF-06700841 30 mg            |

Reporting group description:

The placebo was administered orally from Day 1 to Week 8 and PF-06700841 was administered orally at 30 mg QD from Week 9 to Week 32.

|                       |                                |
|-----------------------|--------------------------------|
| Reporting group title | Pooling Placebo During Chronic |
|-----------------------|--------------------------------|

Reporting group description:

The placebo was administered orally QD from Week 9 to Week 32 regardless of what was administered from Day 1 to Week 8.

|                            |                                                 |
|----------------------------|-------------------------------------------------|
| Subject analysis set title | mITT Analysis Set: Placebo -> PF-06651600 50 mg |
|----------------------------|-------------------------------------------------|

|                           |                             |
|---------------------------|-----------------------------|
| Subject analysis set type | Modified intention-to-treat |
|---------------------------|-----------------------------|

Subject analysis set description:

The placebo was administered orally from Day 1 to Week 8 and PF-06651600 at 50 mg QD from Week 9 to Week 32.

|                            |                                                           |
|----------------------------|-----------------------------------------------------------|
| Subject analysis set title | mITT Analysis Set: PF-06651600 20 mg -> PF-06651600 50 mg |
|----------------------------|-----------------------------------------------------------|

|                           |                             |
|---------------------------|-----------------------------|
| Subject analysis set type | Modified intention-to-treat |
|---------------------------|-----------------------------|

Subject analysis set description:

PF-06651600 tablet was administered orally at 20 mg QD from Day 1 to Week 8 and at 50 mg QD from Week 9 to Week 32.

|                            |                                                           |
|----------------------------|-----------------------------------------------------------|
| Subject analysis set title | mITT Analysis Set: PF-06651600 70 mg -> PF-06651600 50 mg |
|----------------------------|-----------------------------------------------------------|

|                           |                             |
|---------------------------|-----------------------------|
| Subject analysis set type | Modified intention-to-treat |
|---------------------------|-----------------------------|

Subject analysis set description:

PF-06651600 tablet was administered orally at 70 mg QD from Day 1 to Week 8 and at 50 mg QD from Week 9 to Week 32.

|                            |                                                            |
|----------------------------|------------------------------------------------------------|
| Subject analysis set title | mITT Analysis Set: PF-06651600 200 mg -> PF-06651600 50 mg |
|----------------------------|------------------------------------------------------------|

|                           |                             |
|---------------------------|-----------------------------|
| Subject analysis set type | Modified intention-to-treat |
|---------------------------|-----------------------------|

Subject analysis set description:

PF-06651600 tablet was administered orally at 200 mg QD from Day 1 to Week 9 and at 50 mg QD from Week 9 to Week 32.

|                            |                                                 |
|----------------------------|-------------------------------------------------|
| Subject analysis set title | mITT Analysis Set: Placebo -> PF-06700841 30 mg |
|----------------------------|-------------------------------------------------|

|                           |                             |
|---------------------------|-----------------------------|
| Subject analysis set type | Modified intention-to-treat |
|---------------------------|-----------------------------|

Subject analysis set description:

The placebo was administered orally from Day 1 to Week 8 and PF-06700841 was administered orally at 30 mg QD from Week 9 to Week 32.

|                            |                                                           |
|----------------------------|-----------------------------------------------------------|
| Subject analysis set title | mITT Analysis Set: PF-06700841 10 mg -> PF-06700841 30 mg |
|----------------------------|-----------------------------------------------------------|

|                           |                             |
|---------------------------|-----------------------------|
| Subject analysis set type | Modified intention-to-treat |
|---------------------------|-----------------------------|

Subject analysis set description:

PF-06700841 tablet was administered orally at 10 mg QD from Day 1 to Week 8 and at 30 mg QD from Week 9 to Week 32.

|                            |                                                           |
|----------------------------|-----------------------------------------------------------|
| Subject analysis set title | mITT Analysis Set: PF-06700841 30 mg -> PF-06700841 30 mg |
|----------------------------|-----------------------------------------------------------|

|                           |                             |
|---------------------------|-----------------------------|
| Subject analysis set type | Modified intention-to-treat |
|---------------------------|-----------------------------|

Subject analysis set description:

PF-06700841 tablet was administered orally at 30 mg QD from Day 1 to Week 8 and at 30 mg QD from Week 9 to Week 32.

|                            |                                                           |
|----------------------------|-----------------------------------------------------------|
| Subject analysis set title | mITT Analysis Set: PF-06700841 60 mg -> PF-06700841 30 mg |
|----------------------------|-----------------------------------------------------------|

|                           |                             |
|---------------------------|-----------------------------|
| Subject analysis set type | Modified intention-to-treat |
|---------------------------|-----------------------------|

Subject analysis set description:

PF-06700841 tablet was administered orally at 60 mg QD from Day 1 to Week 8 and at 30 mg QD from Week 9 to Week 32.

**Primary: Induction Period: Total Mayo Score at Week 8**

|                                                                                                                                                                                                                                                                         |                                              |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------|
| End point title                                                                                                                                                                                                                                                         | Induction Period: Total Mayo Score at Week 8 |
| End point description:                                                                                                                                                                                                                                                  |                                              |
| The Mayo score ranges from 0 to 12, with higher scores indicating more severe disease. The intent-to-treat (ITT) analysis set was used to analyze this endpoint, defined as all randomized subjects who received at least 1 dose of investigational product or placebo. |                                              |
| End point type                                                                                                                                                                                                                                                          | Primary                                      |
| End point timeframe:                                                                                                                                                                                                                                                    |                                              |
| Week 8                                                                                                                                                                                                                                                                  |                                              |

| End point values                             | Placebo<br>(Induction: 0 to 8 weeks) | PF-06651600<br>20 mg<br>(Induction) | PF-06651600<br>70 mg<br>(Induction) | PF-06651600<br>200 mg<br>(Induction) |
|----------------------------------------------|--------------------------------------|-------------------------------------|-------------------------------------|--------------------------------------|
| Subject group type                           | Reporting group                      | Reporting group                     | Reporting group                     | Reporting group                      |
| Number of subjects analysed                  | 25                                   | 51                                  | 49                                  | 50                                   |
| Units: Unit on a scale                       |                                      |                                     |                                     |                                      |
| least squares mean (confidence interval 90%) | 7.88 (6.95 to 8.81)                  | 5.85 (5.18 to 6.51)                 | 4.00 (3.33 to 4.67)                 | 3.27 (2.58 to 3.96)                  |

| End point values                             | PF-06700841<br>10 mg<br>(Induction) | PF-06700841<br>30 mg<br>(Induction) | PF-06700841<br>60 mg<br>(Induction) |  |
|----------------------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|--|
| Subject group type                           | Reporting group                     | Reporting group                     | Reporting group                     |  |
| Number of subjects analysed                  | 48                                  | 47                                  | 47                                  |  |
| Units: Unit on a scale                       |                                     |                                     |                                     |  |
| least squares mean (confidence interval 90%) | 6.08 (5.43 to 6.74)                 | 5.60 (4.93 to 6.27)                 | 4.67 (4.01 to 5.33)                 |  |

**Statistical analyses**

|                                         |                                                                   |
|-----------------------------------------|-------------------------------------------------------------------|
| <b>Statistical analysis title</b>       | Placebo, PF-06651600 20 mg                                        |
| Comparison groups                       | Placebo (Induction: 0 to 8 weeks) v PF-06651600 20 mg (Induction) |
| Number of subjects included in analysis | 76                                                                |
| Analysis specification                  | Pre-specified                                                     |
| Analysis type                           | superiority                                                       |
| P-value                                 | = 0.0017                                                          |
| Method                                  | Constrained Longitudinal Data Analysis                            |
| Parameter estimate                      | Mean difference (final values)                                    |
| Point estimate                          | -2.03                                                             |
| Confidence interval                     |                                                                   |
| level                                   | 90 %                                                              |
| sides                                   | 2-sided                                                           |
| lower limit                             | -3.17                                                             |
| upper limit                             | -0.89                                                             |



|                      |                            |
|----------------------|----------------------------|
| Variability estimate | Standard error of the mean |
| Dispersion value     | 0.69                       |

|                                         |                                                                   |
|-----------------------------------------|-------------------------------------------------------------------|
| <b>Statistical analysis title</b>       | Placebo, PF-06651600 70 mg                                        |
| Comparison groups                       | Placebo (Induction: 0 to 8 weeks) v PF-06651600 70 mg (Induction) |
| Number of subjects included in analysis | 74                                                                |
| Analysis specification                  | Pre-specified                                                     |
| Analysis type                           | superiority                                                       |
| P-value                                 | < 0.0001                                                          |
| Method                                  | Constrained Longitudinal Data Analysis                            |
| Parameter estimate                      | Mean difference (final values)                                    |
| Point estimate                          | -3.88                                                             |
| Confidence interval                     |                                                                   |
| level                                   | 90 %                                                              |
| sides                                   | 2-sided                                                           |
| lower limit                             | -5.01                                                             |
| upper limit                             | -2.74                                                             |
| Variability estimate                    | Standard error of the mean                                        |
| Dispersion value                        | 0.69                                                              |

|                                         |                                                                    |
|-----------------------------------------|--------------------------------------------------------------------|
| <b>Statistical analysis title</b>       | Placebo, PF-06651600 200 mg                                        |
| Comparison groups                       | Placebo (Induction: 0 to 8 weeks) v PF-06651600 200 mg (Induction) |
| Number of subjects included in analysis | 75                                                                 |
| Analysis specification                  | Pre-specified                                                      |
| Analysis type                           | superiority                                                        |
| P-value                                 | < 0.0001                                                           |
| Method                                  | Constrained Longitudinal Data Analysis                             |
| Parameter estimate                      | Mean difference (final values)                                     |
| Point estimate                          | -4.61                                                              |
| Confidence interval                     |                                                                    |
| level                                   | 90 %                                                               |
| sides                                   | 2-sided                                                            |
| lower limit                             | -5.76                                                              |
| upper limit                             | -3.46                                                              |
| Variability estimate                    | Standard error of the mean                                         |
| Dispersion value                        | 0.7                                                                |

|                                   |                                                                   |
|-----------------------------------|-------------------------------------------------------------------|
| <b>Statistical analysis title</b> | Placebo, PF-06700841 10 mg                                        |
| Comparison groups                 | Placebo (Induction: 0 to 8 weeks) v PF-06700841 10 mg (Induction) |

|                                         |                                        |
|-----------------------------------------|----------------------------------------|
| Number of subjects included in analysis | 73                                     |
| Analysis specification                  | Pre-specified                          |
| Analysis type                           | superiority                            |
| P-value                                 | = 0.0045                               |
| Method                                  | Constrained Longitudinal Data Analysis |
| Parameter estimate                      | Mean difference (final values)         |
| Point estimate                          | -1.79                                  |
| Confidence interval                     |                                        |
| level                                   | 90 %                                   |
| sides                                   | 2-sided                                |
| lower limit                             | -2.92                                  |
| upper limit                             | -0.67                                  |
| Variability estimate                    | Standard error of the mean             |
| Dispersion value                        | 0.68                                   |

|                                         |                                                                   |
|-----------------------------------------|-------------------------------------------------------------------|
| <b>Statistical analysis title</b>       | Placebo, PF-06700841 30 mg                                        |
| Comparison groups                       | Placebo (Induction: 0 to 8 weeks) v PF-06700841 30 mg (Induction) |
| Number of subjects included in analysis | 72                                                                |
| Analysis specification                  | Pre-specified                                                     |
| Analysis type                           | superiority                                                       |
| P-value                                 | = 0.0005                                                          |
| Method                                  | Constrained Longitudinal Data Analysis                            |
| Parameter estimate                      | Mean difference (final values)                                    |
| Point estimate                          | -2.28                                                             |
| Confidence interval                     |                                                                   |
| level                                   | 90 %                                                              |
| sides                                   | 2-sided                                                           |
| lower limit                             | -3.41                                                             |
| upper limit                             | -1.14                                                             |
| Variability estimate                    | Standard error of the mean                                        |
| Dispersion value                        | 0.69                                                              |

|                                         |                                                                   |
|-----------------------------------------|-------------------------------------------------------------------|
| <b>Statistical analysis title</b>       | Placebo, PF-06700841 60 mg                                        |
| Comparison groups                       | Placebo (Induction: 0 to 8 weeks) v PF-06700841 60 mg (Induction) |
| Number of subjects included in analysis | 72                                                                |
| Analysis specification                  | Pre-specified                                                     |
| Analysis type                           | superiority                                                       |
| P-value                                 | < 0.0001                                                          |
| Method                                  | Constrained Longitudinal Data Analysis                            |
| Parameter estimate                      | Mean difference (final values)                                    |
| Point estimate                          | -3.21                                                             |

|                      |                            |
|----------------------|----------------------------|
| Confidence interval  |                            |
| level                | 90 %                       |
| sides                | 2-sided                    |
| lower limit          | -4.34                      |
| upper limit          | -2.08                      |
| Variability estimate | Standard error of the mean |
| Dispersion value     | 0.69                       |

**Primary: Chronic Period: Number of subjects with Treatment-Emergent Adverse Events (AEs), Serious Adverse Events (SAEs) and with withdrawals due to adverse events**

|                 |                                                                                                                                                                          |
|-----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Chronic Period: Number of subjects with Treatment-Emergent Adverse Events (AEs), Serious Adverse Events (SAEs) and with withdrawals due to adverse events <sup>[1]</sup> |
|-----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

End point description:

An AE is any untoward medical occurrence in a study subjects administered a product or medical device; the event need not necessarily have a causal relationship with the treatment or usage. An SAE is any untoward medical occurrence at any dose that: results in death; is life threatening (immediate risk of death); requires inpatient hospitalization or prolongation of existing hospitalization; results in persistent or significant disability/incapacity (substantial disruption of the ability to conduct normal life functions); results in congenital anomaly/birth defect; or that is considered to be an important medical event that may jeopardize the subject or may require intervention to prevent one of the other AE outcomes. Treatment-emergent AEs were those with initial onset or that worsen in severity after the first dose of the study medication. All AEs in the table below were treatment-emergent AEs. All subjects who received at least one dose of the randomized study treatment.

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

End point timeframe:

Baseline of Chronic period (Week 8) to Week 36

Notes:

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

Justification: No statistical analysis was planned for this endpoint.

| End point values                            | PF-06651600<br>200 mg -> PF-<br>06651600 50<br>mg | PF-06651600<br>70 mg -> PF-<br>06651600 50<br>mg | PF-06651600<br>20 mg -> PF-<br>06651600 50<br>mg | Placebo -> PF-<br>06651600 50<br>mg |
|---------------------------------------------|---------------------------------------------------|--------------------------------------------------|--------------------------------------------------|-------------------------------------|
| Subject group type                          | Reporting group                                   | Reporting group                                  | Reporting group                                  | Reporting group                     |
| Number of subjects analysed                 | 35                                                | 36                                               | 39                                               | 10                                  |
| Units: Subjects                             |                                                   |                                                  |                                                  |                                     |
| subjects with AEs                           | 18                                                | 27                                               | 18                                               | 8                                   |
| Subjects with SAEs                          | 3                                                 | 1                                                | 1                                                | 0                                   |
| Subjects with severe adverse events         | 2                                                 | 1                                                | 3                                                | 0                                   |
| Subjects discontinued from study due to AEs | 1                                                 | 1                                                | 3                                                | 1                                   |

| End point values            | PF-06700841<br>60 mg -> PF-<br>06700841 30<br>mg | PF-06700841<br>30 mg -> PF-<br>06700841 30<br>mg | PF-06700841<br>10 mg -> PF-<br>06700841 30<br>mg | Placebo -> PF-<br>06700841 30<br>mg |
|-----------------------------|--------------------------------------------------|--------------------------------------------------|--------------------------------------------------|-------------------------------------|
| Subject group type          | Reporting group                                  | Reporting group                                  | Reporting group                                  | Reporting group                     |
| Number of subjects analysed | 38                                               | 37                                               | 39                                               | 9                                   |

|                                             |    |    |    |   |
|---------------------------------------------|----|----|----|---|
| Units: Subjects                             |    |    |    |   |
| subjects with AEs                           | 21 | 23 | 26 | 4 |
| Subjects with SAEs                          | 2  | 4  | 2  | 0 |
| Subjects with severe adverse events         | 3  | 4  | 4  | 1 |
| Subjects discontinued from study due to AEs | 1  | 4  | 1  | 1 |

|                                             |                                   |  |  |  |
|---------------------------------------------|-----------------------------------|--|--|--|
| <b>End point values</b>                     | Pooling Placebo<br>During Chronic |  |  |  |
| Subject group type                          | Reporting group                   |  |  |  |
| Number of subjects analysed                 | 37                                |  |  |  |
| Units: Subjects                             |                                   |  |  |  |
| subjects with AEs                           | 18                                |  |  |  |
| Subjects with SAEs                          | 0                                 |  |  |  |
| Subjects with severe adverse events         | 4                                 |  |  |  |
| Subjects discontinued from study due to AEs | 6                                 |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Chronic Period: Number of subjects with Laboratory Abnormalities without regard to baseline values - Hematology

|                 |                                                                                                                                |
|-----------------|--------------------------------------------------------------------------------------------------------------------------------|
| End point title | Chronic Period: Number of subjects with Laboratory Abnormalities without regard to baseline values - Hematology <sup>[2]</sup> |
|-----------------|--------------------------------------------------------------------------------------------------------------------------------|

End point description:

Following parameters were analyzed for laboratory examination: hemoglobin, hematocrit, erythrocytes, reticulocytes, ery. Mean Corpuscular Volume, platelets, Reticulocytes/Erythrocytes, Leukocytes, Lymphocytes, Neutrophils, Basophils, Eosinophils, Monocytes, Activated Partial Thromboplastin Time, Prothrombin Time, Prothrombin Intl. Normalized Ratio. The analysis population included all enrolled participants who received at least one dose of study medication.

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

End point timeframe:

Baseline of Chronic period (Week 8) to Week 36

Notes:

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

Justification: No statistical analysis was planned for this endpoint.

|                                                          |                                                   |                                                  |                                                  |                                     |
|----------------------------------------------------------|---------------------------------------------------|--------------------------------------------------|--------------------------------------------------|-------------------------------------|
| <b>End point values</b>                                  | PF-06651600<br>200 mg -> PF-<br>06651600 50<br>mg | PF-06651600<br>70 mg -> PF-<br>06651600 50<br>mg | PF-06651600<br>20 mg -> PF-<br>06651600 50<br>mg | Placebo -> PF-<br>06651600 50<br>mg |
| Subject group type                                       | Reporting group                                   | Reporting group                                  | Reporting group                                  | Reporting group                     |
| Number of subjects analysed                              | 35                                                | 35                                               | 39                                               | 10                                  |
| Units: Subjects                                          |                                                   |                                                  |                                                  |                                     |
| Hemoglobin(g/dL)<0.8x LLN                                | 2                                                 | 2                                                | 1                                                | 1                                   |
| Hematocrit(%)<0.8x LLN                                   | 0                                                 | 2                                                | 1                                                | 0                                   |
| Erythrocytes(10 <sup>6</sup> /mm <sup>3</sup> )<0.8x LLN | 0                                                 | 1                                                | 1                                                | 0                                   |

|                                                                          |   |   |    |   |
|--------------------------------------------------------------------------|---|---|----|---|
| Reticulocytes (ABSOLUTE)<br>(10 <sup>3</sup> /mm <sup>3</sup> )<0.5x LLN | 0 | 0 | 0  | 0 |
| Reticulocytes (ABSOLUTE)<br>(10 <sup>3</sup> /mm <sup>3</sup> )>1.5x ULN | 0 | 0 | 1  | 0 |
| Ery. Mean Corpuscular Volume (10 <sup>-15</sup> L)<0.9x LLN              | 0 | 0 | 1  | 0 |
| Ery. Mean Corpuscular Volume (10 <sup>-15</sup> L)>1.1x ULN              | 0 | 0 | 0  | 0 |
| Platelets (10 <sup>3</sup> /mm <sup>3</sup> )<0.5xLLN                    | 0 | 0 | 0  | 0 |
| Platelets (10 <sup>3</sup> /mm <sup>3</sup> )>1.75xULN                   | 0 | 0 | 0  | 0 |
| Reticulocytes/Erythrocytes<br>(%)<0.5xLLN                                | 0 | 0 | 0  | 0 |
| Reticulocytes/Erythrocytes<br>(%)>1.5xULN                                | 1 | 1 | 2  | 0 |
| Leukocytes (10 <sup>3</sup> /mm <sup>3</sup> )<0.6xLLN                   | 0 | 0 | 0  | 0 |
| Leukocytes (10 <sup>3</sup> /mm <sup>3</sup> )>1.5xULN                   | 0 | 0 | 1  | 1 |
| Lymphocytes (ABSOLUTE)<br>(10 <sup>3</sup> /mm <sup>3</sup> )<0.8xLLN    | 7 | 6 | 6  | 1 |
| Lymphocytes (ABSOLUTE)<br>(10 <sup>3</sup> /mm <sup>3</sup> )>1.2xULN    | 0 | 0 | 0  | 0 |
| Neutrophils (ABSOLUTE)<br>(10 <sup>3</sup> /mm <sup>3</sup> )<0.8xLLN    | 1 | 2 | 0  | 0 |
| Neutrophils (ABSOLUTE)<br>(10 <sup>3</sup> /mm <sup>3</sup> )>1.2xULN    | 3 | 8 | 11 | 1 |
| Basophils<br>(ABSOLUTE)(10 <sup>3</sup> /mm <sup>3</sup> )>1.2xULN       | 0 | 0 | 0  | 0 |
| Eosinophils (ABSOLUTE)<br>(10 <sup>3</sup> /mm <sup>3</sup> )>1.2xULN    | 0 | 0 | 0  | 0 |
| Monocytes (ABSOLUTE)<br>(10 <sup>3</sup> /mm <sup>3</sup> )>1.2xULN      | 0 | 0 | 0  | 0 |
| ActivatedPartialThromboplastinTime<br>(sec)>1.1xULN                      | 0 | 3 | 1  | 0 |
| Prothrombin Time (sec)>1.1xULN                                           | 2 | 3 | 2  | 0 |
| Prothrombin Intl. Normalized<br>Ratio>1.1xULN                            | 2 | 3 | 2  | 0 |

| End point values                                                         | PF-06700841<br>60 mg -> PF-<br>06700841 30<br>mg | PF-06700841<br>30 mg -> PF-<br>06700841 30<br>mg | PF-06700841<br>10 mg -> PF-<br>06700841 30<br>mg | Placebo -> PF-<br>06700841 30<br>mg |
|--------------------------------------------------------------------------|--------------------------------------------------|--------------------------------------------------|--------------------------------------------------|-------------------------------------|
| Subject group type                                                       | Reporting group                                  | Reporting group                                  | Reporting group                                  | Reporting group                     |
| Number of subjects analysed                                              | 38                                               | 37                                               | 39                                               | 9                                   |
| Units: Subjects                                                          |                                                  |                                                  |                                                  |                                     |
| Hemoglobin(g/dL)<0.8x LLN                                                | 3                                                | 3                                                | 6                                                | 2                                   |
| Hematocrit(%)<0.8x LLN                                                   | 1                                                | 1                                                | 1                                                | 1                                   |
| Erythrocytes(10 <sup>6</sup> /mm <sup>3</sup> )<0.8x LLN                 | 1                                                | 0                                                | 1                                                | 1                                   |
| Reticulocytes (ABSOLUTE)<br>(10 <sup>3</sup> /mm <sup>3</sup> )<0.5x LLN | 0                                                | 0                                                | 0                                                | 0                                   |
| Reticulocytes (ABSOLUTE)<br>(10 <sup>3</sup> /mm <sup>3</sup> )>1.5x ULN | 0                                                | 0                                                | 0                                                | 0                                   |
| Ery. Mean Corpuscular Volume (10 <sup>-15</sup> L)<0.9x LLN              | 0                                                | 1                                                | 0                                                | 0                                   |
| Ery. Mean Corpuscular Volume (10 <sup>-15</sup> L)>1.1x ULN              | 0                                                | 0                                                | 0                                                | 0                                   |
| Platelets (10 <sup>3</sup> /mm <sup>3</sup> )<0.5xLLN                    | 0                                                | 0                                                | 0                                                | 0                                   |
| Platelets (10 <sup>3</sup> /mm <sup>3</sup> )>1.75xULN                   | 3                                                | 1                                                | 2                                                | 0                                   |

|                                                                    |   |   |   |   |
|--------------------------------------------------------------------|---|---|---|---|
| Reticulocytes/Erythrocytes (%)<0.5xLLN                             | 0 | 0 | 0 | 0 |
| Reticulocytes/Erythrocytes (%)>1.5xULN                             | 1 | 1 | 0 | 0 |
| Leukocytes (10 <sup>3</sup> /mm <sup>3</sup> )<0.6xLLN             | 0 | 0 | 0 | 0 |
| Leukocytes (10 <sup>3</sup> /mm <sup>3</sup> )>1.5xULN             | 1 | 1 | 1 | 1 |
| Lymphocytes (ABSOLUTE) (10 <sup>3</sup> /mm <sup>3</sup> )<0.8xLLN | 0 | 0 | 3 | 0 |
| Lymphocytes (ABSOLUTE) (10 <sup>3</sup> /mm <sup>3</sup> )>1.2xULN | 0 | 0 | 0 | 1 |
| Neutrophils (ABSOLUTE) (10 <sup>3</sup> /mm <sup>3</sup> )<0.8xLLN | 3 | 1 | 2 | 1 |
| Neutrophils (ABSOLUTE) (10 <sup>3</sup> /mm <sup>3</sup> )>1.2xULN | 8 | 6 | 6 | 3 |
| Basophils (ABSOLUTE)(10 <sup>3</sup> /mm <sup>3</sup> )>1.2xULN    | 2 | 1 | 0 | 0 |
| Eosinophils (ABSOLUTE) (10 <sup>3</sup> /mm <sup>3</sup> )>1.2xULN | 2 | 1 | 0 | 0 |
| Monocytes (ABSOLUTE) (10 <sup>3</sup> /mm <sup>3</sup> )>1.2xULN   | 2 | 2 | 0 | 0 |
| ActivatedPartialThromboplastinTime (sec)>1.1xULN                   | 2 | 0 | 0 | 0 |
| Prothrombin Time (sec)>1.1xULN                                     | 2 | 2 | 0 | 0 |
| Prothrombin Intl. Normalized Ratio>1.1xULN                         | 2 | 1 | 0 | 0 |

| End point values                                                      | Pooling Placebo During Chronic |  |  |  |
|-----------------------------------------------------------------------|--------------------------------|--|--|--|
| Subject group type                                                    | Reporting group                |  |  |  |
| Number of subjects analysed                                           | 37                             |  |  |  |
| Units: Subjects                                                       |                                |  |  |  |
| Hemoglobin(g/dL)<0.8x LLN                                             | 3                              |  |  |  |
| Hematocrit(%)<0.8x LLN                                                | 2                              |  |  |  |
| Erythrocytes(10 <sup>6</sup> /mm <sup>3</sup> )<0.8x LLN              | 1                              |  |  |  |
| Reticulocytes (ABSOLUTE) (10 <sup>3</sup> /mm <sup>3</sup> )<0.5x LLN | 0                              |  |  |  |
| Reticulocytes (ABSOLUTE) (10 <sup>3</sup> /mm <sup>3</sup> )>1.5x ULN | 0                              |  |  |  |
| Ery. Mean Corpuscular Volume (10 <sup>-15</sup> L)<0.9x LLN           | 0                              |  |  |  |
| Ery. Mean Corpuscular Volume (10 <sup>-15</sup> L)>1.1x ULN           | 0                              |  |  |  |
| Platelets (10 <sup>3</sup> /mm <sup>3</sup> )<0.5xLLN                 | 0                              |  |  |  |
| Platelets (10 <sup>3</sup> /mm <sup>3</sup> )>1.75xULN                | 2                              |  |  |  |
| Reticulocytes/Erythrocytes (%)<0.5xLLN                                | 0                              |  |  |  |
| Reticulocytes/Erythrocytes (%)>1.5xULN                                | 1                              |  |  |  |
| Leukocytes (10 <sup>3</sup> /mm <sup>3</sup> )<0.6xLLN                | 0                              |  |  |  |
| Leukocytes (10 <sup>3</sup> /mm <sup>3</sup> )>1.5xULN                | 1                              |  |  |  |
| Lymphocytes (ABSOLUTE) (10 <sup>3</sup> /mm <sup>3</sup> )<0.8xLLN    | 3                              |  |  |  |
| Lymphocytes (ABSOLUTE) (10 <sup>3</sup> /mm <sup>3</sup> )>1.2xULN    | 0                              |  |  |  |
| Neutrophils (ABSOLUTE) (10 <sup>3</sup> /mm <sup>3</sup> )<0.8xLLN    | 1                              |  |  |  |

|                                                                       |   |  |  |  |
|-----------------------------------------------------------------------|---|--|--|--|
| Neutrophils (ABSOLUTE)<br>(10 <sup>3</sup> /mm <sup>3</sup> )>1.2xULN | 6 |  |  |  |
| Basophils<br>(ABSOLUTE)(10 <sup>3</sup> /mm <sup>3</sup> )>1.2xULN    | 1 |  |  |  |
| Eosinophils (ABSOLUTE)<br>(10 <sup>3</sup> /mm <sup>3</sup> )>1.2xULN | 2 |  |  |  |
| Monocytes (ABSOLUTE)<br>(10 <sup>3</sup> /mm <sup>3</sup> )>1.2xULN   | 0 |  |  |  |
| ActivatedPartialThromboplastinTime<br>(sec)>1.1xULN                   | 0 |  |  |  |
| Prothrombin Time (sec)>1.1xULN                                        | 0 |  |  |  |
| Prothrombin Intl. Normalized<br>Ratio>1.1xULN                         | 0 |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Primary: Chronic Period: Number of subjects with Laboratory Abnormalities without regard to baseline values - Clinical Chemistry

|                 |                                                                                                                                        |
|-----------------|----------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Chronic Period: Number of subjects with Laboratory Abnormalities without regard to baseline values - Clinical Chemistry <sup>[3]</sup> |
|-----------------|----------------------------------------------------------------------------------------------------------------------------------------|

End point description:

Following parameters were analyzed for laboratory examination: Bilirubin, Direct Bilirubin, Indirect Bilirubin, Aspartate Aminotransferase, Alanine Aminotransferase, Gamma Glutamyl Transferase, Alkaline Phosphatase, Protein, Albumin, Urea Nitrogen, Creatinine, Urate, HDL Cholesterol, LDL Cholesterol, Triglycerides, Sodium, Potassium, Chloride, Calcium, Glucose, Hemoglobin A1C, Creatine Kinase, Cholesterol. The analysis population included all enrolled participants who received at least one dose of study medication.

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

End point timeframe:

Baseline of Chronic period (Week 8) to Week 36

Notes:

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

Justification: No statistical analysis was planned for this endpoint.

| End point values                             | PF-06651600<br>200 mg -> PF-<br>06651600 50<br>mg | PF-06651600<br>70 mg -> PF-<br>06651600 50<br>mg | PF-06651600<br>20 mg -> PF-<br>06651600 50<br>mg | Placebo -> PF-<br>06651600 50<br>mg |
|----------------------------------------------|---------------------------------------------------|--------------------------------------------------|--------------------------------------------------|-------------------------------------|
| Subject group type                           | Reporting group                                   | Reporting group                                  | Reporting group                                  | Reporting group                     |
| Number of subjects analysed                  | 35                                                | 35                                               | 39                                               | 10                                  |
| Units: Subjects                              |                                                   |                                                  |                                                  |                                     |
| Bilirubin (mg/dL)>1.5x ULN                   | 1                                                 | 0                                                | 1                                                | 0                                   |
| Direct Bilirubin (mg/dL)>1.5x ULN            | 0                                                 | 0                                                | 0                                                | 0                                   |
| Indirect Bilirubin (mg/dL)>1.5x ULN          | 0                                                 | 0                                                | 0                                                | 0                                   |
| Aspartate Aminotransferase (U/L)>3.0x<br>ULN | 0                                                 | 0                                                | 2                                                | 0                                   |
| Alanine Aminotransferase (U/L)>3.0x<br>ULN   | 1                                                 | 0                                                | 1                                                | 0                                   |
| Gamma Glutamyl Transferase<br>(U/L)>3.0x ULN | 0                                                 | 0                                                | 0                                                | 0                                   |
| Alkaline Phosphatase (U/L)>3.0x ULN          | 0                                                 | 0                                                | 1                                                | 0                                   |
| Protein (g/dL)<0.8x LLN                      | 0                                                 | 0                                                | 0                                                | 0                                   |

|                                  |   |   |   |   |
|----------------------------------|---|---|---|---|
| Protein (g/dL)>1.2x ULN          | 0 | 0 | 0 | 0 |
| Albumin (g/dL)<0.8x LLN          | 0 | 0 | 0 | 0 |
| Albumin (g/dL)>1.2x ULN          | 0 | 0 | 0 | 0 |
| Urea Nitrogen (mg/dL)>1.3x ULN   | 0 | 1 | 0 | 0 |
| Creatinine (mg/dL)>1.3x ULN      | 0 | 1 | 0 | 0 |
| Urate (mg/dL)>1.2x ULN           | 0 | 2 | 0 | 0 |
| HDL Cholesterol (mg/dL)<0.8x LLN | 1 | 0 | 0 | 0 |
| LDL Cholesterol (mg/dL)>1.2x ULN | 1 | 1 | 0 | 0 |
| Triglycerides (mg/dL)>1.3x ULN   | 3 | 2 | 1 | 0 |
| Sodium (Meq/L)<0.95x LLN         | 0 | 0 | 0 | 0 |
| Sodium (Meq/L)>1.05x ULN         | 0 | 0 | 0 | 0 |
| Potassium (Meq/L)<0.9x LLN       | 0 | 0 | 0 | 0 |
| Potassium (Meq/L)>1.1x ULN       | 1 | 0 | 0 | 0 |
| Chloride (Meq/L)<0.9x LLN        | 0 | 0 | 0 | 0 |
| Chloride (Meq/L)>1.1x ULN        | 0 | 0 | 0 | 0 |
| Calcium (mg/dL)<0.9x LLN         | 0 | 0 | 0 | 0 |
| Calcium (mg/dL)>1.1x ULN         | 0 | 0 | 0 | 0 |
| Glucose (mg/dL)<0.6x LLN         | 0 | 0 | 0 | 0 |
| Glucose (mg/dL)>1.5x ULN         | 1 | 3 | 3 | 0 |
| Hemoglobin A1C (%)>1.3x ULN      | 0 | 0 | 0 | 0 |
| Creatine Kinase (U/L)>2.0x ULN   | 1 | 3 | 2 | 1 |
| Cholesterol (mg/dl)>1.3x ULN     | 0 | 1 | 0 | 0 |

| <b>End point values</b>                   | PF-06700841<br>60 mg -> PF-<br>06700841 30<br>mg | PF-06700841<br>30 mg -> PF-<br>06700841 30<br>mg | PF-06700841<br>10 mg -> PF-<br>06700841 30<br>mg | Placebo -> PF-<br>06700841 30<br>mg |
|-------------------------------------------|--------------------------------------------------|--------------------------------------------------|--------------------------------------------------|-------------------------------------|
| Subject group type                        | Reporting group                                  | Reporting group                                  | Reporting group                                  | Reporting group                     |
| Number of subjects analysed               | 38                                               | 37                                               | 39                                               | 9                                   |
| Units: Subjects                           |                                                  |                                                  |                                                  |                                     |
| Bilirubin (mg/dL)>1.5x ULN                | 1                                                | 0                                                | 1                                                | 0                                   |
| Direct Bilirubin (mg/dL)>1.5x ULN         | 0                                                | 0                                                | 0                                                | 0                                   |
| Indirect Bilirubin (mg/dL)>1.5x ULN       | 0                                                | 0                                                | 0                                                | 0                                   |
| Aspartate Aminotransferase (U/L)>3.0x ULN | 0                                                | 0                                                | 0                                                | 0                                   |
| Alanine Aminotransferase (U/L)>3.0x ULN   | 0                                                | 0                                                | 2                                                | 0                                   |
| Gamma Glutamyl Transferase (U/L)>3.0x ULN | 0                                                | 0                                                | 0                                                | 0                                   |
| Alkaline Phosphatase (U/L)>3.0x ULN       | 0                                                | 0                                                | 0                                                | 0                                   |
| Protein (g/dL)<0.8x LLN                   | 0                                                | 0                                                | 0                                                | 0                                   |
| Protein (g/dL)>1.2x ULN                   | 0                                                | 0                                                | 0                                                | 0                                   |
| Albumin (g/dL)<0.8x LLN                   | 0                                                | 0                                                | 0                                                | 0                                   |
| Albumin (g/dL)>1.2x ULN                   | 0                                                | 0                                                | 0                                                | 0                                   |
| Urea Nitrogen (mg/dL)>1.3x ULN            | 0                                                | 0                                                | 0                                                | 0                                   |
| Creatinine (mg/dL)>1.3x ULN               | 0                                                | 1                                                | 1                                                | 0                                   |
| Urate (mg/dL)>1.2x ULN                    | 0                                                | 1                                                | 1                                                | 0                                   |
| HDL Cholesterol (mg/dL)<0.8x LLN          | 0                                                | 0                                                | 1                                                | 0                                   |
| LDL Cholesterol (mg/dL)>1.2x ULN          | 1                                                | 0                                                | 2                                                | 1                                   |
| Triglycerides (mg/dL)>1.3x ULN            | 2                                                | 2                                                | 1                                                | 0                                   |
| Sodium (Meq/L)<0.95x LLN                  | 0                                                | 0                                                | 0                                                | 0                                   |



|                                |   |    |   |   |
|--------------------------------|---|----|---|---|
| Sodium (Meq/L)>1.05x ULN       | 0 | 0  | 0 | 0 |
| Potassium (Meq/L)<0.9x LLN     | 0 | 1  | 0 | 0 |
| Potassium (Meq/L)>1.1x ULN     | 2 | 0  | 0 | 0 |
| Chloride (Meq/L)<0.9x LLN      | 0 | 0  | 0 | 0 |
| Chloride (Meq/L)>1.1x ULN      | 0 | 0  | 0 | 0 |
| Calcium (mg/dL)<0.9x LLN       | 0 | 1  | 0 | 0 |
| Calcium (mg/dL)>1.1x ULN       | 0 | 0  | 0 | 0 |
| Glucose (mg/dL)<0.6x LLN       | 0 | 0  | 0 | 0 |
| Glucose (mg/dL)>1.5x ULN       | 1 | 2  | 0 | 0 |
| Hemoglobin A1C (%)>1.3x ULN    | 0 | 0  | 0 | 0 |
| Creatine Kinase (U/L)>2.0x ULN | 3 | 10 | 2 | 0 |
| Cholesterol (mg/dl)>1.3x ULN   | 0 | 0  | 1 | 0 |

| End point values                          | Pooling Placebo<br>During Chronic |  |  |  |
|-------------------------------------------|-----------------------------------|--|--|--|
| Subject group type                        | Reporting group                   |  |  |  |
| Number of subjects analysed               | 37                                |  |  |  |
| Units: Subjects                           |                                   |  |  |  |
| Bilirubin (mg/dL)>1.5x ULN                | 1                                 |  |  |  |
| Direct Bilirubin (mg/dL)>1.5x ULN         | 0                                 |  |  |  |
| Indirect Bilirubin (mg/dL)>1.5x ULN       | 0                                 |  |  |  |
| Aspartate Aminotransferase (U/L)>3.0x ULN | 0                                 |  |  |  |
| Alanine Aminotransferase (U/L)>3.0x ULN   | 0                                 |  |  |  |
| Gamma Glutamyl Transferase (U/L)>3.0x ULN | 0                                 |  |  |  |
| Alkaline Phosphatase (U/L)>3.0x ULN       | 0                                 |  |  |  |
| Protein (g/dL)<0.8x LLN                   | 0                                 |  |  |  |
| Protein (g/dL)>1.2x ULN                   | 0                                 |  |  |  |
| Albumin (g/dL)<0.8x LLN                   | 0                                 |  |  |  |
| Albumin (g/dL)>1.2x ULN                   | 0                                 |  |  |  |
| Urea Nitrogen (mg/dL)>1.3x ULN            | 0                                 |  |  |  |
| Creatinine (mg/dL)>1.3x ULN               | 0                                 |  |  |  |
| Urate (mg/dL)>1.2x ULN                    | 0                                 |  |  |  |
| HDL Cholesterol (mg/dL)<0.8x LLN          | 0                                 |  |  |  |
| LDL Cholesterol (mg/dL)>1.2x ULN          | 0                                 |  |  |  |
| Triglycerides (mg/dL)>1.3x ULN            | 1                                 |  |  |  |
| Sodium (Meq/L)<0.95x LLN                  | 0                                 |  |  |  |
| Sodium (Meq/L)>1.05x ULN                  | 0                                 |  |  |  |
| Potassium (Meq/L)<0.9x LLN                | 0                                 |  |  |  |
| Potassium (Meq/L)>1.1x ULN                | 0                                 |  |  |  |
| Chloride (Meq/L)<0.9x LLN                 | 0                                 |  |  |  |
| Chloride (Meq/L)>1.1x ULN                 | 0                                 |  |  |  |
| Calcium (mg/dL)<0.9x LLN                  | 0                                 |  |  |  |
| Calcium (mg/dL)>1.1x ULN                  | 0                                 |  |  |  |
| Glucose (mg/dL)<0.6x LLN                  | 0                                 |  |  |  |
| Glucose (mg/dL)>1.5x ULN                  | 0                                 |  |  |  |
| Hemoglobin A1C (%)>1.3x ULN               | 0                                 |  |  |  |
| Creatine Kinase (U/L)>2.0x ULN            | 1                                 |  |  |  |

|                              |   |  |  |  |
|------------------------------|---|--|--|--|
| Cholesterol (mg/dl)>1.3x ULN | 0 |  |  |  |
|------------------------------|---|--|--|--|

## Statistical analyses

No statistical analyses for this end point

### Primary: Chronic Period: Number of subjects with Laboratory Abnormalities without regard to baseline values - Urinalysis

|                 |                                                                                                                                |
|-----------------|--------------------------------------------------------------------------------------------------------------------------------|
| End point title | Chronic Period: Number of subjects with Laboratory Abnormalities without regard to baseline values - Urinalysis <sup>[4]</sup> |
|-----------------|--------------------------------------------------------------------------------------------------------------------------------|

End point description:

Following parameters were analyzed for laboratory examination: pH, URINE Glucose, Ketones, URINE Protein, URINE Hemoglobin, Nitrite, Leukocyte Esterase, URINE Erythrocytes, URINE Leukocytes, Hyaline Casts, WBC Casts, Bacteria. The analysis population included all enrolled participants who received at least one dose of study medication.

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

End point timeframe:

Baseline of Chronic period (Week 8) to Week 36

Notes:

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

Justification: No statistical analysis was planned for this endpoint.

| End point values                | PF-06651600<br>200 mg -> PF-<br>06651600 50<br>mg | PF-06651600<br>70 mg -> PF-<br>06651600 50<br>mg | PF-06651600<br>20 mg -> PF-<br>06651600 50<br>mg | Placebo -> PF-<br>06651600 50<br>mg |
|---------------------------------|---------------------------------------------------|--------------------------------------------------|--------------------------------------------------|-------------------------------------|
| Subject group type              | Reporting group                                   | Reporting group                                  | Reporting group                                  | Reporting group                     |
| Number of subjects analysed     | 35                                                | 36                                               | 39                                               | 10                                  |
| Units: Subjects                 |                                                   |                                                  |                                                  |                                     |
| pH (scalar)<4.5                 | 0                                                 | 0                                                | 0                                                | 0                                   |
| pH (scalar)>8                   | 0                                                 | 0                                                | 0                                                | 0                                   |
| URINE Glucose (No Unit)>=1      | 1                                                 | 2                                                | 1                                                | 1                                   |
| Ketones (No Unit)>=1            | 4                                                 | 3                                                | 8                                                | 2                                   |
| URINE Protein (No Unit)>=1      | 0                                                 | 1                                                | 3                                                | 0                                   |
| URINE Hemoglobin (No Unit)>=1   | 7                                                 | 4                                                | 5                                                | 1                                   |
| Nitrite (No Unit)>=1            | 2                                                 | 2                                                | 0                                                | 2                                   |
| Leukocyte Esterase (No Unit)>=1 | 8                                                 | 13                                               | 11                                               | 1                                   |
| URINE Erythrocytes (/HPF)>=20   | 1                                                 | 1                                                | 4                                                | 1                                   |
| URINE Leukocytes (/HPF)>=20     | 0                                                 | 2                                                | 3                                                | 1                                   |
| Hyaline Casts (/LPF)>1          | 5                                                 | 0                                                | 6                                                | 2                                   |
| WBC Casts (/LPF)>1              | 0                                                 | 0                                                | 0                                                | 0                                   |
| Bacteria (No Unit)>20           | 0                                                 | 0                                                | 0                                                | 0                                   |

| End point values | PF-06700841<br>60 mg -> PF-<br>06700841 30<br>mg | PF-06700841<br>30 mg -> PF-<br>06700841 30<br>mg | PF-06700841<br>10 mg -> PF-<br>06700841 30<br>mg | Placebo -> PF-<br>06700841 30<br>mg |
|------------------|--------------------------------------------------|--------------------------------------------------|--------------------------------------------------|-------------------------------------|
|------------------|--------------------------------------------------|--------------------------------------------------|--------------------------------------------------|-------------------------------------|

| Subject group type              | Reporting group | Reporting group | Reporting group | Reporting group |
|---------------------------------|-----------------|-----------------|-----------------|-----------------|
| Number of subjects analysed     | 38              | 37              | 39              | 9               |
| Units: Subjects                 |                 |                 |                 |                 |
| pH (scalar)<4.5                 | 0               | 0               | 0               | 0               |
| pH (scalar)>8                   | 0               | 0               | 0               | 0               |
| URINE Glucose (No Unit)>=1      | 1               | 1               | 0               | 0               |
| Ketones (No Unit)>=1            | 4               | 1               | 3               | 0               |
| URINE Protein (No Unit)>=1      | 1               | 0               | 2               | 0               |
| URINE Hemoglobin (No Unit)>=1   | 7               | 9               | 9               | 0               |
| Nitrite (No Unit)>=1            | 1               | 1               | 1               | 0               |
| Leukocyte Esterase (No Unit)>=1 | 14              | 7               | 8               | 1               |
| URINE Erythrocytes (/HPF)>=20   | 2               | 3               | 5               | 0               |
| URINE Leukocytes (/HPF)>=20     | 3               | 1               | 1               | 0               |
| Hyaline Casts (/LPF)>1          | 4               | 1               | 2               | 1               |
| WBC Casts (/LPF)>1              | 0               | 0               | 0               | 0               |
| Bacteria (No Unit)>20           | 0               | 0               | 1               | 0               |

| End point values                | Pooling Placebo<br>During Chronic |  |  |  |
|---------------------------------|-----------------------------------|--|--|--|
| Subject group type              | Reporting group                   |  |  |  |
| Number of subjects analysed     | 37                                |  |  |  |
| Units: Subjects                 |                                   |  |  |  |
| pH (scalar)<4.5                 | 0                                 |  |  |  |
| pH (scalar)>8                   | 0                                 |  |  |  |
| URINE Glucose (No Unit)>=1      | 1                                 |  |  |  |
| Ketones (No Unit)>=1            | 2                                 |  |  |  |
| URINE Protein (No Unit)>=1      | 1                                 |  |  |  |
| URINE Hemoglobin (No Unit)>=1   | 9                                 |  |  |  |
| Nitrite (No Unit)>=1            | 1                                 |  |  |  |
| Leukocyte Esterase (No Unit)>=1 | 9                                 |  |  |  |
| URINE Erythrocytes (/HPF)>=20   | 1                                 |  |  |  |
| URINE Leukocytes (/HPF)>=20     | 4                                 |  |  |  |
| Hyaline Casts (/LPF)>1          | 2                                 |  |  |  |
| WBC Casts (/LPF)>1              | 1                                 |  |  |  |
| Bacteria (No Unit)>20           | 0                                 |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Primary: Chronic Period: Number of subjects with abnormal electrocardiogram findings

|                 |                                                                                            |
|-----------------|--------------------------------------------------------------------------------------------|
| End point title | Chronic Period: Number of subjects with abnormal electrocardiogram findings <sup>[5]</sup> |
|-----------------|--------------------------------------------------------------------------------------------|

End point description:

The analysis population included all enrolled participants who received at least one dose of study medication. The criteria of test abnormality is defined as one of the following conditions was met: 1)Associated with accompanying symptoms; 2)Test result requires additional diagnostic testing or

medical/surgical intervention; 3)Test result leads to a change in study dosing (outside of any protocol specified dose adjustments) or discontinuation from the study, significant additional concomitant drug treatment, or other therapy; 4)Test result is considered to be an AE by the investigator or sponsor.

|                                                |         |
|------------------------------------------------|---------|
| End point type                                 | Primary |
| End point timeframe:                           |         |
| Baseline of Chronic period (Week 8) to Week 36 |         |

Notes:

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

Justification: No statistical analysis was planned for this endpoint.

| End point values                        | PF-06651600<br>200 mg -> PF-<br>06651600 50<br>mg | PF-06651600<br>70 mg -> PF-<br>06651600 50<br>mg | PF-06651600<br>20 mg -> PF-<br>06651600 50<br>mg | Placebo -> PF-<br>06651600 50<br>mg |
|-----------------------------------------|---------------------------------------------------|--------------------------------------------------|--------------------------------------------------|-------------------------------------|
| Subject group type                      | Reporting group                                   | Reporting group                                  | Reporting group                                  | Reporting group                     |
| Number of subjects analysed             | 33                                                | 34                                               | 37                                               | 10                                  |
| Units: Subjects                         |                                                   |                                                  |                                                  |                                     |
| NORMAL                                  | 30                                                | 28                                               | 35                                               | 9                                   |
| ABNORMAL, NOT CLINICALLY<br>SIGNIFICANT | 3                                                 | 6                                                | 2                                                | 1                                   |
| ABNORMAL, CLINICALLY SIGNIFICANT        | 0                                                 | 0                                                | 0                                                | 0                                   |

| End point values                        | PF-06700841<br>60 mg -> PF-<br>06700841 30<br>mg | PF-06700841<br>30 mg -> PF-<br>06700841 30<br>mg | PF-06700841<br>10 mg -> PF-<br>06700841 30<br>mg | Placebo -> PF-<br>06700841 30<br>mg |
|-----------------------------------------|--------------------------------------------------|--------------------------------------------------|--------------------------------------------------|-------------------------------------|
| Subject group type                      | Reporting group                                  | Reporting group                                  | Reporting group                                  | Reporting group                     |
| Number of subjects analysed             | 32                                               | 30                                               | 36                                               | 9                                   |
| Units: Subjects                         |                                                  |                                                  |                                                  |                                     |
| NORMAL                                  | 31                                               | 28                                               | 32                                               | 7                                   |
| ABNORMAL, NOT CLINICALLY<br>SIGNIFICANT | 1                                                | 2                                                | 4                                                | 2                                   |
| ABNORMAL, CLINICALLY SIGNIFICANT        | 0                                                | 0                                                | 0                                                | 0                                   |

| End point values                        | Pooling Placebo<br>During Chronic |  |  |  |
|-----------------------------------------|-----------------------------------|--|--|--|
| Subject group type                      | Reporting group                   |  |  |  |
| Number of subjects analysed             | 33                                |  |  |  |
| Units: Subjects                         |                                   |  |  |  |
| NORMAL                                  | 29                                |  |  |  |
| ABNORMAL, NOT CLINICALLY<br>SIGNIFICANT | 4                                 |  |  |  |
| ABNORMAL, CLINICALLY SIGNIFICANT        | 0                                 |  |  |  |

## Statistical analyses

**Primary: Chronic Period: Number of subjects with vital signs abnormalities**

|                 |                                                                                  |
|-----------------|----------------------------------------------------------------------------------|
| End point title | Chronic Period: Number of subjects with vital signs abnormalities <sup>[6]</sup> |
|-----------------|----------------------------------------------------------------------------------|

End point description:

The criteria of test are indicated below. The analysis population are the subjects evaluated against the criteria during the chronic period.

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

End point timeframe:

Baseline of Chronic period (Week 8) to Week 36

Notes:

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

Justification: No statistical analysis was planned for this endpoint.

| End point values                                 | PF-06651600<br>200 mg -> PF-<br>06651600 50<br>mg | PF-06651600<br>70 mg -> PF-<br>06651600 50<br>mg | PF-06651600<br>20 mg -> PF-<br>06651600 50<br>mg | Placebo -> PF-<br>06651600 50<br>mg |
|--------------------------------------------------|---------------------------------------------------|--------------------------------------------------|--------------------------------------------------|-------------------------------------|
| Subject group type                               | Reporting group                                   | Reporting group                                  | Reporting group                                  | Reporting group                     |
| Number of subjects analysed                      | 35                                                | 35                                               | 39                                               | 10                                  |
| Units: Subjects                                  |                                                   |                                                  |                                                  |                                     |
| SITTING SYSTOLIC BLOOD PRESSURE<br>Value <90mmHg | 0                                                 | 0                                                | 1                                                | 0                                   |
| SITTING SYSTOLIC BP Chg>=30mmHg<br>increase      | 0                                                 | 3                                                | 4                                                | 0                                   |
| SITTING SYSTOLIC BP Chg >=<br>30mmHg decrease    | 0                                                 | 0                                                | 0                                                | 0                                   |
| SITTING DIASTOLIC BP Value <50<br>mmHg           | 0                                                 | 0                                                | 0                                                | 0                                   |
| SITTING DIASTOLIC BP Chg >=<br>20mmHg increase   | 0                                                 | 1                                                | 6                                                | 1                                   |
| SITTING DIASTOLIC BP Chg >=<br>20mmHg decrease   | 2                                                 | 4                                                | 5                                                | 0                                   |
| SITTING PULSE RATE Value <40 bpm                 | 0                                                 | 0                                                | 0                                                | 0                                   |
| SITTING PULSE RATE Value >120 bpm                | 0                                                 | 0                                                | 1                                                | 0                                   |

| End point values                                 | PF-06700841<br>60 mg -> PF-<br>06700841 30<br>mg | PF-06700841<br>30 mg -> PF-<br>06700841 30<br>mg | PF-06700841<br>10 mg -> PF-<br>06700841 30<br>mg | Placebo -> PF-<br>06700841 30<br>mg |
|--------------------------------------------------|--------------------------------------------------|--------------------------------------------------|--------------------------------------------------|-------------------------------------|
| Subject group type                               | Reporting group                                  | Reporting group                                  | Reporting group                                  | Reporting group                     |
| Number of subjects analysed                      | 38                                               | 37                                               | 39                                               | 9                                   |
| Units: Subjects                                  |                                                  |                                                  |                                                  |                                     |
| SITTING SYSTOLIC BLOOD PRESSURE<br>Value <90mmHg | 0                                                | 0                                                | 1                                                | 0                                   |
| SITTING SYSTOLIC BP Chg>=30mmHg<br>increase      | 3                                                | 2                                                | 3                                                | 0                                   |
| SITTING SYSTOLIC BP Chg >=<br>30mmHg decrease    | 1                                                | 1                                                | 0                                                | 0                                   |
| SITTING DIASTOLIC BP Value <50<br>mmHg           | 0                                                | 0                                                | 0                                                | 0                                   |
| SITTING DIASTOLIC BP Chg >=<br>20mmHg increase   | 4                                                | 2                                                | 1                                                | 1                                   |

|                                             |   |   |   |   |
|---------------------------------------------|---|---|---|---|
| SITTING DIASTOLIC BP Chg >= 20mmHg decrease | 2 | 3 | 1 | 0 |
| SITTING PULSE RATE Value <40 bpm            | 0 | 0 | 0 | 0 |
| SITTING PULSE RATE Value >120 bpm           | 0 | 0 | 0 | 0 |

|                                               |                                |  |  |  |
|-----------------------------------------------|--------------------------------|--|--|--|
| <b>End point values</b>                       | Pooling Placebo During Chronic |  |  |  |
| Subject group type                            | Reporting group                |  |  |  |
| Number of subjects analysed                   | 37                             |  |  |  |
| Units: Subjects                               |                                |  |  |  |
| SITTING SYSTOLIC BLOOD PRESSURE Value <90mmHg | 1                              |  |  |  |
| SITTING SYSTOLIC BP Chg>=30mmHg increase      | 3                              |  |  |  |
| SITTING SYSTOLIC BP Chg >= 30mmHg decrease    | 1                              |  |  |  |
| SITTING DIASTOLIC BP Value <50 mmHg           | 0                              |  |  |  |
| SITTING DIASTOLIC BP Chg >= 20mmHg increase   | 1                              |  |  |  |
| SITTING DIASTOLIC BP Chg >= 20mmHg decrease   | 2                              |  |  |  |
| SITTING PULSE RATE Value <40 bpm              | 0                              |  |  |  |
| SITTING PULSE RATE Value >120 bpm             | 0                              |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Primary: Chronic Period: Number of subjects with Serious Infection

|                 |                                                                          |
|-----------------|--------------------------------------------------------------------------|
| End point title | Chronic Period: Number of subjects with Serious Infection <sup>[7]</sup> |
|-----------------|--------------------------------------------------------------------------|

End point description:

Serious infections are treated infections that: Require parenteral antimicrobial therapy and present with positive pre-treatment culture; and either Require hospitalization for treatment; or Meet other criteria that require the infection to be classified as a SAE. The analysis population included all enrolled participants who received at least one dose of study medication.

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

End point timeframe:

Baseline of Chronic period (Week 8) to Week 36

Notes:

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

Justification: No statistical analysis was planned for this endpoint.

|                             |                                         |                                        |                                        |                              |
|-----------------------------|-----------------------------------------|----------------------------------------|----------------------------------------|------------------------------|
| <b>End point values</b>     | PF-06651600 200 mg -> PF-06651600 50 mg | PF-06651600 70 mg -> PF-06651600 50 mg | PF-06651600 20 mg -> PF-06651600 50 mg | Placebo -> PF-06651600 50 mg |
| Subject group type          | Reporting group                         | Reporting group                        | Reporting group                        | Reporting group              |
| Number of subjects analysed | 35                                      | 36                                     | 39                                     | 10                           |
| Units: Subjects             |                                         |                                        |                                        |                              |

|                    |   |   |   |   |
|--------------------|---|---|---|---|
| COVID 19 pneumonia | 0 | 0 | 0 | 0 |
| viral infection    | 0 | 0 | 0 | 0 |

| End point values            | PF-06700841<br>60 mg -> PF-<br>06700841 30<br>mg | PF-06700841<br>30 mg -> PF-<br>06700841 30<br>mg | PF-06700841<br>10 mg -> PF-<br>06700841 30<br>mg | Placebo -> PF-<br>06700841 30<br>mg |
|-----------------------------|--------------------------------------------------|--------------------------------------------------|--------------------------------------------------|-------------------------------------|
| Subject group type          | Reporting group                                  | Reporting group                                  | Reporting group                                  | Reporting group                     |
| Number of subjects analysed | 38                                               | 37                                               | 39                                               | 9                                   |
| Units: Subjects             |                                                  |                                                  |                                                  |                                     |
| COVID 19 pneumonia          | 0                                                | 0                                                | 1                                                | 0                                   |
| viral infection             | 1                                                | 0                                                | 0                                                | 0                                   |

| End point values            | Pooling Placebo<br>During Chronic |  |  |  |
|-----------------------------|-----------------------------------|--|--|--|
| Subject group type          | Reporting group                   |  |  |  |
| Number of subjects analysed | 37                                |  |  |  |
| Units: Subjects             |                                   |  |  |  |
| COVID 19 pneumonia          | 0                                 |  |  |  |
| viral infection             | 0                                 |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Induction Period: Percentage of subjects achieving remission based on total Mayo score

|                                                                                                                                                                                                                                                                                                                                                                           |                                                                                        |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|
| End point title                                                                                                                                                                                                                                                                                                                                                           | Induction Period: Percentage of subjects achieving remission based on total Mayo score |
| End point description:<br>Remission excludes friability and is based on total Mayo score of less than/equal to 2 with no individual subscore greater than 1 and a rectal bleeding subscore of 0 at Week 8. The ITT analysis set was used to analyze this endpoint, defined as all randomized subjects who received at least 1 dose of investigational product or placebo. |                                                                                        |
| End point type                                                                                                                                                                                                                                                                                                                                                            | Secondary                                                                              |
| End point timeframe:<br>Week 8                                                                                                                                                                                                                                                                                                                                            |                                                                                        |

| End point values                 | Placebo<br>(Induction: 0<br>to 8 weeks) | PF-06651600<br>20 mg<br>(Induction) | PF-06651600<br>70 mg<br>(Induction) | PF-06651600<br>200 mg<br>(Induction) |
|----------------------------------|-----------------------------------------|-------------------------------------|-------------------------------------|--------------------------------------|
| Subject group type               | Reporting group                         | Reporting group                     | Reporting group                     | Reporting group                      |
| Number of subjects analysed      | 25                                      | 51                                  | 49                                  | 50                                   |
| Units: Percentage of subjects    |                                         |                                     |                                     |                                      |
| number (confidence interval 90%) | 0 (0.0 to 11.0)                         | 9.8 (4.8 to 19.1)                   | 28.6 (19.0 to 40.4)                 | 34.0 (24.0 to 45.4)                  |

| End point values                 | PF-06700841<br>10 mg<br>(Induction) | PF-06700841<br>30 mg<br>(Induction) | PF-06700841<br>60 mg<br>(Induction) |  |
|----------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|--|
| Subject group type               | Reporting group                     | Reporting group                     | Reporting group                     |  |
| Number of subjects analysed      | 48                                  | 47                                  | 47                                  |  |
| Units: Percentage of subjects    |                                     |                                     |                                     |  |
| number (confidence interval 90%) | 8.3 (3.7 to 16.8)                   | 23.4 (14.8 to 34.5)                 | 23.4 (14.8 to 34.5)                 |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Induction Period: Percentage of subjects achieving improvement in endoscopic appearance at Week 8

|                 |                                                                                                   |
|-----------------|---------------------------------------------------------------------------------------------------|
| End point title | Induction Period: Percentage of subjects achieving improvement in endoscopic appearance at Week 8 |
|-----------------|---------------------------------------------------------------------------------------------------|

End point description:

Improvement of endoscopic appearance is defined as a Mayo endoscopic subscore of less than/equal to 1. The ITT analysis set was used to analyze this endpoint, defined as all randomized subjects who received at least 1 dose of investigational product or placebo.

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

End point timeframe:

Week 8

| End point values                 | Placebo<br>(Induction: 0<br>to 8 weeks) | PF-06651600<br>20 mg<br>(Induction) | PF-06651600<br>70 mg<br>(Induction) | PF-06651600<br>200 mg<br>(Induction) |
|----------------------------------|-----------------------------------------|-------------------------------------|-------------------------------------|--------------------------------------|
| Subject group type               | Reporting group                         | Reporting group                     | Reporting group                     | Reporting group                      |
| Number of subjects analysed      | 25                                      | 51                                  | 49                                  | 50                                   |
| Units: Percengate of subjects    |                                         |                                     |                                     |                                      |
| number (confidence interval 90%) | 0 (0.0 to 11.0)                         | 21.6 (13.5 to 33.1)                 | 34.7 (24.4 to 46.4)                 | 42.0 (30.3 to 54.6)                  |

| End point values | PF-06700841<br>10 mg<br>(Induction) | PF-06700841<br>30 mg<br>(Induction) | PF-06700841<br>60 mg<br>(Induction) |  |
|------------------|-------------------------------------|-------------------------------------|-------------------------------------|--|
|------------------|-------------------------------------|-------------------------------------|-------------------------------------|--|



|                                  |                     |                     |                     |  |
|----------------------------------|---------------------|---------------------|---------------------|--|
| Subject group type               | Reporting group     | Reporting group     | Reporting group     |  |
| Number of subjects analysed      | 48                  | 47                  | 47                  |  |
| Units: Percentage of subjects    |                     |                     |                     |  |
| number (confidence interval 90%) | 20.8 (11.8 to 31.5) | 31.9 (20.8 to 44.4) | 29.8 (19.9 to 42.3) |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Induction Period: Percentage of subjects achieving clinical response at Week 8

|                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|
| End point title                                                                                                                                                                                                                                                                                                                                                                                                                                        | Induction Period: Percentage of subjects achieving clinical response at Week 8 |
| End point description:<br>Clinical response is defined as a decrease from baseline in total Mayo score of at least 3 points and at least 30%, with an accompanying decrease in the subscore for rectal bleeding of at least 1 point or absolute subscore for rectal bleeding of 0 or 1. The ITT analysis set was used to analyze this endpoint, defined as all randomized subjects who received at least 1 dose of investigational product or placebo. |                                                                                |
| End point type                                                                                                                                                                                                                                                                                                                                                                                                                                         | Secondary                                                                      |
| End point timeframe:<br>Week 8                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                |

| End point values                 | Placebo<br>(Induction: 0 to 8 weeks) | PF-06651600<br>20 mg<br>(Induction) | PF-06651600<br>70 mg<br>(Induction) | PF-06651600<br>200 mg<br>(Induction) |
|----------------------------------|--------------------------------------|-------------------------------------|-------------------------------------|--------------------------------------|
| Subject group type               | Reporting group                      | Reporting group                     | Reporting group                     | Reporting group                      |
| Number of subjects analysed      | 25                                   | 51                                  | 49                                  | 50                                   |
| Units: Percentage of subjects    |                                      |                                     |                                     |                                      |
| number (confidence interval 90%) | 24.0 (11.0 to 41.7)                  | 41.2 (29.9 to 53.6)                 | 69.4 (57.6 to 80.1)                 | 68.0 (56.6 to 78.8)                  |

| End point values                 | PF-06700841<br>10 mg<br>(Induction) | PF-06700841<br>30 mg<br>(Induction) | PF-06700841<br>60 mg<br>(Induction) |  |
|----------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|--|
| Subject group type               | Reporting group                     | Reporting group                     | Reporting group                     |  |
| Number of subjects analysed      | 48                                  | 47                                  | 47                                  |  |
| Units: Percentage of subjects    |                                     |                                     |                                     |  |
| number (confidence interval 90%) | 41.7 (29.6 to 54.5)                 | 53.2 (40.3 to 65.5)                 | 61.7 (48.7 to 72.9)                 |  |

## Statistical analyses

No statistical analyses for this end point

**Secondary: Induction Period: Percentage of subjects in endoscopic remission at Week 8**

|                 |                                                                            |
|-----------------|----------------------------------------------------------------------------|
| End point title | Induction Period: Percentage of subjects in endoscopic remission at Week 8 |
|-----------------|----------------------------------------------------------------------------|

End point description:

Endoscopic remission is defined as an endoscopic subscore of 0. The ITT analysis set was used to analyze this endpoint, defined as all randomized subjects who received at least 1 dose of investigational product or placebo.

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

End point timeframe:

Week 8

| End point values                 | Placebo<br>(Induction: 0<br>to 8 weeks) | PF-06651600<br>20 mg<br>(Induction) | PF-06651600<br>70 mg<br>(Induction) | PF-06651600<br>200 mg<br>(Induction) |
|----------------------------------|-----------------------------------------|-------------------------------------|-------------------------------------|--------------------------------------|
| Subject group type               | Reporting group                         | Reporting group                     | Reporting group                     | Reporting group                      |
| Number of subjects analysed      | 25                                      | 51                                  | 49                                  | 50                                   |
| Units: Percentage of subjects    |                                         |                                     |                                     |                                      |
| number (confidence interval 90%) | 0 (0.0 to 11.0)                         | 3.9 (1.0 to 11.0)                   | 8.2 (3.6 to 16.5)                   | 12.0 (5.4 to 21.2)                   |

| End point values                 | PF-06700841<br>10 mg<br>(Induction) | PF-06700841<br>30 mg<br>(Induction) | PF-06700841<br>60 mg<br>(Induction) |  |
|----------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|--|
| Subject group type               | Reporting group                     | Reporting group                     | Reporting group                     |  |
| Number of subjects analysed      | 48                                  | 47                                  | 47                                  |  |
| Units: Percentage of subjects    |                                     |                                     |                                     |  |
| number (confidence interval 90%) | 2.1 (0.2 to 8.6)                    | 17.0 (8.8 to 28.3)                  | 8.5 (3.8 to 17.2)                   |  |

**Statistical analyses**

No statistical analyses for this end point

**Secondary: Induction Period: Percentage of subjects in symptomatic remission at Week 8**

|                 |                                                                             |
|-----------------|-----------------------------------------------------------------------------|
| End point title | Induction Period: Percentage of subjects in symptomatic remission at Week 8 |
|-----------------|-----------------------------------------------------------------------------|

End point description:

Symptomatic remission is defined as a total Mayo score of 2 points or lower, with no individual subscore exceeding 1 point, and both rectal bleeding and stool frequency subscores of 0. The ITT analysis set was used to analyze this endpoint, defined as all randomized subjects who received at least 1 dose of investigational product or placebo.

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

End point timeframe:

Week 8

| End point values                 | Placebo<br>(Induction: 0 to 8 weeks) | PF-06651600<br>20 mg<br>(Induction) | PF-06651600<br>70 mg<br>(Induction) | PF-06651600<br>200 mg<br>(Induction) |
|----------------------------------|--------------------------------------|-------------------------------------|-------------------------------------|--------------------------------------|
| Subject group type               | Reporting group                      | Reporting group                     | Reporting group                     | Reporting group                      |
| Number of subjects analysed      | 25                                   | 51                                  | 49                                  | 50                                   |
| Units: Percentage of subjects    |                                      |                                     |                                     |                                      |
| number (confidence interval 90%) | 0 (0.0 to 11.0)                      | 7.8 (3.5 to 15.9)                   | 16.3 (8.4 to 27.1)                  | 26.0 (16.2 to 37.6)                  |

| End point values                 | PF-06700841<br>10 mg<br>(Induction) | PF-06700841<br>30 mg<br>(Induction) | PF-06700841<br>60 mg<br>(Induction) |  |
|----------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|--|
| Subject group type               | Reporting group                     | Reporting group                     | Reporting group                     |  |
| Number of subjects analysed      | 48                                  | 47                                  | 47                                  |  |
| Units: Percentage of subjects    |                                     |                                     |                                     |  |
| number (confidence interval 90%) | 6.3 (2.3 to 15.1)                   | 14.9 (8.0 to 25.1)                  | 14.9 (8.0 to 25.1)                  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Induction Period: Percentage of subjects achieving deep remission at Week 8

|                 |                                                                             |
|-----------------|-----------------------------------------------------------------------------|
| End point title | Induction Period: Percentage of subjects achieving deep remission at Week 8 |
|-----------------|-----------------------------------------------------------------------------|

End point description:

Deep remission is defined as a total Mayo score of 2 points or lower, with no individual subscore exceeding 1 point and a 0 on both endoscopic and rectal bleeding subscores. The ITT analysis set was used to analyze this endpoint, defined as all randomized subjects who received at least 1 dose of investigational product or placebo.

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

End point timeframe:

Week 8

| End point values                 | Placebo<br>(Induction: 0 to 8 weeks) | PF-06651600<br>20 mg<br>(Induction) | PF-06651600<br>70 mg<br>(Induction) | PF-06651600<br>200 mg<br>(Induction) |
|----------------------------------|--------------------------------------|-------------------------------------|-------------------------------------|--------------------------------------|
| Subject group type               | Reporting group                      | Reporting group                     | Reporting group                     | Reporting group                      |
| Number of subjects analysed      | 25                                   | 51                                  | 49                                  | 50                                   |
| Units: Percentage of subjects    |                                      |                                     |                                     |                                      |
| number (confidence interval 90%) | 0 (0.0 to 11.0)                      | 3.9 (1.0 to 11.0)                   | 8.2 (3.6 to 16.5)                   | 12.0 (5.4 to 21.2)                   |

| End point values                 | PF-06700841<br>10 mg<br>(Induction) | PF-06700841<br>30 mg<br>(Induction) | PF-06700841<br>60 mg<br>(Induction) |  |
|----------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|--|
| Subject group type               | Reporting group                     | Reporting group                     | Reporting group                     |  |
| Number of subjects analysed      | 48                                  | 47                                  | 47                                  |  |
| Units: Percentage of subjects    |                                     |                                     |                                     |  |
| number (confidence interval 90%) | 0 (0.0 to 5.6)                      | 14.9 (8.0 to 25.1)                  | 6.4 (2.4 to 15.4)                   |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Induction Period: Partial Mayo Scores and changes from baseline at Weeks 2,4,and 8

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                    |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|
| End point title                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Induction Period: Partial Mayo Scores and changes from baseline at Weeks 2,4,and 8 |
| End point description:<br>A partial Mayo Score (Mayo Score without endoscopic subscore) ranges from 0 to 9, with higher scores indicating more severe disease. Baseline value is defined as the last non-missing measurement collected prior to the first administration of study drug at Day 1. ITT analysis set was defined as all randomized subjects who received at least 1 dose of investigational product or placebo. The subjects in the ITT analysis set who had partial Mayo score at each specified time point was used to analyze this endpoint. |                                                                                    |
| End point type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Secondary                                                                          |
| End point timeframe:<br>Weeks 2,4,and 8                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                    |

| End point values                    | Placebo<br>(Induction: 0<br>to 8 weeks) | PF-06651600<br>20 mg<br>(Induction) | PF-06651600<br>70 mg<br>(Induction) | PF-06651600<br>200 mg<br>(Induction) |
|-------------------------------------|-----------------------------------------|-------------------------------------|-------------------------------------|--------------------------------------|
| Subject group type                  | Reporting group                         | Reporting group                     | Reporting group                     | Reporting group                      |
| Number of subjects analysed         | 25                                      | 51                                  | 49                                  | 50                                   |
| Units: Unit on a scale              |                                         |                                     |                                     |                                      |
| least squares mean (standard error) |                                         |                                     |                                     |                                      |
| Week 2                              | -0.66 (± 0.37)                          | -1.65 (± 0.26)                      | -2.56 (± 0.26)                      | -3.19 (± 0.27)                       |
| Week 4                              | -1.64 (± 0.42)                          | -2.24 (± 0.29)                      | -3.29 (± 0.30)                      | -4.24 (± 0.31)                       |
| Week 8                              | -1.15 (± 0.43)                          | -2.54 (± 0.30)                      | -4.06 (± 0.30)                      | -4.69 (± 0.32)                       |

| End point values            | PF-06700841<br>10 mg<br>(Induction) | PF-06700841<br>30 mg<br>(Induction) | PF-06700841<br>60 mg<br>(Induction) |  |
|-----------------------------|-------------------------------------|-------------------------------------|-------------------------------------|--|
| Subject group type          | Reporting group                     | Reporting group                     | Reporting group                     |  |
| Number of subjects analysed | 48                                  | 47                                  | 47                                  |  |
| Units: Unit on a scale      |                                     |                                     |                                     |  |

|                                     |                |                |                |  |
|-------------------------------------|----------------|----------------|----------------|--|
| least squares mean (standard error) |                |                |                |  |
| Week 2                              | -1.60 (± 0.27) | -1.64 (± 0.27) | -2.45 (± 0.27) |  |
| Week 4                              | -2.31 (± 0.30) | -2.06 (± 0.30) | -2.95 (± 0.30) |  |
| Week 8                              | -2.51 (± 0.30) | -2.71 (± 0.31) | -3.47 (± 0.31) |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Induction Period: Change from baseline in total Mayo score

|                 |                                                            |
|-----------------|------------------------------------------------------------|
| End point title | Induction Period: Change from baseline in total Mayo score |
|-----------------|------------------------------------------------------------|

End point description:

Total Mayo Score ranges from 0 to 12, with higher scores indicating more severe disease. Baseline value is defined as the last non-missing measurement collected prior to the first administration of study drug at Day 1. The ITT analysis set was used to analyze this endpoint, defined as all randomized subjects who received at least 1 dose of investigational product or placebo.

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

End point timeframe:

Week 8

| End point values                             | Placebo<br>(Induction: 0<br>to 8 weeks) | PF-06651600<br>20 mg<br>(Induction) | PF-06651600<br>70 mg<br>(Induction) | PF-06651600<br>200 mg<br>(Induction) |
|----------------------------------------------|-----------------------------------------|-------------------------------------|-------------------------------------|--------------------------------------|
| Subject group type                           | Reporting group                         | Reporting group                     | Reporting group                     | Reporting group                      |
| Number of subjects analysed                  | 25                                      | 51                                  | 49                                  | 50                                   |
| Units: Units on a scale                      |                                         |                                     |                                     |                                      |
| least squares mean (confidence interval 90%) | -1.14 (-2.06 to -0.22)                  | -3.17 (-3.83 to -2.51)              | -5.02 (-5.68 to -4.36)              | -5.74 (-6.43 to -5.06)               |

| End point values                             | PF-06700841<br>10 mg<br>(Induction) | PF-06700841<br>30 mg<br>(Induction) | PF-06700841<br>60 mg<br>(Induction) |  |
|----------------------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|--|
| Subject group type                           | Reporting group                     | Reporting group                     | Reporting group                     |  |
| Number of subjects analysed                  | 48                                  | 47                                  | 47                                  |  |
| Units: Units on a scale                      |                                     |                                     |                                     |  |
| least squares mean (confidence interval 90%) | -2.93 (-3.58 to -2.29)              | -3.42 (-4.08 to -2.76)              | -4.35 (-5.00 to -3.69)              |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Induction Period: Changes from baseline in Inflammatory Bowel Disease Questionnaire (IBDQ) total score at Weeks 4 and 8

|                                                                                                                                                                                                                                                                                                                                     |                                                                                                                         |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------|
| End point title                                                                                                                                                                                                                                                                                                                     | Induction Period: Changes from baseline in Inflammatory Bowel Disease Questionnaire (IBDQ) total score at Weeks 4 and 8 |
| End point description:<br>IBDQ is a psychometrically validated PRO instrument for measuring the disease-specific quality of life in subjects with IBD, including UC. A score of at least 170 corresponds to clinical remission and an increase of at least 16 points is considered to indicate a clinically meaningful improvement. |                                                                                                                         |
| End point type                                                                                                                                                                                                                                                                                                                      | Secondary                                                                                                               |
| End point timeframe:<br>Weeks 4 and 8                                                                                                                                                                                                                                                                                               |                                                                                                                         |

| End point values                             | Placebo<br>(Induction: 0<br>to 8 weeks) | PF-06651600<br>20 mg<br>(Induction) | PF-06651600<br>70 mg<br>(Induction) | PF-06651600<br>200 mg<br>(Induction) |
|----------------------------------------------|-----------------------------------------|-------------------------------------|-------------------------------------|--------------------------------------|
| Subject group type                           | Reporting group                         | Reporting group                     | Reporting group                     | Reporting group                      |
| Number of subjects analysed                  | 25                                      | 51                                  | 49                                  | 50                                   |
| Units: Units on a scale                      |                                         |                                     |                                     |                                      |
| least squares mean (confidence interval 90%) |                                         |                                     |                                     |                                      |
| Week 4                                       | 30.30 (19.56<br>to 41.05)               | 33.71 (26.12<br>to 41.30)           | 51.12 (43.52<br>to 58.72)           | 57.01 (49.12<br>to 64.90)            |
| Week 8                                       | 24.23 (12.02<br>to 36.45)               | 37.91 (29.41<br>to 46.42)           | 59.20 (50.56<br>to 67.83)           | 62.17 (53.14<br>to 71.20)            |

| End point values                             | PF-06700841<br>10 mg<br>(Induction) | PF-06700841<br>30 mg<br>(Induction) | PF-06700841<br>60 mg<br>(Induction) |  |
|----------------------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|--|
| Subject group type                           | Reporting group                     | Reporting group                     | Reporting group                     |  |
| Number of subjects analysed                  | 48                                  | 47                                  | 47                                  |  |
| Units: Units on a scale                      |                                     |                                     |                                     |  |
| least squares mean (confidence interval 90%) |                                     |                                     |                                     |  |
| Week 4                                       | 28.45 (20.73<br>to 36.17)           | 37.94 (30.16<br>to 45.72)           | 49.79 (41.99<br>to 57.60)           |  |
| Week 8                                       | 36.6 (27.87 to<br>45.33)            | 48.81 (40.01<br>to 57.61)           | 56.39 (47.60<br>to 65.18)           |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Induction Period: Percentage of subjects with IBDQ total score greater than/equal to 170 at Weeks 4 and 8

|                                                                                                                                                                                                                                                                                                                                     |                                                                                                           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------|
| End point title                                                                                                                                                                                                                                                                                                                     | Induction Period: Percentage of subjects with IBDQ total score greater than/equal to 170 at Weeks 4 and 8 |
| End point description:<br>IBDQ is a psychometrically validated PRO instrument for measuring the disease-specific quality of life in subjects with IBD, including UC. A score of at least 170 corresponds to clinical remission and an increase of at least 16 points is considered to indicate a clinically meaningful improvement. |                                                                                                           |

|                      |           |
|----------------------|-----------|
| End point type       | Secondary |
| End point timeframe: |           |
| Weeks 4 and 8        |           |

| End point values                 | Placebo<br>(Induction: 0 to 8 weeks) | PF-06651600<br>20 mg<br>(Induction) | PF-06651600<br>70 mg<br>(Induction) | PF-06651600<br>200 mg<br>(Induction) |
|----------------------------------|--------------------------------------|-------------------------------------|-------------------------------------|--------------------------------------|
| Subject group type               | Reporting group                      | Reporting group                     | Reporting group                     | Reporting group                      |
| Number of subjects analysed      | 25                                   | 51                                  | 49                                  | 50                                   |
| Units: Percentage of subjects    |                                      |                                     |                                     |                                      |
| number (confidence interval 90%) |                                      |                                     |                                     |                                      |
| Week 4                           | 24.0 (11.0 to 41.7)                  | 21.6 (13.5 to 33.1)                 | 40.8 (28.9 to 53.6)                 | 46.0 (34.2 to 58.5)                  |
| Week 8                           | 20.0 (10.1 to 36.2)                  | 29.4 (19.1 to 40.6)                 | 57.1 (44.4 to 69.2)                 | 44.0 (33.0 to 56.6)                  |

| End point values                 | PF-06700841<br>10 mg<br>(Induction) | PF-06700841<br>30 mg<br>(Induction) | PF-06700841<br>60 mg<br>(Induction) |  |
|----------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|--|
| Subject group type               | Reporting group                     | Reporting group                     | Reporting group                     |  |
| Number of subjects analysed      | 48                                  | 47                                  | 47                                  |  |
| Units: Percentage of subjects    |                                     |                                     |                                     |  |
| number (confidence interval 90%) |                                     |                                     |                                     |  |
| Week 4                           | 27.1 (16.8 to 39.4)                 | 27.7 (17.2 to 40.3)                 | 38.3 (27.1 to 51.3)                 |  |
| Week 8                           | 31.3 (20.4 to 43.4)                 | 40.4 (28.3 to 53.5)                 | 51.1 (38.9 to 62.8)                 |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Induction Period: Percentage of subjects with greater than/equal to 16 point increase in IBDQ total score from baseline at Weeks 4 and 8

|                 |                                                                                                                                          |
|-----------------|------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Induction Period: Percentage of subjects with greater than/equal to 16 point increase in IBDQ total score from baseline at Weeks 4 and 8 |
|-----------------|------------------------------------------------------------------------------------------------------------------------------------------|

End point description:

IBDQ is a psychometrically validated PRO instrument for measuring the disease-specific quality of life in subjects with IBD, including UC. A score of at least 170 corresponds to clinical remission and an increase of at least 16 points is considered to indicate a clinically meaningful improvement.

|                      |           |
|----------------------|-----------|
| End point type       | Secondary |
| End point timeframe: |           |
| Weeks 4 and 8        |           |

| End point values                 | Placebo<br>(Induction: 0 to 8 weeks) | PF-06651600<br>20 mg<br>(Induction) | PF-06651600<br>70 mg<br>(Induction) | PF-06651600<br>200 mg<br>(Induction) |
|----------------------------------|--------------------------------------|-------------------------------------|-------------------------------------|--------------------------------------|
| Subject group type               | Reporting group                      | Reporting group                     | Reporting group                     | Reporting group                      |
| Number of subjects analysed      | 25                                   | 51                                  | 49                                  | 50                                   |
| Units: Percentage of subjects    |                                      |                                     |                                     |                                      |
| number (confidence interval 90%) |                                      |                                     |                                     |                                      |
| Week 4                           | 48.0 (30.7 to 64.0)                  | 60.8 (48.4 to 72.3)                 | 83.7 (72.9 to 91.6)                 | 80.0 (69.7 to 88.7)                  |
| Week 8                           | 56.0 (38.9 to 73.0)                  | 54.9 (42.5 to 66.9)                 | 79.6 (69.2 to 88.5)                 | 70.0 (58.5 to 80.5)                  |

| End point values                 | PF-06700841<br>10 mg<br>(Induction) | PF-06700841<br>30 mg<br>(Induction) | PF-06700841<br>60 mg<br>(Induction) |  |
|----------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|--|
| Subject group type               | Reporting group                     | Reporting group                     | Reporting group                     |  |
| Number of subjects analysed      | 48                                  | 47                                  | 47                                  |  |
| Units: Percentage of subjects    |                                     |                                     |                                     |  |
| number (confidence interval 90%) |                                     |                                     |                                     |  |
| Week 4                           | 64.6 (52.5 to 75.3)                 | 78.7 (67.8 to 88.0)                 | 72.3 (59.7 to 82.8)                 |  |
| Week 8                           | 62.5 (50.0 to 73.6)                 | 80.9 (69.7 to 88.8)                 | 78.7 (67.8 to 88.0)                 |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Indction Period: Percentage of subjects with improvement in IBDQ bowel symptom domain at Weeks 4 and 8

|                                                                                                                                                                          |                                                                                                        |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|
| End point title                                                                                                                                                          | Indction Period: Percentage of subjects with improvement in IBDQ bowel symptom domain at Weeks 4 and 8 |
| End point description:                                                                                                                                                   |                                                                                                        |
| Improvement is defined as an increase of at least 1.2 points from baseline in average score among IBDQ bowel symptom domain (items 1, 5, 9, 13, 17, 20, 22, 24, 26, 29). |                                                                                                        |
| End point type                                                                                                                                                           | Secondary                                                                                              |
| End point timeframe:                                                                                                                                                     |                                                                                                        |
| Weeks 4 and 8                                                                                                                                                            |                                                                                                        |

| End point values                 | Placebo<br>(Induction: 0 to 8 weeks) | PF-06651600<br>20 mg<br>(Induction) | PF-06651600<br>70 mg<br>(Induction) | PF-06651600<br>200 mg<br>(Induction) |
|----------------------------------|--------------------------------------|-------------------------------------|-------------------------------------|--------------------------------------|
| Subject group type               | Reporting group                      | Reporting group                     | Reporting group                     | Reporting group                      |
| Number of subjects analysed      | 25                                   | 51                                  | 49                                  | 50                                   |
| Units: Percentage of subjects    |                                      |                                     |                                     |                                      |
| number (confidence interval 90%) |                                      |                                     |                                     |                                      |
| Week 4                           | 20.0 (10.1 to 36.2)                  | 51.0 (38.7 to 63.2)                 | 65.3 (53.6 to 75.6)                 | 64.0 (52.6 to 75.1)                  |



|        |                     |                     |                     |                     |
|--------|---------------------|---------------------|---------------------|---------------------|
| Week 8 | 24.0 (11.0 to 41.7) | 47.1 (35.0 to 59.4) | 69.4 (57.6 to 80.1) | 62.0 (50.0 to 73.5) |
|--------|---------------------|---------------------|---------------------|---------------------|

| End point values                 | PF-06700841<br>10 mg<br>(Induction) | PF-06700841<br>30 mg<br>(Induction) | PF-06700841<br>60 mg<br>(Induction) |  |
|----------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|--|
| Subject group type               | Reporting group                     | Reporting group                     | Reporting group                     |  |
| Number of subjects analysed      | 48                                  | 47                                  | 47                                  |  |
| Units: Percentage of subjects    |                                     |                                     |                                     |  |
| number (confidence interval 90%) |                                     |                                     |                                     |  |
| Week 4                           | 37.5 (26.4 to 50.0)                 | 53.2 (40.3 to 65.5)                 | 57.4 (44.4 to 69.7)                 |  |
| Week 8                           | 50.0 (37.6 to 62.4)                 | 63.8 (51.3 to 74.9)                 | 66.0 (53.5 to 77.3)                 |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Induction Period: Changes from baseline in Short Form 36 version 2 (SF-36 v2) at Weeks 4 and 8

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------|
| End point title                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Induction Period: Changes from baseline in Short Form 36 version 2 (SF-36 v2) at Weeks 4 and 8 |
| End point description:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                |
| <p>The SF-36 version 2 (Acute version) is a 36-item generic health status measure. It measures 8 general health concepts or domains: Physical Functioning (PF), Role-Physical (RP), Bodily Pain (BP), General Health (GH), Vitality (VT), Social Functioning (SF), Role-Emotional (RE), and Mental Health (MH). These 8 domains can also be summarized as physical and mental component scores. The summary component scores, Physical Component Summary (PCS) and Mental Component Summary (MCS), are based on a normalized sum of the 8 scale scores PF, RP, BP, GH, VT, SF, RE, and MH. All domains and summary components are scored such that a higher score indicates a higher functioning or health level. The minimum and maximum scores of the PCS Score are 6.1 and 79.7, respectively. The minimum and maximum scores of the MCS Score are -3.8 and 78.7, respectively.</p> |                                                                                                |
| End point type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Secondary                                                                                      |
| End point timeframe:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                |
| Weeks 4 and 8                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                |

| End point values                             | Placebo<br>(Induction: 0 to 8 weeks) | PF-06651600<br>20 mg<br>(Induction) | PF-06651600<br>70 mg<br>(Induction) | PF-06651600<br>200 mg<br>(Induction) |
|----------------------------------------------|--------------------------------------|-------------------------------------|-------------------------------------|--------------------------------------|
| Subject group type                           | Reporting group                      | Reporting group                     | Reporting group                     | Reporting group                      |
| Number of subjects analysed                  | 25                                   | 51                                  | 49                                  | 50                                   |
| Units: Units on a scale                      |                                      |                                     |                                     |                                      |
| least squares mean (confidence interval 90%) |                                      |                                     |                                     |                                      |
| PCS at Week 4                                | 4.69 (2.59 to 6.80)                  | 5.90 (4.41 to 7.39)                 | 6.36 (4.88 to 7.85)                 | 9.21 (7.67 to 10.76)                 |
| MCS at Week 4                                | 7.83 (4.59 to 11.06)                 | 4.95 (2.67 to 7.23)                 | 7.79 (5.50 to 10.07)                | 8.81 (6.43 to 11.18)                 |

|               |                     |                     |                      |                       |
|---------------|---------------------|---------------------|----------------------|-----------------------|
| PCS at Week 8 | 5.37 (2.96 to 7.77) | 5.85 (4.19 to 7.52) | 8.66 (6.97 to 10.35) | 10.86 (9.08 to 12.64) |
| MCS at Week 8 | 4.24 (0.69 to 7.78) | 5.18 (2.72 to 7.64) | 9.72 (7.22 to 12.22) | 9.41 (6.79 to 12.03)  |

| End point values                             | PF-06700841<br>10 mg<br>(Induction) | PF-06700841<br>30 mg<br>(Induction) | PF-06700841<br>60 mg<br>(Induction) |  |
|----------------------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|--|
| Subject group type                           | Reporting group                     | Reporting group                     | Reporting group                     |  |
| Number of subjects analysed                  | 48                                  | 47                                  | 47                                  |  |
| Units: Units on a scale                      |                                     |                                     |                                     |  |
| least squares mean (confidence interval 90%) |                                     |                                     |                                     |  |
| PCS at Week 4                                | 5.67 (4.16 to 7.19)                 | 5.85 (4.31 to 7.38)                 | 6.40 (4.87 to 7.93)                 |  |
| MCS at Week 4                                | 2.44 (0.13 to 4.74)                 | 7.46 (5.11 to 9.82)                 | 9.28 (6.93 to 11.62)                |  |
| PCS at Week 8                                | 6.29 (4.57 to 8.02)                 | 8.21 (6.47 to 9.95)                 | 8.55 (6.83 to 10.27)                |  |
| MCS at Week 8                                | 5.22 (2.70 to 7.75)                 | 8.04 (5.48 to 10.61)                | 10.01 (7.47 to 12.55)               |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Induction Period: Changes from baseline in EuroQoL-5 Dimensions at Weeks 4 and 8

|                 |                                                                                  |
|-----------------|----------------------------------------------------------------------------------|
| End point title | Induction Period: Changes from baseline in EuroQoL-5 Dimensions at Weeks 4 and 8 |
|-----------------|----------------------------------------------------------------------------------|

End point description:

For EQ-5D 3L, participant rated questionnaire to assess generic health status in two parts: single utility score and visual analog scale. For utility score, participants rated their current health state on 5 dimensions: mobility, self-care, usual activities, pain and discomfort, and anxiety and depression with each dimension having three levels of function: 1 indicates no problem; 2 indicates some problem; 3 indicates extreme problem. Scoring formula developed by EuroQol Group assigns a utility value for each domain in the profile. Score was transformed and results in a total score range of 0.05 to 1.00; higher scores indicating a better health state. The EQ-5D VAS records the respondent's self rated health on a scale from 0 (worst imaginable health state) to 100 (best imaginable health state).

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

End point timeframe:

Weeks 4 and 8

| End point values                                | Placebo<br>(Induction: 0<br>to 8 weeks) | PF-06651600<br>20 mg<br>(Induction) | PF-06651600<br>70 mg<br>(Induction) | PF-06651600<br>200 mg<br>(Induction) |
|-------------------------------------------------|-----------------------------------------|-------------------------------------|-------------------------------------|--------------------------------------|
| Subject group type                              | Reporting group                         | Reporting group                     | Reporting group                     | Reporting group                      |
| Number of subjects analysed                     | 25                                      | 51                                  | 49                                  | 50                                   |
| Units: Units on a scale                         |                                         |                                     |                                     |                                      |
| least squares mean (confidence interval<br>90%) |                                         |                                     |                                     |                                      |
| EQ5D01-Index Value at week 4                    | 0.11 (0.06 to<br>0.16)                  | 0.07 (0.04 to<br>0.11)              | 0.12 (0.09 to<br>0.15)              | 0.13 (0.10 to<br>0.17)               |
| EQ5D01-Index Value at Week 8                    | 0.08 (0.03 to<br>0.13)                  | 0.08 (0.05 to<br>0.12)              | 0.15 (0.11 to<br>0.18)              | 0.15 (0.12 to<br>0.19)               |
| EQ5D01-EQ VAS Score at Week 4                   | 8.41 (2.18 to<br>14.63)                 | 13.6 (9.20 to<br>18.00)             | 16.35 (11.96<br>to 20.74)           | 17.45 (12.88<br>to 22.02)            |
| EQ5D01-EQ VAS Score at Week 8                   | 13.17 (6.48 to<br>19.85)                | 13.11 (8.48 to<br>17.74)            | 18.88 (14.17<br>to 23.60)           | 22.54 (17.60<br>to 27.49)            |

| End point values                                | PF-06700841<br>10 mg<br>(Induction) | PF-06700841<br>30 mg<br>(Induction) | PF-06700841<br>60 mg<br>(Induction) |  |
|-------------------------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|--|
| Subject group type                              | Reporting group                     | Reporting group                     | Reporting group                     |  |
| Number of subjects analysed                     | 48                                  | 47                                  | 47                                  |  |
| Units: Units on a scale                         |                                     |                                     |                                     |  |
| least squares mean (confidence interval<br>90%) |                                     |                                     |                                     |  |
| EQ5D01-Index Value at week 4                    | 0.07 (0.03 to<br>0.10)              | 0.11 (0.08 to<br>0.14)              | 0.12 (0.09 to<br>0.15)              |  |
| EQ5D01-Index Value at Week 8                    | 0.09 (0.05 to<br>0.13)              | 0.13 (0.10 to<br>0.17)              | 0.14 (0.11 to<br>0.18)              |  |
| EQ5D01-EQ VAS Score at Week 4                   | 10.48 (6.04 to<br>14.92)            | 12.24 (7.72 to<br>16.77)            | 14.44 (9.90 to<br>18.97)            |  |
| EQ5D01-EQ VAS Score at Week 8                   | 10.35 (5.58 to<br>15.12)            | 17.11 (12.28<br>to 21.94)           | 20.01 (15.21<br>to 24.81)           |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Induction Period: Number of subjects with Treatment-Emergent Adverse Events (AEs), Serious Adverse Events (SAEs) and with withdrawals due to adverse events (All-Causalities)

|                 |                                                                                                                                                                               |
|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Induction Period: Number of subjects with Treatment-Emergent Adverse Events (AEs), Serious Adverse Events (SAEs) and with withdrawals due to adverse events (All-Causalities) |
|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

### End point description:

An AE is any untoward medical occurrence in a study subjects administered a product or medical device; the event need not necessarily have a causal relationship with the treatment or usage. An SAE is any untoward medical occurrence at any dose that: results in death; is life threatening (immediate risk of death); requires inpatient hospitalization or prolongation of existing hospitalization; results in persistent or significant disability/incapacity (substantial disruption of the ability to conduct normal life functions); results in congenital anomaly/birth defect; or that is considered to be an important medical event that may jeopardize the subject or may require intervention to prevent one of the other AE outcomes. Treatment-emergent AEs were those with initial onset or that worsen in severity after the first dose of the study medication.

|                      |           |
|----------------------|-----------|
| End point type       | Secondary |
| End point timeframe: |           |
| Baseline, Week 8     |           |

| End point values                            | Placebo<br>(Induction: 0<br>to 8 weeks) | PF-06651600<br>20 mg<br>(Induction) | PF-06651600<br>70 mg<br>(Induction) | PF-06651600<br>200 mg<br>(Induction) |
|---------------------------------------------|-----------------------------------------|-------------------------------------|-------------------------------------|--------------------------------------|
| Subject group type                          | Reporting group                         | Reporting group                     | Reporting group                     | Reporting group                      |
| Number of subjects analysed                 | 25                                      | 51                                  | 49                                  | 50                                   |
| Units: Subjects                             |                                         |                                     |                                     |                                      |
| Subjects with AEs                           | 13                                      | 23                                  | 21                                  | 21                                   |
| Subjects with SAEs                          | 0                                       | 3                                   | 0                                   | 3                                    |
| Subjects with severe AEs                    | 0                                       | 2                                   | 0                                   | 1                                    |
| Subjects discontinued from study due to AEs | 0                                       | 5                                   | 0                                   | 5                                    |

| End point values                            | PF-06700841<br>10 mg<br>(Induction) | PF-06700841<br>30 mg<br>(Induction) | PF-06700841<br>60 mg<br>(Induction) |  |
|---------------------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|--|
| Subject group type                          | Reporting group                     | Reporting group                     | Reporting group                     |  |
| Number of subjects analysed                 | 48                                  | 47                                  | 47                                  |  |
| Units: Subjects                             |                                     |                                     |                                     |  |
| Subjects with AEs                           | 19                                  | 26                                  | 23                                  |  |
| Subjects with SAEs                          | 1                                   | 3                                   | 1                                   |  |
| Subjects with severe AEs                    | 0                                   | 1                                   | 1                                   |  |
| Subjects discontinued from study due to AEs | 1                                   | 2                                   | 1                                   |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Induction Period: Number of subjects with Laboratory Abnormalities without regard to baseline values - Hematology

|                 |                                                                                                                   |
|-----------------|-------------------------------------------------------------------------------------------------------------------|
| End point title | Induction Period: Number of subjects with Laboratory Abnormalities without regard to baseline values - Hematology |
|-----------------|-------------------------------------------------------------------------------------------------------------------|

End point description:

Following parameters were analyzed for laboratory examination: hemoglobin, hematocrit, erythrocytes, reticulocytes, ery. Mean Corpuscular Volume, platelets, Reticulocytes/Erythrocytes, Leukocytes, Lymphocytes, Neutrophils, Basophils, Eosinophils, Monocytes, Activated Partial Thromboplastin Time, Prothrombin Time, Prothrombin Intl. Normalized Ratio. The ITT analysis set was used to analyze this endpoint, defined as all randomized subjects who received at least 1 dose of investigational product or placebo.

|                      |           |
|----------------------|-----------|
| End point type       | Secondary |
| End point timeframe: |           |
| Baseline, Week 8     |           |

| End point values                                                         | Placebo<br>(Induction: 0<br>to 8 weeks) | PF-06651600<br>20 mg<br>(Induction) | PF-06651600<br>70 mg<br>(Induction) | PF-06651600<br>200 mg<br>(Induction) |
|--------------------------------------------------------------------------|-----------------------------------------|-------------------------------------|-------------------------------------|--------------------------------------|
| Subject group type                                                       | Reporting group                         | Reporting group                     | Reporting group                     | Reporting group                      |
| Number of subjects analysed                                              | 25                                      | 51                                  | 49                                  | 50                                   |
| Units: Subjects                                                          |                                         |                                     |                                     |                                      |
| Hemoglobin (g/dL)<0.8x LLN                                               | 3                                       | 2                                   | 5                                   | 9                                    |
| Hematocrit (%)<0.8x LLN                                                  | 2                                       | 0                                   | 3                                   | 4                                    |
| Erythrocytes (10 <sup>6</sup> /mm <sup>3</sup> )<0.8x LLN                | 0                                       | 0                                   | 4                                   | 3                                    |
| Reticulocytes (ABSOLUTE)<br>(10 <sup>3</sup> /mm <sup>3</sup> )<0.5x LLN | 0                                       | 0                                   | 0                                   | 0                                    |
| Reticulocytes (ABSOLUTE)<br>(10 <sup>3</sup> /mm <sup>3</sup> )>1.5x ULN | 1                                       | 1                                   | 2                                   | 2                                    |
| Ery. Mean Corpuscular Volume (10 <sup>-15</sup> L)<0.9x LLN              | 0                                       | 0                                   | 0                                   | 0                                    |
| Ery. Mean Corpuscular Volume (10 <sup>-15</sup> L)>1.1x ULN              | 0                                       | 0                                   | 0                                   | 0                                    |
| Platelets (10 <sup>3</sup> /mm <sup>3</sup> )<0.5x LLN                   | 0                                       | 0                                   | 0                                   | 0                                    |
| Platelets (10 <sup>3</sup> /mm <sup>3</sup> )>1.75x ULN                  | 1                                       | 0                                   | 0                                   | 0                                    |
| Reticulocytes/Erythrocytes (%)<0.5x LLN                                  | 0                                       | 0                                   | 0                                   | 0                                    |
| Reticulocytes/Erythrocytes (%)>1.5x ULN                                  | 1                                       | 2                                   | 3                                   | 3                                    |
| Leukocytes (10 <sup>3</sup> /mm <sup>3</sup> )<0.6x LLN                  | 0                                       | 0                                   | 0                                   | 0                                    |
| Leukocytes (10 <sup>3</sup> /mm <sup>3</sup> )>1.5x ULN                  | 0                                       | 3                                   | 0                                   | 3                                    |
| Lymphocytes (ABSOLUTE)<br>(10 <sup>3</sup> /mm <sup>3</sup> )<0.8x LLN   | 3                                       | 2                                   | 4                                   | 11                                   |
| Lymphocytes (ABSOLUTE)<br>(10 <sup>3</sup> /mm <sup>3</sup> )>1.2x ULN   | 0                                       | 1                                   | 0                                   | 0                                    |
| Neutrophils (ABSOLUTE)<br>(10 <sup>3</sup> /mm <sup>3</sup> )<0.8x LLN   | 1                                       | 0                                   | 0                                   | 0                                    |
| Neutrophils (ABSOLUTE)<br>(10 <sup>3</sup> /mm <sup>3</sup> )>1.2x ULN   | 7                                       | 13                                  | 7                                   | 9                                    |
| Basophils (ABSOLUTE)<br>(10 <sup>3</sup> /mm <sup>3</sup> )>1.2x ULN     | 0                                       | 0                                   | 1                                   | 0                                    |
| Eosinophils (ABSOLUTE)<br>(10 <sup>3</sup> /mm <sup>3</sup> )>1.2x ULN   | 2                                       | 3                                   | 1                                   | 1                                    |
| Monocytes (ABSOLUTE)<br>(10 <sup>3</sup> /mm <sup>3</sup> )>1.2x ULN     | 2                                       | 2                                   | 0                                   | 2                                    |
| Activated Partial Thromboplastin<br>Time>1.1x ULN                        | 1                                       | 0                                   | 1                                   | 0                                    |
| Prothrombin Time (sec)>1.1x ULN                                          | 1                                       | 2                                   | 1                                   | 1                                    |
| Prothrombin Intl. Normalized<br>Ratio>1.1x ULN                           | 1                                       | 2                                   | 1                                   | 1                                    |

| End point values            | PF-06700841<br>10 mg<br>(Induction) | PF-06700841<br>30 mg<br>(Induction) | PF-06700841<br>60 mg<br>(Induction) |  |
|-----------------------------|-------------------------------------|-------------------------------------|-------------------------------------|--|
| Subject group type          | Reporting group                     | Reporting group                     | Reporting group                     |  |
| Number of subjects analysed | 48                                  | 47                                  | 47                                  |  |
| Units: Subjects             |                                     |                                     |                                     |  |

|                                                                          |   |   |    |  |
|--------------------------------------------------------------------------|---|---|----|--|
| Hemoglobin (g/dL)<0.8x LLN                                               | 4 | 4 | 5  |  |
| Hematocrit (%)<0.8x LLN                                                  | 1 | 1 | 0  |  |
| Erythrocytes (10 <sup>6</sup> /mm <sup>3</sup> )<0.8x LLN                | 1 | 1 | 2  |  |
| Reticulocytes (ABSOLUTE)<br>(10 <sup>3</sup> /mm <sup>3</sup> )<0.5x LLN | 0 | 0 | 0  |  |
| Reticulocytes (ABSOLUTE)<br>(10 <sup>3</sup> /mm <sup>3</sup> )>1.5x ULN | 0 | 0 | 0  |  |
| Ery. Mean Corpuscular Volume (10 <sup>-15</sup> L)<0.9x LLN              | 0 | 0 | 0  |  |
| Ery. Mean Corpuscular Volume (10 <sup>-15</sup> L)>1.1x ULN              | 0 | 0 | 0  |  |
| Platelets (10 <sup>3</sup> /mm <sup>3</sup> )<0.5x LLN                   | 0 | 0 | 0  |  |
| Platelets (10 <sup>3</sup> /mm <sup>3</sup> )>1.75x ULN                  | 2 | 2 | 5  |  |
| Reticulocytes/Erythrocytes (%)<0.5x LLN                                  | 0 | 0 | 0  |  |
| Reticulocytes/Erythrocytes (%)>1.5x ULN                                  | 0 | 0 | 2  |  |
| Leukocytes (10 <sup>3</sup> /mm <sup>3</sup> )<0.6x LLN                  | 1 | 0 | 0  |  |
| Leukocytes (10 <sup>3</sup> /mm <sup>3</sup> )>1.5x ULN                  | 2 | 2 | 1  |  |
| Lymphocytes (ABSOLUTE)<br>(10 <sup>3</sup> /mm <sup>3</sup> )<0.8x LLN   | 2 | 1 | 2  |  |
| Lymphocytes (ABSOLUTE)<br>(10 <sup>3</sup> /mm <sup>3</sup> )>1.2x ULN   | 1 | 1 | 1  |  |
| Neutrophils (ABSOLUTE)<br>(10 <sup>3</sup> /mm <sup>3</sup> )<0.8x LLN   | 2 | 3 | 2  |  |
| Neutrophils (ABSOLUTE)<br>(10 <sup>3</sup> /mm <sup>3</sup> )>1.2x ULN   | 7 | 7 | 11 |  |
| Basophils (ABSOLUTE)<br>(10 <sup>3</sup> /mm <sup>3</sup> )>1.2x ULN     | 1 | 1 | 0  |  |
| Eosinophils (ABSOLUTE)<br>(10 <sup>3</sup> /mm <sup>3</sup> )>1.2x ULN   | 1 | 3 | 2  |  |
| Monocytes (ABSOLUTE)<br>(10 <sup>3</sup> /mm <sup>3</sup> )>1.2x ULN     | 1 | 1 | 2  |  |
| Activated Partial Thromboplastin Time>1.1x ULN                           | 0 | 0 | 0  |  |
| Prothrombin Time (sec)>1.1x ULN                                          | 0 | 0 | 0  |  |
| Prothrombin Intl. Normalized Ratio>1.1x ULN                              | 0 | 0 | 0  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Induction Period: Number of subjects with Laboratory Abnormalities without regard to baseline values - Clinical Chemistry

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|
| End point title                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Induction Period: Number of subjects with Laboratory Abnormalities without regard to baseline values - Clinical Chemistry |
| End point description:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                           |
| Following parameters were analyzed for laboratory examination: Bilirubin, Direct Bilirubin, Indirect Bilirubin, Aspartate Aminotransferase, Alanine Aminotransferase, Gamma Glutamyl Transferase, Alkaline Phosphatase, Protein, Albumin, Urea Nitrogen, Creatinine, Urate, HDL Cholesterol, LDL Cholesterol, Triglycerides, Sodium, Potassium, Chloride, Calcium, Glucose, Hemoglobin A1C, Creatine Kinase, Cholesterol. The analysis population included all enrolled participants who received at least one dose of study medication. |                                                                                                                           |
| End point type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Secondary                                                                                                                 |

| End point values                             | Placebo<br>(Induction: 0<br>to 8 weeks) | PF-06651600<br>20 mg<br>(Induction) | PF-06651600<br>70 mg<br>(Induction) | PF-06651600<br>200 mg<br>(Induction) |
|----------------------------------------------|-----------------------------------------|-------------------------------------|-------------------------------------|--------------------------------------|
| Subject group type                           | Reporting group                         | Reporting group                     | Reporting group                     | Reporting group                      |
| Number of subjects analysed                  | 25                                      | 51                                  | 48                                  | 50                                   |
| Units: Subjects                              |                                         |                                     |                                     |                                      |
| Bilirubin (mg/dL)>1.5x ULN                   | 0                                       | 1                                   | 0                                   | 1                                    |
| Direct Bilirubin (mg/dL)>1.5x ULN            | 0                                       | 0                                   | 0                                   | 0                                    |
| Indirect Bilirubin (mg/dL)>1.5x ULN          | 0                                       | 0                                   | 0                                   | 0                                    |
| Aspartate Aminotransferase (U/L)>3.0x<br>ULN | 0                                       | 0                                   | 0                                   | 0                                    |
| Alanine Aminotransferase (U/L)>3.0x<br>ULN   | 0                                       | 0                                   | 0                                   | 0                                    |
| Gamma Glutamyl Transferase<br>(U/L)>3.0x ULN | 0                                       | 0                                   | 0                                   | 0                                    |
| Alkaline Phosphatase (U/L)>3.0x ULN          | 0                                       | 1                                   | 0                                   | 0                                    |
| Protein (g/dL)<0.8x LLN                      | 0                                       | 0                                   | 0                                   | 0                                    |
| Protein (g/dL)>1.2x ULN                      | 0                                       | 0                                   | 0                                   | 0                                    |
| Albumin (g/dL)<0.8x LLN                      | 0                                       | 0                                   | 0                                   | 0                                    |
| Albumin (g/dL)>1.2x ULN                      | 0                                       | 0                                   | 0                                   | 0                                    |
| Urea Nitrogen (mg/dL)>1.3x ULN               | 0                                       | 0                                   | 0                                   | 0                                    |
| Creatinine (mg/dL)>1.3x ULN                  | 0                                       | 0                                   | 0                                   | 0                                    |
| Urate (mg/dL)>1.2x ULN                       | 0                                       | 0                                   | 1                                   | 0                                    |
| HDL Cholesterol (mg/dL)<0.8x LLN             | 0                                       | 0                                   | 0                                   | 0                                    |
| LDL Cholesterol (mg/dL)>1.2x ULN             | 0                                       | 0                                   | 1                                   | 0                                    |
| Triglycerides (mg/dL)>1.3x ULN               | 1                                       | 1                                   | 1                                   | 3                                    |
| Sodium (Meq/L)<0.95x LLN                     | 0                                       | 0                                   | 0                                   | 0                                    |
| Sodium (Meq/L)>1.05xULN                      | 0                                       | 0                                   | 0                                   | 0                                    |
| Potassium (Meq/L)<0.9x LLN                   | 0                                       | 0                                   | 0                                   | 0                                    |
| Potassium (Meq/L)>1.1x ULN                   | 0                                       | 0                                   | 1                                   | 0                                    |
| Chloride (Meq/L)<0.9x LLN                    | 0                                       | 0                                   | 0                                   | 0                                    |
| Chloride (Meq/L)>1.1x ULN                    | 0                                       | 0                                   | 0                                   | 0                                    |
| Calcium (mg/dL)<0.9x LLN                     | 0                                       | 0                                   | 0                                   | 0                                    |
| Calcium (mg/dL)>1.1x ULN                     | 0                                       | 0                                   | 0                                   | 0                                    |
| Glucose (mg/dL)<0.6x LLN                     | 0                                       | 0                                   | 0                                   | 0                                    |
| Glucose (mg/dL)>1.5x ULN                     | 0                                       | 1                                   | 2                                   | 1                                    |
| Hemoglobin A1C (%)>1.3x ULN                  | 0                                       | 0                                   | 0                                   | 0                                    |
| Creatine Kinase (U/L)>2.0x ULN               | 2                                       | 0                                   | 2                                   | 3                                    |
| Cholesterol (mg/dl)>1.3x ULN                 | 0                                       | 0                                   | 1                                   | 0                                    |

| End point values            | PF-06700841<br>10 mg<br>(Induction) | PF-06700841<br>30 mg<br>(Induction) | PF-06700841<br>60 mg<br>(Induction) |  |
|-----------------------------|-------------------------------------|-------------------------------------|-------------------------------------|--|
| Subject group type          | Reporting group                     | Reporting group                     | Reporting group                     |  |
| Number of subjects analysed | 48                                  | 47                                  | 47                                  |  |

| Units: Subjects                           |   |   |   |  |
|-------------------------------------------|---|---|---|--|
| Bilirubin (mg/dL)>1.5x ULN                | 2 | 2 | 1 |  |
| Direct Bilirubin (mg/dL)>1.5x ULN         | 0 | 0 | 0 |  |
| Indirect Bilirubin (mg/dL)>1.5x ULN       | 0 | 0 | 0 |  |
| Aspartate Aminotransferase (U/L)>3.0x ULN | 0 | 0 | 0 |  |
| Alanine Aminotransferase (U/L)>3.0x ULN   | 2 | 0 | 0 |  |
| Gamma Glutamyl Transferase (U/L)>3.0x ULN | 0 | 0 | 0 |  |
| Alkaline Phosphatase (U/L)>3.0x ULN       | 0 | 0 | 0 |  |
| Protein (g/dL)<0.8x LLN                   | 0 | 0 | 0 |  |
| Protein (g/dL)>1.2x ULN                   | 0 | 0 | 0 |  |
| Albumin (g/dL)<0.8x LLN                   | 0 | 0 | 0 |  |
| Albumin (g/dL)>1.2x ULN                   | 0 | 0 | 0 |  |
| Urea Nitrogen (mg/dL)>1.3x ULN            | 0 | 0 | 0 |  |
| Creatinine (mg/dL)>1.3x ULN               | 0 | 1 | 0 |  |
| Urate (mg/dL)>1.2x ULN                    | 0 | 0 | 0 |  |
| HDL Cholesterol (mg/dL)<0.8x LLN          | 0 | 0 | 0 |  |
| LDL Cholesterol (mg/dL)>1.2x ULN          | 0 | 0 | 1 |  |
| Triglycerides (mg/dL)>1.3x ULN            | 1 | 2 | 5 |  |
| Sodium (Meq/L)<0.95x LLN                  | 0 | 0 | 0 |  |
| Sodium (Meq/L)>1.05xULN                   | 0 | 0 | 0 |  |
| Potassium (Meq/L)<0.9x LLN                | 0 | 0 | 0 |  |
| Potassium (Meq/L)>1.1x ULN                | 0 | 0 | 0 |  |
| Chloride (Meq/L)<0.9x LLN                 | 0 | 0 | 0 |  |
| Chloride (Meq/L)>1.1x ULN                 | 0 | 0 | 0 |  |
| Calcium (mg/dL)<0.9x LLN                  | 0 | 0 | 0 |  |
| Calcium (mg/dL)>1.1x ULN                  | 0 | 0 | 0 |  |
| Glucose (mg/dL)<0.6x LLN                  | 0 | 0 | 0 |  |
| Glucose (mg/dL)>1.5x ULN                  | 1 | 0 | 2 |  |
| Hemoglobin A1C (%)>1.3x ULN               | 0 | 0 | 0 |  |
| Creatine Kinase (U/L)>2.0x ULN            | 2 | 3 | 6 |  |
| Cholesterol (mg/dl)>1.3x ULN              | 0 | 1 | 0 |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Induction Period: Number of subjects with Laboratory Abnormalities without regard to baseline values - Urinalysis

|                 |                                                                                                                   |
|-----------------|-------------------------------------------------------------------------------------------------------------------|
| End point title | Induction Period: Number of subjects with Laboratory Abnormalities without regard to baseline values - Urinalysis |
|-----------------|-------------------------------------------------------------------------------------------------------------------|

End point description:

Following parameters were analyzed for laboratory examination: pH, URINE Glucose, Ketones, URINE Protein, URINE Hemoglobin, Nitrite, Leukocyte Esterase, URINE Erythrocytes, URINE Leukocytes, Hyaline Casts, WBC Casts, Bacteria. The analysis population included all enrolled participants who received at least one dose of study medication.

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

End point timeframe:

Baseline through Week 8



| <b>End point values</b>         | Placebo<br>(Induction: 0<br>to 8 weeks) | PF-06651600<br>20 mg<br>(Induction) | PF-06651600<br>70 mg<br>(Induction) | PF-06651600<br>200 mg<br>(Induction) |
|---------------------------------|-----------------------------------------|-------------------------------------|-------------------------------------|--------------------------------------|
| Subject group type              | Reporting group                         | Reporting group                     | Reporting group                     | Reporting group                      |
| Number of subjects analysed     | 25                                      | 49                                  | 48                                  | 50                                   |
| Units: Subjects                 |                                         |                                     |                                     |                                      |
| pH (scalar)<4.5                 | 0                                       | 0                                   | 0                                   | 0                                    |
| pH (scalar)>8                   | 0                                       | 0                                   | 0                                   | 0                                    |
| URINE Glucose (No Unit)>=1      | 0                                       | 1                                   | 4                                   | 1                                    |
| Ketones (No Unit)>=1            | 1                                       | 4                                   | 1                                   | 1                                    |
| URINE Protein (No Unit)>=1      | 0                                       | 2                                   | 0                                   | 1                                    |
| URINE Hemoglobin (No Unit)>=1   | 2                                       | 4                                   | 4                                   | 4                                    |
| Nitrite (No Unit)>=1            | 1                                       | 1                                   | 2                                   | 1                                    |
| Leukocyte Esterase (No Unit)>=1 | 3                                       | 11                                  | 4                                   | 10                                   |
| URINE Erythrocytes (/HPF)>=20   | 0                                       | 0                                   | 1                                   | 1                                    |
| URINE Leukocytes (/HPF)>=20     | 1                                       | 2                                   | 1                                   | 4                                    |
| Granular Casts (/LPF)>1         | 1                                       | 0                                   | 0                                   | 1                                    |
| Hyaline Casts (/LPF)>1          | 3                                       | 2                                   | 2                                   | 4                                    |
| WBC Casts (/LPF)>1              | 0                                       | 0                                   | 1                                   | 0                                    |
| Bacteria (No Unit)>20           | 0                                       | 0                                   | 0                                   | 0                                    |

| <b>End point values</b>         | PF-06700841<br>10 mg<br>(Induction) | PF-06700841<br>30 mg<br>(Induction) | PF-06700841<br>60 mg<br>(Induction) |  |
|---------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|--|
| Subject group type              | Reporting group                     | Reporting group                     | Reporting group                     |  |
| Number of subjects analysed     | 48                                  | 47                                  | 47                                  |  |
| Units: Subjects                 |                                     |                                     |                                     |  |
| pH (scalar)<4.5                 | 0                                   | 0                                   | 0                                   |  |
| pH (scalar)>8                   | 0                                   | 0                                   | 0                                   |  |
| URINE Glucose (No Unit)>=1      | 0                                   | 1                                   | 1                                   |  |
| Ketones (No Unit)>=1            | 7                                   | 4                                   | 4                                   |  |
| URINE Protein (No Unit)>=1      | 1                                   | 2                                   | 0                                   |  |
| URINE Hemoglobin (No Unit)>=1   | 5                                   | 8                                   | 4                                   |  |
| Nitrite (No Unit)>=1            | 2                                   | 0                                   | 1                                   |  |
| Leukocyte Esterase (No Unit)>=1 | 7                                   | 8                                   | 14                                  |  |
| URINE Erythrocytes (/HPF)>=20   | 0                                   | 0                                   | 0                                   |  |
| URINE Leukocytes (/HPF)>=20     | 3                                   | 1                                   | 3                                   |  |
| Granular Casts (/LPF)>1         | 0                                   | 0                                   | 0                                   |  |
| Hyaline Casts (/LPF)>1          | 4                                   | 2                                   | 1                                   |  |
| WBC Casts (/LPF)>1              | 0                                   | 0                                   | 0                                   |  |
| Bacteria (No Unit)>20           | 0                                   | 0                                   | 0                                   |  |

## Statistical analyses

No statistical analyses for this end point

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**Secondary: Induction Period: Number of subjects with abnormal electrocardiogram findings**

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|                 |                                                                               |
|-----------------|-------------------------------------------------------------------------------|
| End point title | Induction Period: Number of subjects with abnormal electrocardiogram findings |
|-----------------|-------------------------------------------------------------------------------|

End point description:

The analysis population included all enrolled participants who received at least one dose of study medication.

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

End point timeframe:

Baseline through Week 8

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| End point values                        | Placebo<br>(Induction: 0<br>to 8 weeks) | PF-06651600<br>20 mg<br>(Induction) | PF-06651600<br>70 mg<br>(Induction) | PF-06651600<br>200 mg<br>(Induction) |
|-----------------------------------------|-----------------------------------------|-------------------------------------|-------------------------------------|--------------------------------------|
| Subject group type                      | Reporting group                         | Reporting group                     | Reporting group                     | Reporting group                      |
| Number of subjects analysed             | 20                                      | 42                                  | 42                                  | 40                                   |
| Units: Subjects                         |                                         |                                     |                                     |                                      |
| NORMAL                                  | 18                                      | 35                                  | 34                                  | 35                                   |
| ABNORMAL, NOT CLINICALLY<br>SIGNIFICANT | 2                                       | 7                                   | 8                                   | 4                                    |
| ABNORMAL, CLINICALLY SIGNIFICANT        | 0                                       | 0                                   | 0                                   | 1                                    |
| NOT EVALUABLE                           | 0                                       | 0                                   | 0                                   | 0                                    |

| End point values                        | PF-06700841<br>10 mg<br>(Induction) | PF-06700841<br>30 mg<br>(Induction) | PF-06700841<br>60 mg<br>(Induction) |  |
|-----------------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|--|
| Subject group type                      | Reporting group                     | Reporting group                     | Reporting group                     |  |
| Number of subjects analysed             | 44                                  | 42                                  | 43                                  |  |
| Units: Subjects                         |                                     |                                     |                                     |  |
| NORMAL                                  | 39                                  | 37                                  | 40                                  |  |
| ABNORMAL, NOT CLINICALLY<br>SIGNIFICANT | 5                                   | 4                                   | 3                                   |  |
| ABNORMAL, CLINICALLY SIGNIFICANT        | 0                                   | 0                                   | 0                                   |  |
| NOT EVALUABLE                           | 0                                   | 1                                   | 0                                   |  |

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**Statistical analyses**

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No statistical analyses for this end point

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**Secondary: Induction Period: Number of subjects with vital signs abnormalities**

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|                 |                                                                     |
|-----------------|---------------------------------------------------------------------|
| End point title | Induction Period: Number of subjects with vital signs abnormalities |
|-----------------|---------------------------------------------------------------------|

End point description:

The criteria of test are indicated below. The analysis population are the subjects evaluated against the

criteria during the induction period.

|                         |           |
|-------------------------|-----------|
| End point type          | Secondary |
| End point timeframe:    |           |
| Baseline through Week 8 |           |

| End point values                                 | Placebo<br>(Induction: 0<br>to 8 weeks) | PF-06651600<br>20 mg<br>(Induction) | PF-06651600<br>70 mg<br>(Induction) | PF-06651600<br>200 mg<br>(Induction) |
|--------------------------------------------------|-----------------------------------------|-------------------------------------|-------------------------------------|--------------------------------------|
| Subject group type                               | Reporting group                         | Reporting group                     | Reporting group                     | Reporting group                      |
| Number of subjects analysed                      | 25                                      | 48                                  | 48                                  | 49                                   |
| Units: Subjects                                  |                                         |                                     |                                     |                                      |
| SITTING SYSTOLIC BLOOD PRESSURE<br>Value <90mmHg | 0                                       | 1                                   | 1                                   | 0                                    |
| SITTING SYSTOLIC BP Chg >=<br>30mmHg increase    | 0                                       | 1                                   | 3                                   | 0                                    |
| SITTING SYSTOLIC BP Chg >=<br>30mmHg decrease    | 0                                       | 1                                   | 0                                   | 0                                    |
| SITTING DIASTOLIC BP Value <50<br>mmHg           | 0                                       | 0                                   | 1                                   | 0                                    |
| SITTING DIASTOLIC BP Chg >=<br>20mmHg increase   | 0                                       | 2                                   | 3                                   | 0                                    |
| SITTING DIASTOLIC BP Chg >=<br>20mmHg decrease   | 0                                       | 4                                   | 4                                   | 2                                    |
| SITTING PULSE RATE Value <40 bpm                 | 0                                       | 0                                   | 0                                   | 0                                    |
| SITTING PULSE RATE Value >120 bpm                | 0                                       | 1                                   | 0                                   | 0                                    |

| End point values                                 | PF-06700841<br>10 mg<br>(Induction) | PF-06700841<br>30 mg<br>(Induction) | PF-06700841<br>60 mg<br>(Induction) |  |
|--------------------------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|--|
| Subject group type                               | Reporting group                     | Reporting group                     | Reporting group                     |  |
| Number of subjects analysed                      | 47                                  | 46                                  | 45                                  |  |
| Units: Subjects                                  |                                     |                                     |                                     |  |
| SITTING SYSTOLIC BLOOD PRESSURE<br>Value <90mmHg | 3                                   | 0                                   | 0                                   |  |
| SITTING SYSTOLIC BP Chg >=<br>30mmHg increase    | 0                                   | 0                                   | 3                                   |  |
| SITTING SYSTOLIC BP Chg >=<br>30mmHg decrease    | 0                                   | 1                                   | 0                                   |  |
| SITTING DIASTOLIC BP Value <50<br>mmHg           | 0                                   | 0                                   | 0                                   |  |
| SITTING DIASTOLIC BP Chg >=<br>20mmHg increase   | 2                                   | 1                                   | 5                                   |  |
| SITTING DIASTOLIC BP Chg >=<br>20mmHg decrease   | 2                                   | 1                                   | 2                                   |  |
| SITTING PULSE RATE Value <40 bpm                 | 0                                   | 0                                   | 0                                   |  |
| SITTING PULSE RATE Value >120 bpm                | 0                                   | 0                                   | 0                                   |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Induction Period: Number of subjects with Serious Infection

End point title Induction Period: Number of subjects with Serious Infection

End point description:

Serious infections are treated infections that: Require parenteral antimicrobial therapy and present with positive pre-treatment culture; and either Require hospitalization for treatment; or Meet other criteria that require the infection to be classified as a SAE. The analysis population included all enrolled participants who received at least one dose of study medication.

End point type Secondary

End point timeframe:

Baseline through Week 8

| End point values            | Placebo<br>(Induction: 0<br>to 8 weeks) | PF-06651600<br>20 mg<br>(Induction) | PF-06651600<br>70 mg<br>(Induction) | PF-06651600<br>200 mg<br>(Induction) |
|-----------------------------|-----------------------------------------|-------------------------------------|-------------------------------------|--------------------------------------|
| Subject group type          | Reporting group                         | Reporting group                     | Reporting group                     | Reporting group                      |
| Number of subjects analysed | 25                                      | 51                                  | 49                                  | 50                                   |
| Units: Subjects             |                                         |                                     |                                     |                                      |
| Listeria encephalitis       | 0                                       | 0                                   | 0                                   | 1                                    |
| Pneumonia                   | 0                                       | 1                                   | 0                                   | 0                                    |
| Viral infection             | 0                                       | 1                                   | 0                                   | 0                                    |

| End point values            | PF-06700841<br>10 mg<br>(Induction) | PF-06700841<br>30 mg<br>(Induction) | PF-06700841<br>60 mg<br>(Induction) |  |
|-----------------------------|-------------------------------------|-------------------------------------|-------------------------------------|--|
| Subject group type          | Reporting group                     | Reporting group                     | Reporting group                     |  |
| Number of subjects analysed | 48                                  | 47                                  | 47                                  |  |
| Units: Subjects             |                                     |                                     |                                     |  |
| Listeria encephalitis       | 0                                   | 0                                   | 0                                   |  |
| Pneumonia                   | 0                                   | 0                                   | 0                                   |  |
| Viral infection             | 0                                   | 0                                   | 0                                   |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Chronic Period: Total Mayo Score at Week 32

End point title Chronic Period: Total Mayo Score at Week 32

End point description:

The Mayo score ranges from 0 to 12, with higher scores indicating more severe disease. The mITT analysis set was used to analyze this endpoint, defined as all randomized subjects who received at least 1 dose of investigational product or placebo.

End point type Secondary

End point timeframe:

Week 32

|                                              |                                                   |                                                  |                                                  |                                     |
|----------------------------------------------|---------------------------------------------------|--------------------------------------------------|--------------------------------------------------|-------------------------------------|
| <b>End point values</b>                      | PF-06651600<br>200 mg -> PF-<br>06651600 50<br>mg | PF-06651600<br>70 mg -> PF-<br>06651600 50<br>mg | PF-06651600<br>20 mg -> PF-<br>06651600 50<br>mg | Placebo -> PF-<br>06651600 50<br>mg |
| Subject group type                           | Reporting group                                   | Reporting group                                  | Reporting group                                  | Reporting group                     |
| Number of subjects analysed                  | 35                                                | 36                                               | 39                                               | 10                                  |
| Units: Unit on a scale                       |                                                   |                                                  |                                                  |                                     |
| least squares mean (confidence interval 90%) | 2.89 (2.18 to 3.60)                               | 3.46 (2.77 to 4.16)                              | 3.47 (2.75 to 4.19)                              | 4.13 (2.82 to 5.44)                 |

|                                              |                                                  |                                                  |                                                  |                                     |
|----------------------------------------------|--------------------------------------------------|--------------------------------------------------|--------------------------------------------------|-------------------------------------|
| <b>End point values</b>                      | PF-06700841<br>60 mg -> PF-<br>06700841 30<br>mg | PF-06700841<br>30 mg -> PF-<br>06700841 30<br>mg | PF-06700841<br>10 mg -> PF-<br>06700841 30<br>mg | Placebo -> PF-<br>06700841 30<br>mg |
| Subject group type                           | Reporting group                                  | Reporting group                                  | Reporting group                                  | Reporting group                     |
| Number of subjects analysed                  | 38                                               | 37                                               | 39                                               | 9                                   |
| Units: Unit on a scale                       |                                                  |                                                  |                                                  |                                     |
| least squares mean (confidence interval 90%) | 3.86 (2.98 to 4.75)                              | 3.63 (2.67 to 4.59)                              | 3.81 (2.94 to 4.68)                              | 4.62 (2.62 to 6.61)                 |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Chronic Period: Percentage of subjects achieving remission based on total Mayo score at Week 32

|                                                                                                                                                                                                                                                                                                                                                   |                                                                                                 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|
| End point title                                                                                                                                                                                                                                                                                                                                   | Chronic Period: Percentage of subjects achieving remission based on total Mayo score at Week 32 |
| End point description:                                                                                                                                                                                                                                                                                                                            |                                                                                                 |
| Remission excludes friability and is based on total Mayo score of less than/equal to 2 with no individual subscore greater than 1 and a rectal bleeding subscore of 0 at week 32. The mITT analysis set was used to analyze this endpoint, defined as all randomized subjects who received at least 1 dose of investigational product or placebo. |                                                                                                 |
| End point type                                                                                                                                                                                                                                                                                                                                    | Secondary                                                                                       |
| End point timeframe:                                                                                                                                                                                                                                                                                                                              |                                                                                                 |
| Week 32                                                                                                                                                                                                                                                                                                                                           |                                                                                                 |

|                             |                                                           |                                                                            |                                                                            |                                                                             |
|-----------------------------|-----------------------------------------------------------|----------------------------------------------------------------------------|----------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| <b>End point values</b>     | mITT Analysis<br>Set: Placebo -<br>> PF-06651600<br>50 mg | mITT Analysis<br>Set: PF-<br>06651600 20<br>mg -> PF-<br>06651600 50<br>mg | mITT Analysis<br>Set: PF-<br>06651600 70<br>mg -> PF-<br>06651600 50<br>mg | mITT Analysis<br>Set: PF-<br>06651600 200<br>mg -> PF-<br>06651600 50<br>mg |
| Subject group type          | Subject analysis set                                      | Subject analysis set                                                       | Subject analysis set                                                       | Subject analysis set                                                        |
| Number of subjects analysed | 12                                                        | 46                                                                         | 42                                                                         | 44                                                                          |

|                                  |                    |                     |                     |                     |
|----------------------------------|--------------------|---------------------|---------------------|---------------------|
| Units: Percentage of subjects    |                    |                     |                     |                     |
| number (confidence interval 90%) | 16.7 (4.5 to 39.8) | 23.9 (15.1 to 35.0) | 28.6 (17.4 to 41.0) | 34.1 (22.3 to 46.5) |

|                                  |                                                  |                                                           |                                                           |                                                           |
|----------------------------------|--------------------------------------------------|-----------------------------------------------------------|-----------------------------------------------------------|-----------------------------------------------------------|
| <b>End point values</b>          | mITT Analysis Set: Placebo - > PF-06700841 30 mg | mITT Analysis Set: PF-06700841 10 mg -> PF-06700841 30 mg | mITT Analysis Set: PF-06700841 30 mg -> PF-06700841 30 mg | mITT Analysis Set: PF-06700841 60 mg -> PF-06700841 30 mg |
| Subject group type               | Subject analysis set                             | Subject analysis set                                      | Subject analysis set                                      | Subject analysis set                                      |
| Number of subjects analysed      | 11                                               | 42                                                        | 41                                                        | 41                                                        |
| Units: Percentage of subjects    |                                                  |                                                           |                                                           |                                                           |
| number (confidence interval 90%) | 18.2 (4.9 to 43.6)                               | 21.4 (12.6 to 34.2)                                       | 26.8 (17.1 to 39.8)                                       | 26.8 (17.1 to 39.8)                                       |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Chronic Period: Percentage of subjects achieving improvement in endoscopic appearance at Week 32

|                        |                                                                                                                                                                                                                                                                        |
|------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title        | Chronic Period: Percentage of subjects achieving improvement in endoscopic appearance at Week 32                                                                                                                                                                       |
| End point description: | Improvement of endoscopic appearance is defined as a Mayo endoscopic subscore of less than/equal to 1. The mITT analysis set was used to analyze this endpoint, defined as all randomized subjects who received at least 1 dose of investigational product or placebo. |
| End point type         | Secondary                                                                                                                                                                                                                                                              |
| End point timeframe:   | Week 32                                                                                                                                                                                                                                                                |

|                                  |                                                  |                                                           |                                                           |                                                            |
|----------------------------------|--------------------------------------------------|-----------------------------------------------------------|-----------------------------------------------------------|------------------------------------------------------------|
| <b>End point values</b>          | mITT Analysis Set: Placebo - > PF-06651600 50 mg | mITT Analysis Set: PF-06651600 20 mg -> PF-06651600 50 mg | mITT Analysis Set: PF-06651600 70 mg -> PF-06651600 50 mg | mITT Analysis Set: PF-06651600 200 mg -> PF-06651600 50 mg |
| Subject group type               | Subject analysis set                             | Subject analysis set                                      | Subject analysis set                                      | Subject analysis set                                       |
| Number of subjects analysed      | 12                                               | 46                                                        | 42                                                        | 44                                                         |
| Units: Percentage of subjects    |                                                  |                                                           |                                                           |                                                            |
| number (confidence interval 90%) | 33.3 (15.4 to 60.2)                              | 26.1 (15.8 to 37.7)                                       | 40.5 (27.7 to 54.3)                                       | 34.1 (22.3 to 46.5)                                        |

|                         |                                            |                                   |                                   |                                   |
|-------------------------|--------------------------------------------|-----------------------------------|-----------------------------------|-----------------------------------|
| <b>End point values</b> | mITT Analysis Set: Placebo - > PF-06700841 | mITT Analysis Set: PF-06700841 10 | mITT Analysis Set: PF-06700841 30 | mITT Analysis Set: PF-06700841 60 |
|-------------------------|--------------------------------------------|-----------------------------------|-----------------------------------|-----------------------------------|

|                                  | 30 mg                | mg -> PF-06700841 30 mg | mg -> PF-06700841 30 mg | mg -> PF-06700841 30 mg |
|----------------------------------|----------------------|-------------------------|-------------------------|-------------------------|
| Subject group type               | Subject analysis set | Subject analysis set    | Subject analysis set    | Subject analysis set    |
| Number of subjects analysed      | 11                   | 42                      | 41                      | 41                      |
| Units: Percentage of subjects    |                      |                         |                         |                         |
| number (confidence interval 90%) | 18.2 (4.9 to 43.6)   | 31.0 (19.4 to 43.3)     | 34.1 (23.0 to 46.9)     | 36.6 (24.6 to 50.0)     |

## Statistical analyses

No statistical analyses for this end point

## Other pre-specified: Chronic Period: Change from baseline in total Mayo score

|                                                                                                                                                                                                                                                                                                                                                                                            |                                                          |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------|
| End point title                                                                                                                                                                                                                                                                                                                                                                            | Chronic Period: Change from baseline in total Mayo score |
| End point description:                                                                                                                                                                                                                                                                                                                                                                     |                                                          |
| Total Mayo Score ranges from 0 to 12, with higher scores indicating more severe disease. Baseline value is defined as the last non-missing measurement collected prior to the first administration of study drug at Day 1. The mITT analysis set was used to analyze this endpoint, defined as all randomized subjects who received at least 1 dose of investigational product or placebo. |                                                          |
| End point type                                                                                                                                                                                                                                                                                                                                                                             | Other pre-specified                                      |
| End point timeframe:                                                                                                                                                                                                                                                                                                                                                                       |                                                          |
| Week 32                                                                                                                                                                                                                                                                                                                                                                                    |                                                          |

| End point values                             | PF-06651600 200 mg -> PF-06651600 50 mg | PF-06651600 70 mg -> PF-06651600 50 mg | PF-06651600 20 mg -> PF-06651600 50 mg | Placebo -> PF-06651600 50 mg |
|----------------------------------------------|-----------------------------------------|----------------------------------------|----------------------------------------|------------------------------|
| Subject group type                           | Reporting group                         | Reporting group                        | Reporting group                        | Reporting group              |
| Number of subjects analysed                  | 35                                      | 36                                     | 39                                     | 10                           |
| Units: Units on a scale                      |                                         |                                        |                                        |                              |
| least squares mean (confidence interval 90%) | -6.12 (-6.83 to -5.41)                  | -5.55 (-6.24 to -4.85)                 | -5.54 (-6.26 to -4.82)                 | -4.88 (-6.19 to -3.57)       |

| End point values                             | PF-06700841 60 mg -> PF-06700841 30 mg | PF-06700841 30 mg -> PF-06700841 30 mg | PF-06700841 10 mg -> PF-06700841 30 mg | Placebo -> PF-06700841 30 mg |
|----------------------------------------------|----------------------------------------|----------------------------------------|----------------------------------------|------------------------------|
| Subject group type                           | Reporting group                        | Reporting group                        | Reporting group                        | Reporting group              |
| Number of subjects analysed                  | 38                                     | 37                                     | 39                                     | 9                            |
| Units: Units on a scale                      |                                        |                                        |                                        |                              |
| least squares mean (confidence interval 90%) | -5.21 (-6.09 to -4.32)                 | -5.44 (-6.39 to -4.48)                 | -5.26 (-6.12 to -4.39)                 | -4.45 (-6.45 to -2.45)       |

## Statistical analyses





## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

From the time the subject took at least 1 dose of study treatment up to 28 days after the last treatment administration. (approximately 36 Weeks)

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

### Dictionary used

|                 |        |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

|                    |      |
|--------------------|------|
| Dictionary version | 24.0 |
|--------------------|------|

### Reporting groups

|                       |                                   |
|-----------------------|-----------------------------------|
| Reporting group title | Placebo (Induction: 0 to 8 weeks) |
|-----------------------|-----------------------------------|

Reporting group description:

The placebo was administered orally once daily (QD) from Day 1 to Week 8.

|                       |                               |
|-----------------------|-------------------------------|
| Reporting group title | PF-06651600 20 mg (Induction) |
|-----------------------|-------------------------------|

Reporting group description:

PF-06651600 tablet was administered orally at 20 mg QD from Day 1 to Week 8.

|                       |                               |
|-----------------------|-------------------------------|
| Reporting group title | PF-06651600 70 mg (Induction) |
|-----------------------|-------------------------------|

Reporting group description:

PF-06651600 tablet was administered orally at 70 mg QD from Day 1 to Week 8.

|                       |                                |
|-----------------------|--------------------------------|
| Reporting group title | PF-06651600 200 mg (Induction) |
|-----------------------|--------------------------------|

Reporting group description:

PF-06651600 tablet was administered orally at 200 mg QD from Day 1 to Week 8.

|                       |                               |
|-----------------------|-------------------------------|
| Reporting group title | PF-06700841 10 mg (Induction) |
|-----------------------|-------------------------------|

Reporting group description:

PF-06700841 tablet was administered orally at 10 mg QD from Day 1 to Week 8.

|                       |                               |
|-----------------------|-------------------------------|
| Reporting group title | PF-06700841 30 mg (Induction) |
|-----------------------|-------------------------------|

Reporting group description:

PF-06700841 tablet was administered orally at 30 mg QD from Day 1 to Week 8.

|                       |                               |
|-----------------------|-------------------------------|
| Reporting group title | PF-06700841 60 mg (Induction) |
|-----------------------|-------------------------------|

Reporting group description:

PF-06700841 tablet was administered orally at 60 mg QD from Day 1 to Week 8.

|                       |                                         |
|-----------------------|-----------------------------------------|
| Reporting group title | PF-06651600 200 mg -> PF-06651600 50 mg |
|-----------------------|-----------------------------------------|

Reporting group description:

PF-06651600 tablet was administered orally at 200 mg QD from Day 1 to Week 8 and at 50 mg QD from Week 9 to Week 32.

|                       |                              |
|-----------------------|------------------------------|
| Reporting group title | Placebo -> PF-06651600 50 mg |
|-----------------------|------------------------------|

Reporting group description:

The placebo was administered orally QD from Day 1 to Week 8 and PF-06651600 was administered at 50 mg QD from Week 9 to Week 32.

|                       |                                        |
|-----------------------|----------------------------------------|
| Reporting group title | PF-06651600 20 mg -> PF-06651600 50 mg |
|-----------------------|----------------------------------------|

Reporting group description:

PF-06651600 tablet was administered orally at 20 mg QD from Day 1 to Week 8 and at 50 mg QD from Week 9 to Week 32.

|                       |                                        |
|-----------------------|----------------------------------------|
| Reporting group title | PF-06651600 70 mg -> PF-06651600 50 mg |
|-----------------------|----------------------------------------|

Reporting group description:

PF-06651600 tablet was administered orally at 70 mg QD from Day 1 to Week 8 and at 50 mg QD from Week 9 to Week 32.

|                       |                                        |
|-----------------------|----------------------------------------|
| Reporting group title | PF-06700841 60 mg -> PF-06700841 30 mg |
|-----------------------|----------------------------------------|

Reporting group description:

PF-06700841 tablet was administered orally at 60 mg QD from Day 1 to Week 8 and at 30 mg QD from Week 9 to Week 32.

|                                                                                                                                                                      |                                        |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|
| Reporting group title                                                                                                                                                | Placebo -> PF-06700841 30 mg           |
| Reporting group description:<br>The placebo was administered orally from Day 1 to Week 8 and PF-06700841 was administered orally at 30 mg QD from Week 9 to Week 32. |                                        |
| Reporting group title                                                                                                                                                | PF-06700841 10 mg -> PF-06700841 30 mg |
| Reporting group description:<br>PF-06700841 tablet was administered orally at 10 mg QD from Day 1 to Week 8 and at 30 mg QD from Week 9 to Week 32.                  |                                        |
| Reporting group title                                                                                                                                                | PF-06700841 30 mg -> PF-06700841 30 mg |
| Reporting group description:<br>PF-06700841 tablet was administered orally at 30 mg QD from Day 1 to Week 8 and at 30 mg QD from Week 9 to Week 32.                  |                                        |
| Reporting group title                                                                                                                                                | Pooling Placebo During Chronic         |
| Reporting group description:<br>The placebo was administered orally QD from Week 9 to Week 32 regardless of what was administered from Day 1 to Week 8.              |                                        |

| Serious adverse events                                           | Placebo (Induction: 0 to 8 weeks)                    | PF-06651600 20 mg (Induction) | PF-06651600 70 mg (Induction) |
|------------------------------------------------------------------|------------------------------------------------------|-------------------------------|-------------------------------|
| Total subjects affected by serious adverse events                |                                                      |                               |                               |
| subjects affected / exposed                                      | 0 / 25 (0.00%)                                       | 3 / 51 (5.88%)                | 0 / 49 (0.00%)                |
| number of deaths (all causes)                                    | 0                                                    | 1                             | 0                             |
| number of deaths resulting from adverse events                   | 0                                                    | 1                             | 0                             |
| Injury, poisoning and procedural complications                   |                                                      |                               |                               |
| Ankle injury                                                     | Additional description: Ankle fracture               |                               |                               |
| subjects affected / exposed                                      | 0 / 25 (0.00%)                                       | 0 / 51 (0.00%)                | 0 / 49 (0.00%)                |
| occurrences causally related to treatment / all                  | 0 / 0                                                | 0 / 0                         | 0 / 0                         |
| deaths causally related to treatment / all                       | 0 / 0                                                | 0 / 0                         | 0 / 0                         |
| Fracture bone                                                    | Additional description: Femur fracture               |                               |                               |
| subjects affected / exposed                                      | 0 / 25 (0.00%)                                       | 0 / 51 (0.00%)                | 0 / 49 (0.00%)                |
| occurrences causally related to treatment / all                  | 0 / 0                                                | 0 / 0                         | 0 / 0                         |
| deaths causally related to treatment / all                       | 0 / 0                                                | 0 / 0                         | 0 / 0                         |
| Vascular disorders                                               |                                                      |                               |                               |
| Peripheral vasoconstriction, necrosis and vascular insufficiency | Additional description: Peripheral artery thrombosis |                               |                               |
| subjects affected / exposed                                      | 0 / 25 (0.00%)                                       | 0 / 51 (0.00%)                | 0 / 49 (0.00%)                |
| occurrences causally related to treatment / all                  | 0 / 0                                                | 0 / 0                         | 0 / 0                         |
| deaths causally related to treatment / all                       | 0 / 0                                                | 0 / 0                         | 0 / 0                         |
| Cardiac disorders                                                |                                                      |                               |                               |
| Myocardial infarction                                            |                                                      |                               |                               |

|                                                      |                                               |                |                |
|------------------------------------------------------|-----------------------------------------------|----------------|----------------|
| subjects affected / exposed                          | 0 / 25 (0.00%)                                | 1 / 51 (1.96%) | 0 / 49 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0                                         | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0                                         | 1 / 1          | 0 / 0          |
| Myocardial ischemia                                  |                                               |                |                |
| subjects affected / exposed                          | 0 / 25 (0.00%)                                | 0 / 51 (0.00%) | 0 / 49 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0                                         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0                                         | 0 / 0          | 0 / 0          |
| Surgical and medical procedures                      |                                               |                |                |
| Haemorrhoid                                          | Additional description: Haemorrhoid operation |                |                |
| subjects affected / exposed                          | 0 / 25 (0.00%)                                | 0 / 51 (0.00%) | 0 / 49 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0                                         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0                                         | 0 / 0          | 0 / 0          |
| Blood and lymphatic system disorders                 |                                               |                |                |
| Anaemia                                              |                                               |                |                |
| subjects affected / exposed                          | 0 / 25 (0.00%)                                | 0 / 51 (0.00%) | 0 / 49 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0                                         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0                                         | 0 / 0          | 0 / 0          |
| General disorders and administration site conditions |                                               |                |                |
| Pyrexia                                              |                                               |                |                |
| subjects affected / exposed                          | 0 / 25 (0.00%)                                | 0 / 51 (0.00%) | 0 / 49 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0                                         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0                                         | 0 / 0          | 0 / 0          |
| Gastrointestinal disorders                           |                                               |                |                |
| Colitis ulcerative                                   |                                               |                |                |
| subjects affected / exposed                          | 0 / 25 (0.00%)                                | 1 / 51 (1.96%) | 0 / 49 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0                                         | 1 / 1          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0                                         | 0 / 0          | 0 / 0          |
| Large intestine perforation                          |                                               |                |                |
| subjects affected / exposed                          | 0 / 25 (0.00%)                                | 0 / 51 (0.00%) | 0 / 49 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0                                         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0                                         | 0 / 0          | 0 / 0          |
| Respiratory, thoracic and mediastinal disorders      |                                               |                |                |
| Interstitial lung fibrosis                           |                                               |                |                |

|                                                 |                                             |                |                |
|-------------------------------------------------|---------------------------------------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 25 (0.00%)                              | 0 / 51 (0.00%) | 0 / 49 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                       | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                                       | 0 / 0          | 0 / 0          |
| Skin and subcutaneous tissue disorders          |                                             |                |                |
| Urticaria generalised                           |                                             |                |                |
| subjects affected / exposed                     | 0 / 25 (0.00%)                              | 0 / 51 (0.00%) | 0 / 49 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                       | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                                       | 0 / 0          | 0 / 0          |
| Renal and urinary disorders                     |                                             |                |                |
| Kidney dysfunction                              |                                             |                |                |
|                                                 | Additional description: Acute kidney injury |                |                |
| subjects affected / exposed                     | 0 / 25 (0.00%)                              | 0 / 51 (0.00%) | 0 / 49 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                       | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                                       | 0 / 0          | 0 / 0          |
| Infections and infestations                     |                                             |                |                |
| Listeria encephalitis                           |                                             |                |                |
| subjects affected / exposed                     | 0 / 25 (0.00%)                              | 0 / 51 (0.00%) | 0 / 49 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                       | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                                       | 0 / 0          | 0 / 0          |
| Pneumonia                                       |                                             |                |                |
| subjects affected / exposed                     | 0 / 25 (0.00%)                              | 1 / 51 (1.96%) | 0 / 49 (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          |
| Viral DNA test positive                         |                                             |                |                |
|                                                 | Additional description: Viral infection     |                |                |
| subjects affected / exposed                     | 0 / 25 (0.00%)                              | 1 / 51 (1.96%) | 0 / 49 (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          |
| Pneumonia viral                                 |                                             |                |                |
|                                                 | Additional description: COVID-19            |                |                |
| subjects affected / exposed                     | 0 / 25 (0.00%)                              | 0 / 51 (0.00%) | 0 / 49 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                       | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                                       | 0 / 0          | 0 / 0          |
| Metabolism and nutrition disorders              |                                             |                |                |
| Dehydration                                     |                                             |                |                |

|                                                 |                |                |                |
|-------------------------------------------------|----------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 25 (0.00%) | 0 / 51 (0.00%) | 0 / 49 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |

| <b>Serious adverse events</b>                                    | PF-06651600 200 mg (Induction)                       | PF-06700841 10 mg (Induction) | PF-06700841 30 mg (Induction) |
|------------------------------------------------------------------|------------------------------------------------------|-------------------------------|-------------------------------|
| Total subjects affected by serious adverse events                |                                                      |                               |                               |
| subjects affected / exposed                                      | 3 / 50 (6.00%)                                       | 1 / 48 (2.08%)                | 3 / 47 (6.38%)                |
| number of deaths (all causes)                                    | 0                                                    | 0                             | 0                             |
| number of deaths resulting from adverse events                   | 0                                                    | 0                             | 0                             |
| Injury, poisoning and procedural complications                   |                                                      |                               |                               |
| Ankle injury                                                     | Additional description: Ankle fracture               |                               |                               |
| subjects affected / exposed                                      | 0 / 50 (0.00%)                                       | 0 / 48 (0.00%)                | 0 / 47 (0.00%)                |
| occurrences causally related to treatment / all                  | 0 / 0                                                | 0 / 0                         | 0 / 0                         |
| deaths causally related to treatment / all                       | 0 / 0                                                | 0 / 0                         | 0 / 0                         |
| Fracture bone                                                    | Additional description: Femur fracture               |                               |                               |
| subjects affected / exposed                                      | 0 / 50 (0.00%)                                       | 0 / 48 (0.00%)                | 0 / 47 (0.00%)                |
| occurrences causally related to treatment / all                  | 0 / 0                                                | 0 / 0                         | 0 / 0                         |
| deaths causally related to treatment / all                       | 0 / 0                                                | 0 / 0                         | 0 / 0                         |
| Vascular disorders                                               |                                                      |                               |                               |
| Peripheral vasoconstriction, necrosis and vascular insufficiency | Additional description: Peripheral artery thrombosis |                               |                               |
| subjects affected / exposed                                      | 0 / 50 (0.00%)                                       | 0 / 48 (0.00%)                | 1 / 47 (2.13%)                |
| occurrences causally related to treatment / all                  | 0 / 0                                                | 0 / 0                         | 0 / 1                         |
| deaths causally related to treatment / all                       | 0 / 0                                                | 0 / 0                         | 0 / 0                         |
| Cardiac disorders                                                |                                                      |                               |                               |
| Myocardial infarction                                            |                                                      |                               |                               |
| subjects affected / exposed                                      | 0 / 50 (0.00%)                                       | 0 / 48 (0.00%)                | 0 / 47 (0.00%)                |
| occurrences causally related to treatment / all                  | 0 / 0                                                | 0 / 0                         | 0 / 0                         |
| deaths causally related to treatment / all                       | 0 / 0                                                | 0 / 0                         | 0 / 0                         |
| Myocardial ischemia                                              |                                                      |                               |                               |
| subjects affected / exposed                                      | 0 / 50 (0.00%)                                       | 0 / 48 (0.00%)                | 0 / 47 (0.00%)                |
| occurrences causally related to treatment / all                  | 0 / 0                                                | 0 / 0                         | 0 / 0                         |
| deaths causally related to treatment / all                       | 0 / 0                                                | 0 / 0                         | 0 / 0                         |
| Surgical and medical procedures                                  |                                                      |                               |                               |
| Haemorrhoid                                                      | Additional description: Haemorrhoid operation        |                               |                               |

|                                                      |                |                |                |
|------------------------------------------------------|----------------|----------------|----------------|
| subjects affected / exposed                          | 0 / 50 (0.00%) | 0 / 48 (0.00%) | 1 / 47 (2.13%) |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |
| Blood and lymphatic system disorders                 |                |                |                |
| Anaemia                                              |                |                |                |
| subjects affected / exposed                          | 0 / 50 (0.00%) | 0 / 48 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |
| General disorders and administration site conditions |                |                |                |
| Pyrexia                                              |                |                |                |
| subjects affected / exposed                          | 0 / 50 (0.00%) | 0 / 48 (0.00%) | 1 / 47 (2.13%) |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |
| Gastrointestinal disorders                           |                |                |                |
| Colitis ulcerative                                   |                |                |                |
| subjects affected / exposed                          | 1 / 50 (2.00%) | 1 / 48 (2.08%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 1          | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |
| Large intestine perforation                          |                |                |                |
| subjects affected / exposed                          | 0 / 50 (0.00%) | 0 / 48 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |
| Respiratory, thoracic and mediastinal disorders      |                |                |                |
| Interstitial lung fibrosis                           |                |                |                |
| subjects affected / exposed                          | 1 / 50 (2.00%) | 0 / 48 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 1          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |
| Skin and subcutaneous tissue disorders               |                |                |                |
| Urticaria generalised                                |                |                |                |
| subjects affected / exposed                          | 0 / 50 (0.00%) | 0 / 48 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |
| Renal and urinary disorders                          |                |                |                |
| Kidney dysfunction                                   |                |                |                |
| Additional description: Acute kidney injury          |                |                |                |

|                                                 |                |                |                |
|-------------------------------------------------|----------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 50 (0.00%) | 0 / 48 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| <b>Infections and infestations</b>              |                |                |                |
| Listeria encephalitis                           |                |                |                |
| subjects affected / exposed                     | 1 / 50 (2.00%) | 0 / 48 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Pneumonia                                       |                |                |                |
| subjects affected / exposed                     | 0 / 50 (0.00%) | 0 / 48 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| <b>Viral DNA test positive</b>                  |                |                |                |
| Additional description: Viral infection         |                |                |                |
| subjects affected / exposed                     | 0 / 50 (0.00%) | 0 / 48 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| <b>Pneumonia viral</b>                          |                |                |                |
| Additional description: COVID-19                |                |                |                |
| subjects affected / exposed                     | 0 / 50 (0.00%) | 0 / 48 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| <b>Metabolism and nutrition disorders</b>       |                |                |                |
| Dehydration                                     |                |                |                |
| subjects affected / exposed                     | 0 / 50 (0.00%) | 0 / 48 (0.00%) | 0 / 47 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |

|                                                          |                               |                                         |                              |
|----------------------------------------------------------|-------------------------------|-----------------------------------------|------------------------------|
| <b>Serious adverse events</b>                            | PF-06700841 60 mg (Induction) | PF-06651600 200 mg -> PF-06651600 50 mg | Placebo -> PF-06651600 50 mg |
| <b>Total subjects affected by serious adverse events</b> |                               |                                         |                              |
| subjects affected / exposed                              | 1 / 47 (2.13%)                | 3 / 35 (8.57%)                          | 0 / 10 (0.00%)               |
| number of deaths (all causes)                            | 0                             | 0                                       | 0                            |
| number of deaths resulting from adverse events           | 0                             | 0                                       | 0                            |
| <b>Injury, poisoning and procedural complications</b>    |                               |                                         |                              |
| Ankle injury                                             |                               |                                         |                              |
| Additional description: Ankle fracture                   |                               |                                         |                              |

|                                                                  |                                                      |                |                |
|------------------------------------------------------------------|------------------------------------------------------|----------------|----------------|
| subjects affected / exposed                                      | 0 / 47 (0.00%)                                       | 1 / 35 (2.86%) | 0 / 10 (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          |
| Fracture bone                                                    | Additional description: Femur fracture               |                |                |
| subjects affected / exposed                                      | 0 / 47 (0.00%)                                       | 1 / 35 (2.86%) | 0 / 10 (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          |
| Vascular disorders                                               |                                                      |                |                |
| Peripheral vasoconstriction, necrosis and vascular insufficiency | Additional description: Peripheral artery thrombosis |                |                |
| subjects affected / exposed                                      | 0 / 47 (0.00%)                                       | 0 / 35 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all                  | 0 / 0                                                | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all                       | 0 / 0                                                | 0 / 0          | 0 / 0          |
| Cardiac disorders                                                |                                                      |                |                |
| Myocardial infarction                                            |                                                      |                |                |
| subjects affected / exposed                                      | 0 / 47 (0.00%)                                       | 0 / 35 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all                  | 0 / 0                                                | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all                       | 0 / 0                                                | 0 / 0          | 0 / 0          |
| Myocardial ischemia                                              |                                                      |                |                |
| subjects affected / exposed                                      | 0 / 47 (0.00%)                                       | 0 / 35 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all                  | 0 / 0                                                | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all                       | 0 / 0                                                | 0 / 0          | 0 / 0          |
| Surgical and medical procedures                                  |                                                      |                |                |
| Haemorrhoid                                                      | Additional description: Haemorrhoid operation        |                |                |
| subjects affected / exposed                                      | 0 / 47 (0.00%)                                       | 0 / 35 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all                  | 0 / 0                                                | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all                       | 0 / 0                                                | 0 / 0          | 0 / 0          |
| Blood and lymphatic system disorders                             |                                                      |                |                |
| Anaemia                                                          |                                                      |                |                |
| subjects affected / exposed                                      | 1 / 47 (2.13%)                                       | 0 / 35 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all                  | 0 / 1                                                | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all                       | 0 / 0                                                | 0 / 0          | 0 / 0          |
| General disorders and administration site conditions             |                                                      |                |                |
| Pyrexia                                                          |                                                      |                |                |



|                                                        |                                             |                |                |
|--------------------------------------------------------|---------------------------------------------|----------------|----------------|
| subjects affected / exposed                            | 0 / 47 (0.00%)                              | 0 / 35 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all        | 0 / 0                                       | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all             | 0 / 0                                       | 0 / 0          | 0 / 0          |
| <b>Gastrointestinal disorders</b>                      |                                             |                |                |
| Colitis ulcerative                                     |                                             |                |                |
| subjects affected / exposed                            | 0 / 47 (0.00%)                              | 0 / 35 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all        | 0 / 0                                       | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all             | 0 / 0                                       | 0 / 0          | 0 / 0          |
| Large intestine perforation                            |                                             |                |                |
| subjects affected / exposed                            | 0 / 47 (0.00%)                              | 0 / 35 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all        | 0 / 0                                       | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all             | 0 / 0                                       | 0 / 0          | 0 / 0          |
| <b>Respiratory, thoracic and mediastinal disorders</b> |                                             |                |                |
| Interstitial lung fibrosis                             |                                             |                |                |
| subjects affected / exposed                            | 0 / 47 (0.00%)                              | 0 / 35 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all        | 0 / 0                                       | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all             | 0 / 0                                       | 0 / 0          | 0 / 0          |
| <b>Skin and subcutaneous tissue disorders</b>          |                                             |                |                |
| Urticaria generalised                                  |                                             |                |                |
| subjects affected / exposed                            | 0 / 47 (0.00%)                              | 1 / 35 (2.86%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all        | 0 / 0                                       | 1 / 1          | 0 / 0          |
| deaths causally related to treatment / all             | 0 / 0                                       | 0 / 0          | 0 / 0          |
| <b>Renal and urinary disorders</b>                     |                                             |                |                |
| Kidney dysfunction                                     | Additional description: Acute kidney injury |                |                |
| subjects affected / exposed                            | 0 / 47 (0.00%)                              | 0 / 35 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all        | 0 / 0                                       | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all             | 0 / 0                                       | 0 / 0          | 0 / 0          |
| <b>Infections and infestations</b>                     |                                             |                |                |
| Listeria encephalitis                                  |                                             |                |                |
| subjects affected / exposed                            | 0 / 47 (0.00%)                              | 0 / 35 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all        | 0 / 0                                       | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all             | 0 / 0                                       | 0 / 0          | 0 / 0          |
| Pneumonia                                              |                                             |                |                |

|                                                 |                                         |                |                |
|-------------------------------------------------|-----------------------------------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 47 (0.00%)                          | 0 / 35 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                   | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                                   | 0 / 0          | 0 / 0          |
| Viral DNA test positive                         | Additional description: Viral infection |                |                |
| subjects affected / exposed                     | 0 / 47 (0.00%)                          | 0 / 35 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                   | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                                   | 0 / 0          | 0 / 0          |
| Pneumonia viral                                 | Additional description: COVID-19        |                |                |
| subjects affected / exposed                     | 0 / 47 (0.00%)                          | 0 / 35 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                   | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                                   | 0 / 0          | 0 / 0          |
| Metabolism and nutrition disorders              |                                         |                |                |
| Dehydration                                     |                                         |                |                |
| subjects affected / exposed                     | 0 / 47 (0.00%)                          | 0 / 35 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                   | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                                   | 0 / 0          | 0 / 0          |

| <b>Serious adverse events</b>                                    | PF-06651600 20 mg<br>-> PF-06651600 50 mg            | PF-06651600 70 mg<br>-> PF-06651600 50 mg | PF-06700841 60 mg<br>-> PF-06700841 30 mg |
|------------------------------------------------------------------|------------------------------------------------------|-------------------------------------------|-------------------------------------------|
| Total subjects affected by serious adverse events                |                                                      |                                           |                                           |
| subjects affected / exposed                                      | 1 / 39 (2.56%)                                       | 1 / 36 (2.78%)                            | 2 / 38 (5.26%)                            |
| number of deaths (all causes)                                    | 0                                                    | 0                                         | 0                                         |
| number of deaths resulting from adverse events                   | 0                                                    | 0                                         | 0                                         |
| Injury, poisoning and procedural complications                   |                                                      |                                           |                                           |
| Ankle injury                                                     | Additional description: Ankle fracture               |                                           |                                           |
| subjects affected / exposed                                      | 0 / 39 (0.00%)                                       | 0 / 36 (0.00%)                            | 0 / 38 (0.00%)                            |
| occurrences causally related to treatment / all                  | 0 / 0                                                | 0 / 0                                     | 0 / 0                                     |
| deaths causally related to treatment / all                       | 0 / 0                                                | 0 / 0                                     | 0 / 0                                     |
| Fracture bone                                                    | Additional description: Femur fracture               |                                           |                                           |
| subjects affected / exposed                                      | 0 / 39 (0.00%)                                       | 0 / 36 (0.00%)                            | 0 / 38 (0.00%)                            |
| occurrences causally related to treatment / all                  | 0 / 0                                                | 0 / 0                                     | 0 / 0                                     |
| deaths causally related to treatment / all                       | 0 / 0                                                | 0 / 0                                     | 0 / 0                                     |
| Vascular disorders                                               |                                                      |                                           |                                           |
| Peripheral vasoconstriction, necrosis and vascular insufficiency | Additional description: Peripheral artery thrombosis |                                           |                                           |

|                                                      |                                               |                |                |
|------------------------------------------------------|-----------------------------------------------|----------------|----------------|
| subjects affected / exposed                          | 0 / 39 (0.00%)                                | 0 / 36 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0                                         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0                                         | 0 / 0          | 0 / 0          |
| Cardiac disorders                                    |                                               |                |                |
| Myocardial infarction                                |                                               |                |                |
| subjects affected / exposed                          | 0 / 39 (0.00%)                                | 0 / 36 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0                                         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0                                         | 0 / 0          | 0 / 0          |
| Myocardial ischemia                                  |                                               |                |                |
| subjects affected / exposed                          | 0 / 39 (0.00%)                                | 0 / 36 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0                                         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0                                         | 0 / 0          | 0 / 0          |
| Surgical and medical procedures                      |                                               |                |                |
| Haemorrhoid                                          | Additional description: Haemorrhoid operation |                |                |
| subjects affected / exposed                          | 0 / 39 (0.00%)                                | 0 / 36 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0                                         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0                                         | 0 / 0          | 0 / 0          |
| Blood and lymphatic system disorders                 |                                               |                |                |
| Anaemia                                              |                                               |                |                |
| subjects affected / exposed                          | 0 / 39 (0.00%)                                | 0 / 36 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0                                         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0                                         | 0 / 0          | 0 / 0          |
| General disorders and administration site conditions |                                               |                |                |
| Pyrexia                                              |                                               |                |                |
| subjects affected / exposed                          | 0 / 39 (0.00%)                                | 0 / 36 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0                                         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0                                         | 0 / 0          | 0 / 0          |
| Gastrointestinal disorders                           |                                               |                |                |
| Colitis ulcerative                                   |                                               |                |                |
| subjects affected / exposed                          | 1 / 39 (2.56%)                                | 1 / 36 (2.78%) | 1 / 38 (2.63%) |
| occurrences causally related to treatment / all      | 1 / 1                                         | 0 / 1          | 1 / 1          |
| deaths causally related to treatment / all           | 0 / 0                                         | 0 / 0          | 0 / 0          |
| Large intestine perforation                          |                                               |                |                |

|                                                 |                                             |                |                |
|-------------------------------------------------|---------------------------------------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 39 (0.00%)                              | 0 / 36 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                       | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                                       | 0 / 0          | 0 / 0          |
| Respiratory, thoracic and mediastinal disorders |                                             |                |                |
| Interstitial lung fibrosis                      |                                             |                |                |
| subjects affected / exposed                     | 0 / 39 (0.00%)                              | 0 / 36 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                       | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                                       | 0 / 0          | 0 / 0          |
| Skin and subcutaneous tissue disorders          |                                             |                |                |
| Urticaria generalised                           |                                             |                |                |
| subjects affected / exposed                     | 0 / 39 (0.00%)                              | 0 / 36 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                       | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                                       | 0 / 0          | 0 / 0          |
| Renal and urinary disorders                     |                                             |                |                |
| Kidney dysfunction                              | Additional description: Acute kidney injury |                |                |
| subjects affected / exposed                     | 0 / 39 (0.00%)                              | 0 / 36 (0.00%) | 1 / 38 (2.63%) |
| occurrences causally related to treatment / all | 0 / 0                                       | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0                                       | 0 / 0          | 0 / 0          |
| Infections and infestations                     |                                             |                |                |
| Listeria encephalitis                           |                                             |                |                |
| subjects affected / exposed                     | 0 / 39 (0.00%)                              | 0 / 36 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                       | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                                       | 0 / 0          | 0 / 0          |
| Pneumonia                                       |                                             |                |                |
| subjects affected / exposed                     | 0 / 39 (0.00%)                              | 0 / 36 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                       | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                                       | 0 / 0          | 0 / 0          |
| Viral DNA test positive                         | Additional description: Viral infection     |                |                |
| subjects affected / exposed                     | 0 / 39 (0.00%)                              | 0 / 36 (0.00%) | 1 / 38 (2.63%) |
| occurrences causally related to treatment / all | 0 / 0                                       | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0                                       | 0 / 0          | 0 / 0          |
| Pneumonia viral                                 | Additional description: COVID-19            |                |                |

|                                                 |                |                |                |
|-------------------------------------------------|----------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 39 (0.00%) | 0 / 36 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Metabolism and nutrition disorders              |                |                |                |
| Dehydration                                     |                |                |                |
| subjects affected / exposed                     | 0 / 39 (0.00%) | 0 / 36 (0.00%) | 1 / 38 (2.63%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |

| <b>Serious adverse events</b>                                    | Placebo -> PF-06700841 30 mg                         | PF-06700841 10 mg -> PF-06700841 30 mg | PF-06700841 30 mg -> PF-06700841 30 mg |
|------------------------------------------------------------------|------------------------------------------------------|----------------------------------------|----------------------------------------|
| Total subjects affected by serious adverse events                |                                                      |                                        |                                        |
| subjects affected / exposed                                      | 0 / 9 (0.00%)                                        | 2 / 39 (5.13%)                         | 4 / 37 (10.81%)                        |
| number of deaths (all causes)                                    | 0                                                    | 0                                      | 0                                      |
| number of deaths resulting from adverse events                   | 0                                                    | 0                                      | 0                                      |
| Injury, poisoning and procedural complications                   |                                                      |                                        |                                        |
| Ankle injury                                                     | Additional description: Ankle fracture               |                                        |                                        |
| subjects affected / exposed                                      | 0 / 9 (0.00%)                                        | 0 / 39 (0.00%)                         | 0 / 37 (0.00%)                         |
| occurrences causally related to treatment / all                  | 0 / 0                                                | 0 / 0                                  | 0 / 0                                  |
| deaths causally related to treatment / all                       | 0 / 0                                                | 0 / 0                                  | 0 / 0                                  |
| Fracture bone                                                    | Additional description: Femur fracture               |                                        |                                        |
| subjects affected / exposed                                      | 0 / 9 (0.00%)                                        | 0 / 39 (0.00%)                         | 0 / 37 (0.00%)                         |
| occurrences causally related to treatment / all                  | 0 / 0                                                | 0 / 0                                  | 0 / 0                                  |
| deaths causally related to treatment / all                       | 0 / 0                                                | 0 / 0                                  | 0 / 0                                  |
| Vascular disorders                                               |                                                      |                                        |                                        |
| Peripheral vasoconstriction, necrosis and vascular insufficiency | Additional description: Peripheral artery thrombosis |                                        |                                        |
| subjects affected / exposed                                      | 0 / 9 (0.00%)                                        | 0 / 39 (0.00%)                         | 0 / 37 (0.00%)                         |
| occurrences causally related to treatment / all                  | 0 / 0                                                | 0 / 0                                  | 0 / 0                                  |
| deaths causally related to treatment / all                       | 0 / 0                                                | 0 / 0                                  | 0 / 0                                  |
| Cardiac disorders                                                |                                                      |                                        |                                        |
| Myocardial infarction                                            |                                                      |                                        |                                        |
| subjects affected / exposed                                      | 0 / 9 (0.00%)                                        | 0 / 39 (0.00%)                         | 0 / 37 (0.00%)                         |
| occurrences causally related to treatment / all                  | 0 / 0                                                | 0 / 0                                  | 0 / 0                                  |
| deaths causally related to treatment / all                       | 0 / 0                                                | 0 / 0                                  | 0 / 0                                  |
| Myocardial ischemia                                              |                                                      |                                        |                                        |

|                                                      |                                               |                |                |
|------------------------------------------------------|-----------------------------------------------|----------------|----------------|
| subjects affected / exposed                          | 0 / 9 (0.00%)                                 | 0 / 39 (0.00%) | 1 / 37 (2.70%) |
| occurrences causally related to treatment / all      | 0 / 0                                         | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all           | 0 / 0                                         | 0 / 0          | 0 / 0          |
| Surgical and medical procedures                      |                                               |                |                |
| Haemorrhoid                                          | Additional description: Haemorrhoid operation |                |                |
| subjects affected / exposed                          | 0 / 9 (0.00%)                                 | 0 / 39 (0.00%) | 0 / 37 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0                                         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0                                         | 0 / 0          | 0 / 0          |
| Blood and lymphatic system disorders                 |                                               |                |                |
| Anaemia                                              |                                               |                |                |
| subjects affected / exposed                          | 0 / 9 (0.00%)                                 | 0 / 39 (0.00%) | 0 / 37 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0                                         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0                                         | 0 / 0          | 0 / 0          |
| General disorders and administration site conditions |                                               |                |                |
| Pyrexia                                              |                                               |                |                |
| subjects affected / exposed                          | 0 / 9 (0.00%)                                 | 0 / 39 (0.00%) | 0 / 37 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0                                         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0                                         | 0 / 0          | 0 / 0          |
| Gastrointestinal disorders                           |                                               |                |                |
| Colitis ulcerative                                   |                                               |                |                |
| subjects affected / exposed                          | 0 / 9 (0.00%)                                 | 1 / 39 (2.56%) | 2 / 37 (5.41%) |
| occurrences causally related to treatment / all      | 0 / 0                                         | 0 / 1          | 1 / 2          |
| deaths causally related to treatment / all           | 0 / 0                                         | 0 / 0          | 0 / 0          |
| Large intestine perforation                          |                                               |                |                |
| subjects affected / exposed                          | 0 / 9 (0.00%)                                 | 0 / 39 (0.00%) | 1 / 37 (2.70%) |
| occurrences causally related to treatment / all      | 0 / 0                                         | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all           | 0 / 0                                         | 0 / 0          | 0 / 0          |
| Respiratory, thoracic and mediastinal disorders      |                                               |                |                |
| Interstitial lung fibrosis                           |                                               |                |                |
| subjects affected / exposed                          | 0 / 9 (0.00%)                                 | 0 / 39 (0.00%) | 0 / 37 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0                                         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0                                         | 0 / 0          | 0 / 0          |
| Skin and subcutaneous tissue disorders               |                                               |                |                |
| Urticaria generalised                                |                                               |                |                |

|                                                   |                                             |                |                |
|---------------------------------------------------|---------------------------------------------|----------------|----------------|
| subjects affected / exposed                       | 0 / 9 (0.00%)                               | 0 / 39 (0.00%) | 0 / 37 (0.00%) |
| occurrences causally related to treatment / all   | 0 / 0                                       | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all        | 0 / 0                                       | 0 / 0          | 0 / 0          |
| Renal and urinary disorders                       |                                             |                |                |
| Kidney dysfunction                                | Additional description: Acute kidney injury |                |                |
| subjects affected / exposed                       | 0 / 9 (0.00%)                               | 0 / 39 (0.00%) | 0 / 37 (0.00%) |
| occurrences causally related to treatment / all   | 0 / 0                                       | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all        | 0 / 0                                       | 0 / 0          | 0 / 0          |
| Infections and infestations                       |                                             |                |                |
| Listeria encephalitis                             |                                             |                |                |
| subjects affected / exposed                       | 0 / 9 (0.00%)                               | 0 / 39 (0.00%) | 0 / 37 (0.00%) |
| occurrences causally related to treatment / all   | 0 / 0                                       | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all        | 0 / 0                                       | 0 / 0          | 0 / 0          |
| Pneumonia                                         |                                             |                |                |
| subjects affected / exposed                       | 0 / 9 (0.00%)                               | 0 / 39 (0.00%) | 0 / 37 (0.00%) |
| occurrences causally related to treatment / all   | 0 / 0                                       | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all        | 0 / 0                                       | 0 / 0          | 0 / 0          |
| Viral DNA test positive                           | Additional description: Viral infection     |                |                |
| subjects affected / exposed                       | 0 / 9 (0.00%)                               | 0 / 39 (0.00%) | 0 / 37 (0.00%) |
| occurrences causally related to treatment / all   | 0 / 0                                       | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all        | 0 / 0                                       | 0 / 0          | 0 / 0          |
| Pneumonia viral                                   | Additional description: COVID-19            |                |                |
| subjects affected / exposed                       | 0 / 9 (0.00%)                               | 1 / 39 (2.56%) | 0 / 37 (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          |
| Metabolism and nutrition disorders                |                                             |                |                |
| Dehydration                                       |                                             |                |                |
| subjects affected / exposed                       | 0 / 9 (0.00%)                               | 0 / 39 (0.00%) | 0 / 37 (0.00%) |
| occurrences causally related to treatment / all   | 0 / 0                                       | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all        | 0 / 0                                       | 0 / 0          | 0 / 0          |
| <b>Serious adverse events</b>                     | Pooling Placebo<br>During Chronic           |                |                |
| Total subjects affected by serious adverse events |                                             |                |                |
| subjects affected / exposed                       | 0 / 37 (0.00%)                              |                |                |
| number of deaths (all causes)                     | 0                                           |                |                |

|                                                                  |                                                      |  |  |
|------------------------------------------------------------------|------------------------------------------------------|--|--|
| number of deaths resulting from adverse events                   | 0                                                    |  |  |
| Injury, poisoning and procedural complications                   |                                                      |  |  |
| Ankle injury                                                     | Additional description: Ankle fracture               |  |  |
| subjects affected / exposed                                      | 0 / 37 (0.00%)                                       |  |  |
| occurrences causally related to treatment / all                  | 0 / 0                                                |  |  |
| deaths causally related to treatment / all                       | 0 / 0                                                |  |  |
| Fracture bone                                                    | Additional description: Femur fracture               |  |  |
| subjects affected / exposed                                      | 0 / 37 (0.00%)                                       |  |  |
| occurrences causally related to treatment / all                  | 0 / 0                                                |  |  |
| deaths causally related to treatment / all                       | 0 / 0                                                |  |  |
| Vascular disorders                                               |                                                      |  |  |
| Peripheral vasoconstriction, necrosis and vascular insufficiency | Additional description: Peripheral artery thrombosis |  |  |
| subjects affected / exposed                                      | 0 / 37 (0.00%)                                       |  |  |
| occurrences causally related to treatment / all                  | 0 / 0                                                |  |  |
| deaths causally related to treatment / all                       | 0 / 0                                                |  |  |
| Cardiac disorders                                                |                                                      |  |  |
| Myocardial infarction                                            |                                                      |  |  |
| subjects affected / exposed                                      | 0 / 37 (0.00%)                                       |  |  |
| occurrences causally related to treatment / all                  | 0 / 0                                                |  |  |
| deaths causally related to treatment / all                       | 0 / 0                                                |  |  |
| Myocardial ischemia                                              |                                                      |  |  |
| subjects affected / exposed                                      | 0 / 37 (0.00%)                                       |  |  |
| occurrences causally related to treatment / all                  | 0 / 0                                                |  |  |
| deaths causally related to treatment / all                       | 0 / 0                                                |  |  |
| Surgical and medical procedures                                  |                                                      |  |  |
| Haemorrhoid                                                      | Additional description: Haemorrhoid operation        |  |  |
| subjects affected / exposed                                      | 0 / 37 (0.00%)                                       |  |  |
| occurrences causally related to treatment / all                  | 0 / 0                                                |  |  |
| deaths causally related to treatment / all                       | 0 / 0                                                |  |  |
| Blood and lymphatic system disorders                             |                                                      |  |  |
| Anaemia                                                          |                                                      |  |  |
| subjects affected / exposed                                      | 0 / 37 (0.00%)                                       |  |  |
| occurrences causally related to treatment / all                  | 0 / 0                                                |  |  |
| deaths causally related to treatment / all                       | 0 / 0                                                |  |  |



|                                                      |                                             |  |  |
|------------------------------------------------------|---------------------------------------------|--|--|
| General disorders and administration site conditions |                                             |  |  |
| Pyrexia                                              |                                             |  |  |
| subjects affected / exposed                          | 0 / 37 (0.00%)                              |  |  |
| occurrences causally related to treatment / all      | 0 / 0                                       |  |  |
| deaths causally related to treatment / all           | 0 / 0                                       |  |  |
| Gastrointestinal disorders                           |                                             |  |  |
| Colitis ulcerative                                   |                                             |  |  |
| subjects affected / exposed                          | 0 / 37 (0.00%)                              |  |  |
| occurrences causally related to treatment / all      | 0 / 0                                       |  |  |
| deaths causally related to treatment / all           | 0 / 0                                       |  |  |
| Large intestine perforation                          |                                             |  |  |
| subjects affected / exposed                          | 0 / 37 (0.00%)                              |  |  |
| occurrences causally related to treatment / all      | 0 / 0                                       |  |  |
| deaths causally related to treatment / all           | 0 / 0                                       |  |  |
| Respiratory, thoracic and mediastinal disorders      |                                             |  |  |
| Interstitial lung fibrosis                           |                                             |  |  |
| subjects affected / exposed                          | 0 / 37 (0.00%)                              |  |  |
| occurrences causally related to treatment / all      | 0 / 0                                       |  |  |
| deaths causally related to treatment / all           | 0 / 0                                       |  |  |
| Skin and subcutaneous tissue disorders               |                                             |  |  |
| Urticaria generalised                                |                                             |  |  |
| subjects affected / exposed                          | 0 / 37 (0.00%)                              |  |  |
| occurrences causally related to treatment / all      | 0 / 0                                       |  |  |
| deaths causally related to treatment / all           | 0 / 0                                       |  |  |
| Renal and urinary disorders                          |                                             |  |  |
| Kidney dysfunction                                   | Additional description: Acute kidney injury |  |  |
| subjects affected / exposed                          | 0 / 37 (0.00%)                              |  |  |
| occurrences causally related to treatment / all      | 0 / 0                                       |  |  |
| deaths causally related to treatment / all           | 0 / 0                                       |  |  |
| Infections and infestations                          |                                             |  |  |
| Listeria encephalitis                                |                                             |  |  |
| subjects affected / exposed                          | 0 / 37 (0.00%)                              |  |  |
| occurrences causally related to treatment / all      | 0 / 0                                       |  |  |
| deaths causally related to treatment / all           | 0 / 0                                       |  |  |
| Pneumonia                                            |                                             |  |  |

|                                                 |                                         |  |  |
|-------------------------------------------------|-----------------------------------------|--|--|
| subjects affected / exposed                     | 0 / 37 (0.00%)                          |  |  |
| occurrences causally related to treatment / all | 0 / 0                                   |  |  |
| deaths causally related to treatment / all      | 0 / 0                                   |  |  |
| Viral DNA test positive                         | Additional description: Viral infection |  |  |
| subjects affected / exposed                     | 0 / 37 (0.00%)                          |  |  |
| occurrences causally related to treatment / all | 0 / 0                                   |  |  |
| deaths causally related to treatment / all      | 0 / 0                                   |  |  |
| Pneumonia viral                                 | Additional description: COVID-19        |  |  |
| subjects affected / exposed                     | 0 / 37 (0.00%)                          |  |  |
| occurrences causally related to treatment / all | 0 / 0                                   |  |  |
| deaths causally related to treatment / all      | 0 / 0                                   |  |  |
| Metabolism and nutrition disorders              |                                         |  |  |
| Dehydration                                     |                                         |  |  |
| subjects affected / exposed                     | 0 / 37 (0.00%)                          |  |  |
| occurrences causally related to treatment / all | 0 / 0                                   |  |  |
| deaths causally related to treatment / all      | 0 / 0                                   |  |  |

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

| <b>Non-serious adverse events</b>                     | Placebo (Induction: 0 to 8 weeks)              | PF-06651600 20 mg (Induction) | PF-06651600 70 mg (Induction) |
|-------------------------------------------------------|------------------------------------------------|-------------------------------|-------------------------------|
| Total subjects affected by non-serious adverse events |                                                |                               |                               |
| subjects affected / exposed                           | 4 / 25 (16.00%)                                | 8 / 51 (15.69%)               | 6 / 49 (12.24%)               |
| Vascular disorders                                    |                                                |                               |                               |
| Hypertension                                          |                                                |                               |                               |
| subjects affected / exposed                           | 0 / 25 (0.00%)                                 | 0 / 51 (0.00%)                | 0 / 49 (0.00%)                |
| occurrences (all)                                     | 0                                              | 0                             | 0                             |
| General disorders and administration site conditions  |                                                |                               |                               |
| Feeling hot                                           |                                                |                               |                               |
| subjects affected / exposed                           | 0 / 25 (0.00%)                                 | 0 / 51 (0.00%)                | 0 / 49 (0.00%)                |
| occurrences (all)                                     | 0                                              | 0                             | 0                             |
| Feeling bad                                           | Additional description: Influenza like illness |                               |                               |
| subjects affected / exposed                           | 0 / 25 (0.00%)                                 | 0 / 51 (0.00%)                | 0 / 49 (0.00%)                |
| occurrences (all)                                     | 0                                              | 0                             | 0                             |
| Oedema peripheral                                     |                                                |                               |                               |

|                                                                                                              |                                               |                     |                     |
|--------------------------------------------------------------------------------------------------------------|-----------------------------------------------|---------------------|---------------------|
| subjects affected / exposed<br>occurrences (all)                                                             | 0 / 25 (0.00%)<br>0                           | 0 / 51 (0.00%)<br>0 | 0 / 49 (0.00%)<br>0 |
| Pyrexia<br>subjects affected / exposed<br>occurrences (all)                                                  | 0 / 25 (0.00%)<br>0                           | 0 / 51 (0.00%)<br>0 | 0 / 49 (0.00%)<br>0 |
| Swelling face<br>subjects affected / exposed<br>occurrences (all)                                            | 0 / 25 (0.00%)<br>0                           | 0 / 51 (0.00%)<br>0 | 0 / 49 (0.00%)<br>0 |
| Respiratory, thoracic and mediastinal disorders<br>Cough<br>subjects affected / exposed<br>occurrences (all) | 0 / 25 (0.00%)<br>0                           | 0 / 51 (0.00%)<br>0 | 0 / 49 (0.00%)<br>0 |
| Rhinorrhoea<br>subjects affected / exposed<br>occurrences (all)                                              | 0 / 25 (0.00%)<br>0                           | 0 / 51 (0.00%)<br>0 | 0 / 49 (0.00%)<br>0 |
| Psychiatric disorders<br>Anxiety<br>subjects affected / exposed<br>occurrences (all)                         | 0 / 25 (0.00%)<br>0                           | 0 / 51 (0.00%)<br>0 | 0 / 49 (0.00%)<br>0 |
| Irritable mood                                                                                               | Additional description: Irritability          |                     |                     |
| subjects affected / exposed<br>occurrences (all)                                                             | 0 / 25 (0.00%)<br>0                           | 0 / 51 (0.00%)<br>0 | 0 / 49 (0.00%)<br>0 |
| Investigations<br>Blood creatine phosphokinase increased<br>subjects affected / exposed<br>occurrences (all) | 0 / 25 (0.00%)<br>0                           | 0 / 51 (0.00%)<br>0 | 0 / 49 (0.00%)<br>0 |
| Blood urine present<br>subjects affected / exposed<br>occurrences (all)                                      | 0 / 25 (0.00%)<br>0                           | 0 / 51 (0.00%)<br>0 | 0 / 49 (0.00%)<br>0 |
| Urine protein, quantitative                                                                                  | Additional description: Protein urine present |                     |                     |
| subjects affected / exposed<br>occurrences (all)                                                             | 0 / 25 (0.00%)<br>0                           | 0 / 51 (0.00%)<br>0 | 0 / 49 (0.00%)<br>0 |
| Nervous system disorders<br>Headache<br>subjects affected / exposed<br>occurrences (all)                     | 2 / 25 (8.00%)<br>3                           | 3 / 51 (5.88%)<br>3 | 3 / 49 (6.12%)<br>6 |

|                                                                                                            |                                           |                     |                     |
|------------------------------------------------------------------------------------------------------------|-------------------------------------------|---------------------|---------------------|
| Sciatica<br>subjects affected / exposed<br>occurrences (all)                                               | 0 / 25 (0.00%)<br>0                       | 0 / 51 (0.00%)<br>0 | 0 / 49 (0.00%)<br>0 |
| Blood and lymphatic system disorders<br>Anaemia<br>subjects affected / exposed<br>occurrences (all)        | 1 / 25 (4.00%)<br>1                       | 1 / 51 (1.96%)<br>1 | 2 / 49 (4.08%)<br>2 |
| Ear and labyrinth disorders<br>Hearing loss unilateral<br>subjects affected / exposed<br>occurrences (all) | 0 / 25 (0.00%)<br>0                       | 0 / 51 (0.00%)<br>0 | 0 / 49 (0.00%)<br>0 |
| Eye disorders                                                                                              |                                           |                     |                     |
| Visual field tests abnormal                                                                                | Additional description: Visual impairment |                     |                     |
| subjects affected / exposed<br>occurrences (all)                                                           | 0 / 25 (0.00%)<br>0                       | 0 / 51 (0.00%)<br>0 | 0 / 49 (0.00%)<br>0 |
| Gastrointestinal disorders                                                                                 |                                           |                     |                     |
| Abdominal pain<br>subjects affected / exposed<br>occurrences (all)                                         | 2 / 25 (8.00%)<br>2                       | 1 / 51 (1.96%)<br>1 | 1 / 49 (2.04%)<br>1 |
| Anal exam abnormal                                                                                         | Additional description: Anal fissure      |                     |                     |
| subjects affected / exposed<br>occurrences (all)                                                           | 0 / 25 (0.00%)<br>0                       | 0 / 51 (0.00%)<br>0 | 0 / 49 (0.00%)<br>0 |
| Ulcerative colitis<br>subjects affected / exposed<br>occurrences (all)                                     | 0 / 25 (0.00%)<br>0                       | 0 / 51 (0.00%)<br>0 | 0 / 49 (0.00%)<br>0 |
| Diarrhoea<br>subjects affected / exposed<br>occurrences (all)                                              | 0 / 25 (0.00%)<br>0                       | 0 / 51 (0.00%)<br>0 | 0 / 49 (0.00%)<br>0 |
| Nausea<br>subjects affected / exposed<br>occurrences (all)                                                 | 0 / 25 (0.00%)<br>0                       | 0 / 51 (0.00%)<br>0 | 0 / 49 (0.00%)<br>0 |
| Flatulence<br>subjects affected / exposed<br>occurrences (all)                                             | 0 / 25 (0.00%)<br>0                       | 0 / 51 (0.00%)<br>0 | 0 / 49 (0.00%)<br>0 |
| Dyspepsia<br>subjects affected / exposed<br>occurrences (all)                                              | 0 / 25 (0.00%)<br>0                       | 0 / 51 (0.00%)<br>0 | 0 / 49 (0.00%)<br>0 |

|                                                 |                |                |                |
|-------------------------------------------------|----------------|----------------|----------------|
| Skin and subcutaneous tissue disorders          |                |                |                |
| Acne                                            |                |                |                |
| subjects affected / exposed                     | 0 / 25 (0.00%) | 0 / 51 (0.00%) | 0 / 49 (0.00%) |
| occurrences (all)                               | 0              | 0              | 0              |
| Alopecia                                        |                |                |                |
| subjects affected / exposed                     | 0 / 25 (0.00%) | 0 / 51 (0.00%) | 0 / 49 (0.00%) |
| occurrences (all)                               | 0              | 0              | 0              |
| Dermatitis atopic                               |                |                |                |
| subjects affected / exposed                     | 0 / 25 (0.00%) | 0 / 51 (0.00%) | 0 / 49 (0.00%) |
| occurrences (all)                               | 0              | 0              | 0              |
| Rash                                            |                |                |                |
| subjects affected / exposed                     | 0 / 25 (0.00%) | 0 / 51 (0.00%) | 0 / 49 (0.00%) |
| occurrences (all)                               | 0              | 0              | 0              |
| Musculoskeletal and connective tissue disorders |                |                |                |
| Arthralgia                                      |                |                |                |
| subjects affected / exposed                     | 0 / 25 (0.00%) | 2 / 51 (3.92%) | 1 / 49 (2.04%) |
| occurrences (all)                               | 0              | 2              | 1              |
| Arthritis                                       |                |                |                |
| subjects affected / exposed                     | 0 / 25 (0.00%) | 0 / 51 (0.00%) | 0 / 49 (0.00%) |
| occurrences (all)                               | 0              | 0              | 0              |
| Contracture of palmar fascia                    |                |                |                |
| Additional description: Dupuytren's contracture |                |                |                |
| subjects affected / exposed                     | 0 / 25 (0.00%) | 0 / 51 (0.00%) | 0 / 49 (0.00%) |
| occurrences (all)                               | 0              | 0              | 0              |
| Osteoarthritis                                  |                |                |                |
| subjects affected / exposed                     | 0 / 25 (0.00%) | 0 / 51 (0.00%) | 0 / 49 (0.00%) |
| occurrences (all)                               | 0              | 0              | 0              |
| Pain                                            |                |                |                |
| Additional description: Pain in extremity       |                |                |                |
| subjects affected / exposed                     | 0 / 25 (0.00%) | 0 / 51 (0.00%) | 0 / 49 (0.00%) |
| occurrences (all)                               | 0              | 0              | 0              |
| Infections and infestations                     |                |                |                |
| Nasopharyngitis                                 |                |                |                |
| subjects affected / exposed                     | 0 / 25 (0.00%) | 2 / 51 (3.92%) | 0 / 49 (0.00%) |
| occurrences (all)                               | 0              | 2              | 0              |
| COVID-19                                        |                |                |                |
| subjects affected / exposed                     | 0 / 25 (0.00%) | 0 / 51 (0.00%) | 0 / 49 (0.00%) |
| occurrences (all)                               | 0              | 0              | 0              |

|                                    |                |                |                |
|------------------------------------|----------------|----------------|----------------|
| Conjunctivitis                     |                |                |                |
| subjects affected / exposed        | 0 / 25 (0.00%) | 0 / 51 (0.00%) | 0 / 49 (0.00%) |
| occurrences (all)                  | 0              | 0              | 0              |
| Herpes zoster                      |                |                |                |
| subjects affected / exposed        | 0 / 25 (0.00%) | 0 / 51 (0.00%) | 0 / 49 (0.00%) |
| occurrences (all)                  | 0              | 0              | 0              |
| Influenza                          |                |                |                |
| subjects affected / exposed        | 0 / 25 (0.00%) | 0 / 51 (0.00%) | 0 / 49 (0.00%) |
| occurrences (all)                  | 0              | 0              | 0              |
| Urinary tract infection            |                |                |                |
| subjects affected / exposed        | 0 / 25 (0.00%) | 0 / 51 (0.00%) | 0 / 49 (0.00%) |
| occurrences (all)                  | 0              | 0              | 0              |
| Metabolism and nutrition disorders |                |                |                |
| Hypermatraemia                     |                |                |                |
| subjects affected / exposed        | 0 / 25 (0.00%) | 0 / 51 (0.00%) | 0 / 49 (0.00%) |
| occurrences (all)                  | 0              | 0              | 0              |

| <b>Non-serious adverse events</b>                     | PF-06651600 200 mg (Induction)                 | PF-06700841 10 mg (Induction) | PF-06700841 30 mg (Induction) |
|-------------------------------------------------------|------------------------------------------------|-------------------------------|-------------------------------|
| Total subjects affected by non-serious adverse events |                                                |                               |                               |
| subjects affected / exposed                           | 5 / 50 (10.00%)                                | 2 / 48 (4.17%)                | 11 / 47 (23.40%)              |
| Vascular disorders                                    |                                                |                               |                               |
| Hypertension                                          |                                                |                               |                               |
| subjects affected / exposed                           | 0 / 50 (0.00%)                                 | 0 / 48 (0.00%)                | 0 / 47 (0.00%)                |
| occurrences (all)                                     | 0                                              | 0                             | 0                             |
| General disorders and administration site conditions  |                                                |                               |                               |
| Feeling hot                                           |                                                |                               |                               |
| subjects affected / exposed                           | 0 / 50 (0.00%)                                 | 0 / 48 (0.00%)                | 0 / 47 (0.00%)                |
| occurrences (all)                                     | 0                                              | 0                             | 0                             |
| Feeling bad                                           | Additional description: Influenza like illness |                               |                               |
| subjects affected / exposed                           | 0 / 50 (0.00%)                                 | 0 / 48 (0.00%)                | 0 / 47 (0.00%)                |
| occurrences (all)                                     | 0                                              | 0                             | 0                             |
| Oedema peripheral                                     |                                                |                               |                               |
| subjects affected / exposed                           | 0 / 50 (0.00%)                                 | 0 / 48 (0.00%)                | 0 / 47 (0.00%)                |
| occurrences (all)                                     | 0                                              | 0                             | 0                             |
| Pyrexia                                               |                                                |                               |                               |

|                                                                                                              |                                               |                     |                     |
|--------------------------------------------------------------------------------------------------------------|-----------------------------------------------|---------------------|---------------------|
| subjects affected / exposed<br>occurrences (all)                                                             | 0 / 50 (0.00%)<br>0                           | 0 / 48 (0.00%)<br>0 | 0 / 47 (0.00%)<br>0 |
| Swelling face<br>subjects affected / exposed<br>occurrences (all)                                            | 0 / 50 (0.00%)<br>0                           | 0 / 48 (0.00%)<br>0 | 0 / 47 (0.00%)<br>0 |
| Respiratory, thoracic and mediastinal disorders<br>Cough<br>subjects affected / exposed<br>occurrences (all) | 0 / 50 (0.00%)<br>0                           | 0 / 48 (0.00%)<br>0 | 0 / 47 (0.00%)<br>0 |
| Rhinorrhoea<br>subjects affected / exposed<br>occurrences (all)                                              | 0 / 50 (0.00%)<br>0                           | 0 / 48 (0.00%)<br>0 | 0 / 47 (0.00%)<br>0 |
| Psychiatric disorders<br>Anxiety<br>subjects affected / exposed<br>occurrences (all)                         | 0 / 50 (0.00%)<br>0                           | 0 / 48 (0.00%)<br>0 | 0 / 47 (0.00%)<br>0 |
| Irritable mood<br>subjects affected / exposed<br>occurrences (all)                                           | Additional description: Irritability          |                     |                     |
|                                                                                                              | 0 / 50 (0.00%)<br>0                           | 0 / 48 (0.00%)<br>0 | 0 / 47 (0.00%)<br>0 |
| Investigations<br>Blood creatine phosphokinase increased<br>subjects affected / exposed<br>occurrences (all) | 0 / 50 (0.00%)<br>0                           | 0 / 48 (0.00%)<br>0 | 0 / 47 (0.00%)<br>0 |
| Blood urine present<br>subjects affected / exposed<br>occurrences (all)                                      | 0 / 50 (0.00%)<br>0                           | 0 / 48 (0.00%)<br>0 | 0 / 47 (0.00%)<br>0 |
| Urine protein, quantitative<br>subjects affected / exposed<br>occurrences (all)                              | Additional description: Protein urine present |                     |                     |
|                                                                                                              | 0 / 50 (0.00%)<br>0                           | 0 / 48 (0.00%)<br>0 | 0 / 47 (0.00%)<br>0 |
| Nervous system disorders<br>Headache<br>subjects affected / exposed<br>occurrences (all)                     | 0 / 50 (0.00%)<br>0                           | 1 / 48 (2.08%)<br>1 | 4 / 47 (8.51%)<br>4 |
| Sciatica<br>subjects affected / exposed<br>occurrences (all)                                                 | 0 / 50 (0.00%)<br>0                           | 0 / 48 (0.00%)<br>0 | 0 / 47 (0.00%)<br>0 |

|                                        |                                           |                |                |
|----------------------------------------|-------------------------------------------|----------------|----------------|
| Blood and lymphatic system disorders   |                                           |                |                |
| Anaemia                                |                                           |                |                |
| subjects affected / exposed            | 4 / 50 (8.00%)                            | 1 / 48 (2.08%) | 1 / 47 (2.13%) |
| occurrences (all)                      | 4                                         | 1              | 1              |
| Ear and labyrinth disorders            |                                           |                |                |
| Hearing loss unilateral                |                                           |                |                |
| subjects affected / exposed            | 0 / 50 (0.00%)                            | 0 / 48 (0.00%) | 0 / 47 (0.00%) |
| occurrences (all)                      | 0                                         | 0              | 0              |
| Eye disorders                          |                                           |                |                |
| Visual field tests abnormal            | Additional description: Visual impairment |                |                |
| subjects affected / exposed            | 0 / 50 (0.00%)                            | 0 / 48 (0.00%) | 0 / 47 (0.00%) |
| occurrences (all)                      | 0                                         | 0              | 0              |
| Gastrointestinal disorders             |                                           |                |                |
| Abdominal pain                         |                                           |                |                |
| subjects affected / exposed            | 0 / 50 (0.00%)                            | 0 / 48 (0.00%) | 2 / 47 (4.26%) |
| occurrences (all)                      | 0                                         | 0              | 2              |
| Anal exam abnormal                     | Additional description: Anal fissure      |                |                |
| subjects affected / exposed            | 0 / 50 (0.00%)                            | 0 / 48 (0.00%) | 0 / 47 (0.00%) |
| occurrences (all)                      | 0                                         | 0              | 0              |
| Ulcerative colitis                     |                                           |                |                |
| subjects affected / exposed            | 0 / 50 (0.00%)                            | 0 / 48 (0.00%) | 0 / 47 (0.00%) |
| occurrences (all)                      | 0                                         | 0              | 0              |
| Diarrhoea                              |                                           |                |                |
| subjects affected / exposed            | 0 / 50 (0.00%)                            | 0 / 48 (0.00%) | 0 / 47 (0.00%) |
| occurrences (all)                      | 0                                         | 0              | 0              |
| Nausea                                 |                                           |                |                |
| subjects affected / exposed            | 0 / 50 (0.00%)                            | 0 / 48 (0.00%) | 0 / 47 (0.00%) |
| occurrences (all)                      | 0                                         | 0              | 0              |
| Flatulence                             |                                           |                |                |
| subjects affected / exposed            | 0 / 50 (0.00%)                            | 0 / 48 (0.00%) | 0 / 47 (0.00%) |
| occurrences (all)                      | 0                                         | 0              | 0              |
| Dyspepsia                              |                                           |                |                |
| subjects affected / exposed            | 0 / 50 (0.00%)                            | 0 / 48 (0.00%) | 0 / 47 (0.00%) |
| occurrences (all)                      | 0                                         | 0              | 0              |
| Skin and subcutaneous tissue disorders |                                           |                |                |
| Acne                                   |                                           |                |                |



|                                                 |                                                 |                |                 |
|-------------------------------------------------|-------------------------------------------------|----------------|-----------------|
| subjects affected / exposed                     | 0 / 50 (0.00%)                                  | 0 / 48 (0.00%) | 0 / 47 (0.00%)  |
| occurrences (all)                               | 0                                               | 0              | 0               |
| Alopecia                                        |                                                 |                |                 |
| subjects affected / exposed                     | 0 / 50 (0.00%)                                  | 0 / 48 (0.00%) | 0 / 47 (0.00%)  |
| occurrences (all)                               | 0                                               | 0              | 0               |
| Dermatitis atopic                               |                                                 |                |                 |
| subjects affected / exposed                     | 0 / 50 (0.00%)                                  | 0 / 48 (0.00%) | 0 / 47 (0.00%)  |
| occurrences (all)                               | 0                                               | 0              | 0               |
| Rash                                            |                                                 |                |                 |
| subjects affected / exposed                     | 0 / 50 (0.00%)                                  | 0 / 48 (0.00%) | 0 / 47 (0.00%)  |
| occurrences (all)                               | 0                                               | 0              | 0               |
| Musculoskeletal and connective tissue disorders |                                                 |                |                 |
| Arthralgia                                      |                                                 |                |                 |
| subjects affected / exposed                     | 0 / 50 (0.00%)                                  | 1 / 48 (2.08%) | 3 / 47 (6.38%)  |
| occurrences (all)                               | 0                                               | 1              | 3               |
| Arthritis                                       |                                                 |                |                 |
| subjects affected / exposed                     | 0 / 50 (0.00%)                                  | 0 / 48 (0.00%) | 0 / 47 (0.00%)  |
| occurrences (all)                               | 0                                               | 0              | 0               |
| Contracture of palmar fascia                    | Additional description: Dupuytren's contracture |                |                 |
| subjects affected / exposed                     | 0 / 50 (0.00%)                                  | 0 / 48 (0.00%) | 0 / 47 (0.00%)  |
| occurrences (all)                               | 0                                               | 0              | 0               |
| Osteoarthritis                                  |                                                 |                |                 |
| subjects affected / exposed                     | 0 / 50 (0.00%)                                  | 0 / 48 (0.00%) | 0 / 47 (0.00%)  |
| occurrences (all)                               | 0                                               | 0              | 0               |
| Pain                                            | Additional description: Pain in extremity       |                |                 |
| subjects affected / exposed                     | 0 / 50 (0.00%)                                  | 0 / 48 (0.00%) | 0 / 47 (0.00%)  |
| occurrences (all)                               | 0                                               | 0              | 0               |
| Infections and infestations                     |                                                 |                |                 |
| Nasopharyngitis                                 |                                                 |                |                 |
| subjects affected / exposed                     | 1 / 50 (2.00%)                                  | 0 / 48 (0.00%) | 5 / 47 (10.64%) |
| occurrences (all)                               | 1                                               | 0              | 5               |
| COVID-19                                        |                                                 |                |                 |
| subjects affected / exposed                     | 0 / 50 (0.00%)                                  | 0 / 48 (0.00%) | 0 / 47 (0.00%)  |
| occurrences (all)                               | 0                                               | 0              | 0               |
| Conjunctivitis                                  |                                                 |                |                 |

|                                    |                |                |                |
|------------------------------------|----------------|----------------|----------------|
| subjects affected / exposed        | 0 / 50 (0.00%) | 0 / 48 (0.00%) | 0 / 47 (0.00%) |
| occurrences (all)                  | 0              | 0              | 0              |
| Herpes zoster                      |                |                |                |
| subjects affected / exposed        | 0 / 50 (0.00%) | 0 / 48 (0.00%) | 0 / 47 (0.00%) |
| occurrences (all)                  | 0              | 0              | 0              |
| Influenza                          |                |                |                |
| subjects affected / exposed        | 0 / 50 (0.00%) | 0 / 48 (0.00%) | 0 / 47 (0.00%) |
| occurrences (all)                  | 0              | 0              | 0              |
| Urinary tract infection            |                |                |                |
| subjects affected / exposed        | 0 / 50 (0.00%) | 0 / 48 (0.00%) | 0 / 47 (0.00%) |
| occurrences (all)                  | 0              | 0              | 0              |
| Metabolism and nutrition disorders |                |                |                |
| Hypermatraemia                     |                |                |                |
| subjects affected / exposed        | 0 / 50 (0.00%) | 0 / 48 (0.00%) | 0 / 47 (0.00%) |
| occurrences (all)                  | 0              | 0              | 0              |

| <b>Non-serious adverse events</b>                        | PF-06700841 60 mg<br>(Induction)               | PF-06651600 200<br>mg -> PF-06651600<br>50 mg | Placebo -> PF-<br>06651600 50 mg |
|----------------------------------------------------------|------------------------------------------------|-----------------------------------------------|----------------------------------|
| Total subjects affected by non-serious<br>adverse events |                                                |                                               |                                  |
| subjects affected / exposed                              | 9 / 47 (19.15%)                                | 9 / 35 (25.71%)                               | 8 / 10 (80.00%)                  |
| Vascular disorders                                       |                                                |                                               |                                  |
| Hypertension                                             |                                                |                                               |                                  |
| subjects affected / exposed                              | 0 / 47 (0.00%)                                 | 0 / 35 (0.00%)                                | 2 / 10 (20.00%)                  |
| occurrences (all)                                        | 0                                              | 0                                             | 2                                |
| General disorders and administration<br>site conditions  |                                                |                                               |                                  |
| Feeling hot                                              |                                                |                                               |                                  |
| subjects affected / exposed                              | 0 / 47 (0.00%)                                 | 0 / 35 (0.00%)                                | 1 / 10 (10.00%)                  |
| occurrences (all)                                        | 0                                              | 0                                             | 2                                |
| Feeling bad                                              | Additional description: Influenza like illness |                                               |                                  |
| subjects affected / exposed                              | 0 / 47 (0.00%)                                 | 0 / 35 (0.00%)                                | 0 / 10 (0.00%)                   |
| occurrences (all)                                        | 0                                              | 0                                             | 0                                |
| Oedema peripheral                                        |                                                |                                               |                                  |
| subjects affected / exposed                              | 0 / 47 (0.00%)                                 | 0 / 35 (0.00%)                                | 1 / 10 (10.00%)                  |
| occurrences (all)                                        | 0                                              | 0                                             | 2                                |
| Pyrexia                                                  |                                                |                                               |                                  |
| subjects affected / exposed                              | 0 / 47 (0.00%)                                 | 1 / 35 (2.86%)                                | 1 / 10 (10.00%)                  |
| occurrences (all)                                        | 0                                              | 1                                             | 1                                |

|                                                                                                              |                                               |                     |                      |
|--------------------------------------------------------------------------------------------------------------|-----------------------------------------------|---------------------|----------------------|
| Swelling face<br>subjects affected / exposed<br>occurrences (all)                                            | 0 / 47 (0.00%)<br>0                           | 1 / 35 (2.86%)<br>1 | 1 / 10 (10.00%)<br>1 |
| Respiratory, thoracic and mediastinal disorders<br>Cough<br>subjects affected / exposed<br>occurrences (all) | 0 / 47 (0.00%)<br>0                           | 0 / 35 (0.00%)<br>0 | 0 / 10 (0.00%)<br>0  |
| Rhinorrhoea<br>subjects affected / exposed<br>occurrences (all)                                              | 0 / 47 (0.00%)<br>0                           | 0 / 35 (0.00%)<br>0 | 0 / 10 (0.00%)<br>0  |
| Psychiatric disorders<br>Anxiety<br>subjects affected / exposed<br>occurrences (all)                         | 0 / 47 (0.00%)<br>0                           | 0 / 35 (0.00%)<br>0 | 0 / 10 (0.00%)<br>0  |
| Irritable mood                                                                                               | Additional description: Irritability          |                     |                      |
| subjects affected / exposed<br>occurrences (all)                                                             | 0 / 47 (0.00%)<br>0                           | 0 / 35 (0.00%)<br>0 | 0 / 10 (0.00%)<br>0  |
| Investigations<br>Blood creatine phosphokinase increased<br>subjects affected / exposed<br>occurrences (all) | 0 / 47 (0.00%)<br>0                           | 0 / 35 (0.00%)<br>0 | 0 / 10 (0.00%)<br>0  |
| Blood urine present<br>subjects affected / exposed<br>occurrences (all)                                      | 0 / 47 (0.00%)<br>0                           | 0 / 35 (0.00%)<br>0 | 0 / 10 (0.00%)<br>0  |
| Urine protein, quantitative                                                                                  | Additional description: Protein urine present |                     |                      |
| subjects affected / exposed<br>occurrences (all)                                                             | 0 / 47 (0.00%)<br>0                           | 0 / 35 (0.00%)<br>0 | 0 / 10 (0.00%)<br>0  |
| Nervous system disorders<br>Headache<br>subjects affected / exposed<br>occurrences (all)                     | 0 / 47 (0.00%)<br>0                           | 0 / 35 (0.00%)<br>0 | 2 / 10 (20.00%)<br>7 |
| Sciatica<br>subjects affected / exposed<br>occurrences (all)                                                 | 0 / 47 (0.00%)<br>0                           | 0 / 35 (0.00%)<br>0 | 0 / 10 (0.00%)<br>0  |
| Blood and lymphatic system disorders                                                                         |                                               |                     |                      |

|                                                                                                            |                                           |                      |                      |
|------------------------------------------------------------------------------------------------------------|-------------------------------------------|----------------------|----------------------|
| Anaemia<br>subjects affected / exposed<br>occurrences (all)                                                | 4 / 47 (8.51%)<br>4                       | 1 / 35 (2.86%)<br>1  | 1 / 10 (10.00%)<br>1 |
| Ear and labyrinth disorders<br>Hearing loss unilateral<br>subjects affected / exposed<br>occurrences (all) | 0 / 47 (0.00%)<br>0                       | 0 / 35 (0.00%)<br>0  | 2 / 10 (20.00%)<br>2 |
| Eye disorders<br>Visual field tests abnormal<br>subjects affected / exposed<br>occurrences (all)           | Additional description: Visual impairment |                      |                      |
|                                                                                                            | 0 / 47 (0.00%)<br>0                       | 0 / 35 (0.00%)<br>0  | 1 / 10 (10.00%)<br>1 |
| Gastrointestinal disorders<br>Abdominal pain<br>subjects affected / exposed<br>occurrences (all)           | 2 / 47 (4.26%)<br>2                       | 0 / 35 (0.00%)<br>0  | 0 / 10 (0.00%)<br>0  |
| Anal exam abnormal<br>subjects affected / exposed<br>occurrences (all)                                     | Additional description: Anal fissure      |                      |                      |
|                                                                                                            | 0 / 47 (0.00%)<br>0                       | 0 / 35 (0.00%)<br>0  | 0 / 10 (0.00%)<br>0  |
| Ulcerative colitis<br>subjects affected / exposed<br>occurrences (all)                                     | 0 / 47 (0.00%)<br>0                       | 4 / 35 (11.43%)<br>5 | 3 / 10 (30.00%)<br>3 |
| Diarrhoea<br>subjects affected / exposed<br>occurrences (all)                                              | 0 / 47 (0.00%)<br>0                       | 1 / 35 (2.86%)<br>1  | 2 / 10 (20.00%)<br>2 |
| Nausea<br>subjects affected / exposed<br>occurrences (all)                                                 | 0 / 47 (0.00%)<br>0                       | 0 / 35 (0.00%)<br>0  | 0 / 10 (0.00%)<br>0  |
| Flatulence<br>subjects affected / exposed<br>occurrences (all)                                             | 0 / 47 (0.00%)<br>0                       | 0 / 35 (0.00%)<br>0  | 0 / 10 (0.00%)<br>0  |
| Dyspepsia<br>subjects affected / exposed<br>occurrences (all)                                              | 0 / 47 (0.00%)<br>0                       | 0 / 35 (0.00%)<br>0  | 1 / 10 (10.00%)<br>1 |
| Skin and subcutaneous tissue disorders<br>Acne<br>subjects affected / exposed<br>occurrences (all)         | 0 / 47 (0.00%)<br>0                       | 1 / 35 (2.86%)<br>1  | 1 / 10 (10.00%)<br>1 |

|                                                                                  |                                                 |                     |                      |
|----------------------------------------------------------------------------------|-------------------------------------------------|---------------------|----------------------|
| Alopecia<br>subjects affected / exposed<br>occurrences (all)                     | 0 / 47 (0.00%)<br>0                             | 1 / 35 (2.86%)<br>1 | 1 / 10 (10.00%)<br>1 |
|                                                                                  |                                                 |                     |                      |
|                                                                                  |                                                 |                     |                      |
| Dermatitis atopic<br>subjects affected / exposed<br>occurrences (all)            | 0 / 47 (0.00%)<br>0                             | 0 / 35 (0.00%)<br>0 | 1 / 10 (10.00%)<br>1 |
|                                                                                  |                                                 |                     |                      |
|                                                                                  |                                                 |                     |                      |
| Rash<br>subjects affected / exposed<br>occurrences (all)                         | 0 / 47 (0.00%)<br>0                             | 1 / 35 (2.86%)<br>2 | 1 / 10 (10.00%)<br>1 |
|                                                                                  |                                                 |                     |                      |
|                                                                                  |                                                 |                     |                      |
| Musculoskeletal and connective tissue disorders                                  |                                                 |                     |                      |
| Arthralgia<br>subjects affected / exposed<br>occurrences (all)                   | 1 / 47 (2.13%)<br>1                             | 2 / 35 (5.71%)<br>3 | 1 / 10 (10.00%)<br>1 |
|                                                                                  |                                                 |                     |                      |
|                                                                                  |                                                 |                     |                      |
| Arthritis<br>subjects affected / exposed<br>occurrences (all)                    | 0 / 47 (0.00%)<br>0                             | 0 / 35 (0.00%)<br>0 | 1 / 10 (10.00%)<br>1 |
|                                                                                  |                                                 |                     |                      |
|                                                                                  |                                                 |                     |                      |
| Contracture of palmar fascia<br>subjects affected / exposed<br>occurrences (all) | Additional description: Dupuytren's contracture |                     |                      |
|                                                                                  | 0 / 47 (0.00%)<br>0                             | 0 / 35 (0.00%)<br>0 | 1 / 10 (10.00%)<br>1 |
|                                                                                  |                                                 |                     |                      |
| Osteoarthritis<br>subjects affected / exposed<br>occurrences (all)               | 0 / 47 (0.00%)<br>0                             | 0 / 35 (0.00%)<br>0 | 2 / 10 (20.00%)<br>2 |
|                                                                                  |                                                 |                     |                      |
|                                                                                  |                                                 |                     |                      |
| Pain<br>subjects affected / exposed<br>occurrences (all)                         | Additional description: Pain in extremity       |                     |                      |
|                                                                                  | 0 / 47 (0.00%)<br>0                             | 0 / 35 (0.00%)<br>0 | 1 / 10 (10.00%)<br>2 |
|                                                                                  |                                                 |                     |                      |
| Infections and infestations                                                      |                                                 |                     |                      |
| Nasopharyngitis<br>subjects affected / exposed<br>occurrences (all)              | 3 / 47 (6.38%)<br>3                             | 1 / 35 (2.86%)<br>1 | 0 / 10 (0.00%)<br>0  |
|                                                                                  |                                                 |                     |                      |
|                                                                                  |                                                 |                     |                      |
| COVID-19<br>subjects affected / exposed<br>occurrences (all)                     | 0 / 47 (0.00%)<br>0                             | 0 / 35 (0.00%)<br>0 | 0 / 10 (0.00%)<br>0  |
|                                                                                  |                                                 |                     |                      |
|                                                                                  |                                                 |                     |                      |
| Conjunctivitis<br>subjects affected / exposed<br>occurrences (all)               | 0 / 47 (0.00%)<br>0                             | 0 / 35 (0.00%)<br>0 | 1 / 10 (10.00%)<br>1 |
|                                                                                  |                                                 |                     |                      |
|                                                                                  |                                                 |                     |                      |
| Herpes zoster                                                                    |                                                 |                     |                      |

|                                    |                |                |                 |
|------------------------------------|----------------|----------------|-----------------|
| subjects affected / exposed        | 0 / 47 (0.00%) | 0 / 35 (0.00%) | 0 / 10 (0.00%)  |
| occurrences (all)                  | 0              | 0              | 0               |
| Influenza                          |                |                |                 |
| subjects affected / exposed        | 0 / 47 (0.00%) | 0 / 35 (0.00%) | 0 / 10 (0.00%)  |
| occurrences (all)                  | 0              | 0              | 0               |
| Urinary tract infection            |                |                |                 |
| subjects affected / exposed        | 0 / 47 (0.00%) | 0 / 35 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all)                  | 0              | 0              | 1               |
| Metabolism and nutrition disorders |                |                |                 |
| Hypermatraemia                     |                |                |                 |
| subjects affected / exposed        | 0 / 47 (0.00%) | 0 / 35 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all)                  | 0              | 0              | 1               |

| <b>Non-serious adverse events</b>                     | PF-06651600 20 mg<br>-> PF-06651600 50 mg      | PF-06651600 70 mg<br>-> PF-06651600 50 mg | PF-06700841 60 mg<br>-> PF-06700841 30 mg |
|-------------------------------------------------------|------------------------------------------------|-------------------------------------------|-------------------------------------------|
| Total subjects affected by non-serious adverse events |                                                |                                           |                                           |
| subjects affected / exposed                           | 11 / 39 (28.21%)                               | 21 / 36 (58.33%)                          | 15 / 38 (39.47%)                          |
| Vascular disorders                                    |                                                |                                           |                                           |
| Hypertension                                          |                                                |                                           |                                           |
| subjects affected / exposed                           | 0 / 39 (0.00%)                                 | 4 / 36 (11.11%)                           | 0 / 38 (0.00%)                            |
| occurrences (all)                                     | 0                                              | 4                                         | 0                                         |
| General disorders and administration site conditions  |                                                |                                           |                                           |
| Feeling hot                                           |                                                |                                           |                                           |
| subjects affected / exposed                           | 0 / 39 (0.00%)                                 | 0 / 36 (0.00%)                            | 0 / 38 (0.00%)                            |
| occurrences (all)                                     | 0                                              | 0                                         | 0                                         |
| Feeling bad                                           | Additional description: Influenza like illness |                                           |                                           |
| subjects affected / exposed                           | 0 / 39 (0.00%)                                 | 2 / 36 (5.56%)                            | 0 / 38 (0.00%)                            |
| occurrences (all)                                     | 0                                              | 2                                         | 0                                         |
| Oedema peripheral                                     |                                                |                                           |                                           |
| subjects affected / exposed                           | 0 / 39 (0.00%)                                 | 0 / 36 (0.00%)                            | 0 / 38 (0.00%)                            |
| occurrences (all)                                     | 0                                              | 0                                         | 0                                         |
| Pyrexia                                               |                                                |                                           |                                           |
| subjects affected / exposed                           | 1 / 39 (2.56%)                                 | 2 / 36 (5.56%)                            | 1 / 38 (2.63%)                            |
| occurrences (all)                                     | 1                                              | 2                                         | 1                                         |
| Swelling face                                         |                                                |                                           |                                           |
| subjects affected / exposed                           | 0 / 39 (0.00%)                                 | 0 / 36 (0.00%)                            | 0 / 38 (0.00%)                            |
| occurrences (all)                                     | 0                                              | 0                                         | 0                                         |

|                                                 |                                               |                |                |
|-------------------------------------------------|-----------------------------------------------|----------------|----------------|
| Respiratory, thoracic and mediastinal disorders |                                               |                |                |
| Cough                                           |                                               |                |                |
| subjects affected / exposed                     | 0 / 39 (0.00%)                                | 0 / 36 (0.00%) | 2 / 38 (5.26%) |
| occurrences (all)                               | 0                                             | 0              | 2              |
| Rhinorrhoea                                     |                                               |                |                |
| subjects affected / exposed                     | 0 / 39 (0.00%)                                | 0 / 36 (0.00%) | 0 / 38 (0.00%) |
| occurrences (all)                               | 0                                             | 0              | 0              |
| Psychiatric disorders                           |                                               |                |                |
| Anxiety                                         |                                               |                |                |
| subjects affected / exposed                     | 0 / 39 (0.00%)                                | 1 / 36 (2.78%) | 0 / 38 (0.00%) |
| occurrences (all)                               | 0                                             | 1              | 0              |
| Irritable mood                                  | Additional description: Irritability          |                |                |
| subjects affected / exposed                     | 0 / 39 (0.00%)                                | 0 / 36 (0.00%) | 0 / 38 (0.00%) |
| occurrences (all)                               | 0                                             | 0              | 0              |
| Investigations                                  |                                               |                |                |
| Blood creatine phosphokinase increased          |                                               |                |                |
| subjects affected / exposed                     | 1 / 39 (2.56%)                                | 1 / 36 (2.78%) | 1 / 38 (2.63%) |
| occurrences (all)                               | 1                                             | 1              | 1              |
| Blood urine present                             |                                               |                |                |
| subjects affected / exposed                     | 0 / 39 (0.00%)                                | 0 / 36 (0.00%) | 0 / 38 (0.00%) |
| occurrences (all)                               | 0                                             | 0              | 0              |
| Urine protein, quantitative                     | Additional description: Protein urine present |                |                |
| subjects affected / exposed                     | 0 / 39 (0.00%)                                | 0 / 36 (0.00%) | 0 / 38 (0.00%) |
| occurrences (all)                               | 0                                             | 0              | 0              |
| Nervous system disorders                        |                                               |                |                |
| Headache                                        |                                               |                |                |
| subjects affected / exposed                     | 0 / 39 (0.00%)                                | 0 / 36 (0.00%) | 1 / 38 (2.63%) |
| occurrences (all)                               | 0                                             | 0              | 1              |
| Sciatica                                        |                                               |                |                |
| subjects affected / exposed                     | 0 / 39 (0.00%)                                | 0 / 36 (0.00%) | 0 / 38 (0.00%) |
| occurrences (all)                               | 0                                             | 0              | 0              |
| Blood and lymphatic system disorders            |                                               |                |                |
| Anaemia                                         |                                               |                |                |
| subjects affected / exposed                     | 0 / 39 (0.00%)                                | 0 / 36 (0.00%) | 1 / 38 (2.63%) |
| occurrences (all)                               | 0                                             | 0              | 1              |
| Ear and labyrinth disorders                     |                                               |                |                |

|                                                                             |                                           |                     |                     |
|-----------------------------------------------------------------------------|-------------------------------------------|---------------------|---------------------|
| Hearing loss unilateral<br>subjects affected / exposed<br>occurrences (all) | 1 / 39 (2.56%)<br>2                       | 0 / 36 (0.00%)<br>0 | 0 / 38 (0.00%)<br>0 |
| Eye disorders                                                               |                                           |                     |                     |
| Visual field tests abnormal                                                 | Additional description: Visual impairment |                     |                     |
| subjects affected / exposed                                                 | 0 / 39 (0.00%)                            | 0 / 36 (0.00%)      | 0 / 38 (0.00%)      |
| occurrences (all)                                                           | 0                                         | 0                   | 0                   |
| Gastrointestinal disorders                                                  |                                           |                     |                     |
| Abdominal pain                                                              |                                           |                     |                     |
| subjects affected / exposed                                                 | 1 / 39 (2.56%)                            | 1 / 36 (2.78%)      | 1 / 38 (2.63%)      |
| occurrences (all)                                                           | 1                                         | 1                   | 1                   |
| Anal exam abnormal                                                          | Additional description: Anal fissure      |                     |                     |
| subjects affected / exposed                                                 | 0 / 39 (0.00%)                            | 2 / 36 (5.56%)      | 0 / 38 (0.00%)      |
| occurrences (all)                                                           | 0                                         | 2                   | 0                   |
| Ulcerative colitis                                                          |                                           |                     |                     |
| subjects affected / exposed                                                 | 4 / 39 (10.26%)                           | 5 / 36 (13.89%)     | 2 / 38 (5.26%)      |
| occurrences (all)                                                           | 4                                         | 6                   | 2                   |
| Diarrhoea                                                                   |                                           |                     |                     |
| subjects affected / exposed                                                 | 0 / 39 (0.00%)                            | 2 / 36 (5.56%)      | 1 / 38 (2.63%)      |
| occurrences (all)                                                           | 0                                         | 3                   | 1                   |
| Nausea                                                                      |                                           |                     |                     |
| subjects affected / exposed                                                 | 0 / 39 (0.00%)                            | 0 / 36 (0.00%)      | 1 / 38 (2.63%)      |
| occurrences (all)                                                           | 0                                         | 0                   | 1                   |
| Flatulence                                                                  |                                           |                     |                     |
| subjects affected / exposed                                                 | 2 / 39 (5.13%)                            | 1 / 36 (2.78%)      | 0 / 38 (0.00%)      |
| occurrences (all)                                                           | 2                                         | 1                   | 0                   |
| Dyspepsia                                                                   |                                           |                     |                     |
| subjects affected / exposed                                                 | 0 / 39 (0.00%)                            | 1 / 36 (2.78%)      | 0 / 38 (0.00%)      |
| occurrences (all)                                                           | 0                                         | 2                   | 0                   |
| Skin and subcutaneous tissue disorders                                      |                                           |                     |                     |
| Acne                                                                        |                                           |                     |                     |
| subjects affected / exposed                                                 | 0 / 39 (0.00%)                            | 0 / 36 (0.00%)      | 2 / 38 (5.26%)      |
| occurrences (all)                                                           | 0                                         | 0                   | 2                   |
| Alopecia                                                                    |                                           |                     |                     |
| subjects affected / exposed                                                 | 1 / 39 (2.56%)                            | 1 / 36 (2.78%)      | 0 / 38 (0.00%)      |
| occurrences (all)                                                           | 1                                         | 1                   | 0                   |
| Dermatitis atopic                                                           |                                           |                     |                     |



|                                                 |                                                 |                |                 |
|-------------------------------------------------|-------------------------------------------------|----------------|-----------------|
| subjects affected / exposed                     | 0 / 39 (0.00%)                                  | 0 / 36 (0.00%) | 0 / 38 (0.00%)  |
| occurrences (all)                               | 0                                               | 0              | 0               |
| Rash                                            |                                                 |                |                 |
| subjects affected / exposed                     | 1 / 39 (2.56%)                                  | 0 / 36 (0.00%) | 0 / 38 (0.00%)  |
| occurrences (all)                               | 1                                               | 0              | 0               |
| Musculoskeletal and connective tissue disorders |                                                 |                |                 |
| Arthralgia                                      |                                                 |                |                 |
| subjects affected / exposed                     | 0 / 39 (0.00%)                                  | 1 / 36 (2.78%) | 2 / 38 (5.26%)  |
| occurrences (all)                               | 0                                               | 1              | 2               |
| Arthritis                                       |                                                 |                |                 |
| subjects affected / exposed                     | 0 / 39 (0.00%)                                  | 1 / 36 (2.78%) | 0 / 38 (0.00%)  |
| occurrences (all)                               | 0                                               | 1              | 0               |
| Contracture of palmar fascia                    | Additional description: Dupuytren's contracture |                |                 |
| subjects affected / exposed                     | 0 / 39 (0.00%)                                  | 0 / 36 (0.00%) | 0 / 38 (0.00%)  |
| occurrences (all)                               | 0                                               | 0              | 0               |
| Osteoarthritis                                  |                                                 |                |                 |
| subjects affected / exposed                     | 0 / 39 (0.00%)                                  | 0 / 36 (0.00%) | 0 / 38 (0.00%)  |
| occurrences (all)                               | 0                                               | 0              | 0               |
| Pain                                            | Additional description: Pain in extremity       |                |                 |
| subjects affected / exposed                     | 0 / 39 (0.00%)                                  | 1 / 36 (2.78%) | 1 / 38 (2.63%)  |
| occurrences (all)                               | 0                                               | 1              | 1               |
| Infections and infestations                     |                                                 |                |                 |
| Nasopharyngitis                                 |                                                 |                |                 |
| subjects affected / exposed                     | 0 / 39 (0.00%)                                  | 1 / 36 (2.78%) | 4 / 38 (10.53%) |
| occurrences (all)                               | 0                                               | 1              | 5               |
| COVID-19                                        |                                                 |                |                 |
| subjects affected / exposed                     | 2 / 39 (5.13%)                                  | 1 / 36 (2.78%) | 1 / 38 (2.63%)  |
| occurrences (all)                               | 2                                               | 1              | 1               |
| Conjunctivitis                                  |                                                 |                |                 |
| subjects affected / exposed                     | 0 / 39 (0.00%)                                  | 0 / 36 (0.00%) | 1 / 38 (2.63%)  |
| occurrences (all)                               | 0                                               | 0              | 1               |
| Herpes zoster                                   |                                                 |                |                 |
| subjects affected / exposed                     | 0 / 39 (0.00%)                                  | 3 / 36 (8.33%) | 0 / 38 (0.00%)  |
| occurrences (all)                               | 0                                               | 3              | 0               |
| Influenza                                       |                                                 |                |                 |

|                                    |                |                |                |
|------------------------------------|----------------|----------------|----------------|
| subjects affected / exposed        | 2 / 39 (5.13%) | 0 / 36 (0.00%) | 0 / 38 (0.00%) |
| occurrences (all)                  | 2              | 0              | 0              |
| Urinary tract infection            |                |                |                |
| subjects affected / exposed        | 0 / 39 (0.00%) | 0 / 36 (0.00%) | 2 / 38 (5.26%) |
| occurrences (all)                  | 0              | 0              | 2              |
| Metabolism and nutrition disorders |                |                |                |
| Hypermatraemia                     |                |                |                |
| subjects affected / exposed        | 0 / 39 (0.00%) | 0 / 36 (0.00%) | 0 / 38 (0.00%) |
| occurrences (all)                  | 0              | 0              | 0              |

| <b>Non-serious adverse events</b>                     | Placebo -> PF-06700841 30 mg                   | PF-06700841 10 mg -> PF-06700841 30 mg | PF-06700841 30 mg -> PF-06700841 30 mg |
|-------------------------------------------------------|------------------------------------------------|----------------------------------------|----------------------------------------|
| Total subjects affected by non-serious adverse events |                                                |                                        |                                        |
| subjects affected / exposed                           | 4 / 9 (44.44%)                                 | 20 / 39 (51.28%)                       | 15 / 37 (40.54%)                       |
| Vascular disorders                                    |                                                |                                        |                                        |
| Hypertension                                          |                                                |                                        |                                        |
| subjects affected / exposed                           | 0 / 9 (0.00%)                                  | 2 / 39 (5.13%)                         | 1 / 37 (2.70%)                         |
| occurrences (all)                                     | 0                                              | 2                                      | 1                                      |
| General disorders and administration site conditions  |                                                |                                        |                                        |
| Feeling hot                                           |                                                |                                        |                                        |
| subjects affected / exposed                           | 0 / 9 (0.00%)                                  | 0 / 39 (0.00%)                         | 0 / 37 (0.00%)                         |
| occurrences (all)                                     | 0                                              | 0                                      | 0                                      |
| Feeling bad                                           | Additional description: Influenza like illness |                                        |                                        |
| subjects affected / exposed                           | 0 / 9 (0.00%)                                  | 0 / 39 (0.00%)                         | 0 / 37 (0.00%)                         |
| occurrences (all)                                     | 0                                              | 0                                      | 0                                      |
| Oedema peripheral                                     |                                                |                                        |                                        |
| subjects affected / exposed                           | 0 / 9 (0.00%)                                  | 0 / 39 (0.00%)                         | 1 / 37 (2.70%)                         |
| occurrences (all)                                     | 0                                              | 0                                      | 1                                      |
| Pyrexia                                               |                                                |                                        |                                        |
| subjects affected / exposed                           | 1 / 9 (11.11%)                                 | 2 / 39 (5.13%)                         | 0 / 37 (0.00%)                         |
| occurrences (all)                                     | 1                                              | 2                                      | 0                                      |
| Swelling face                                         |                                                |                                        |                                        |
| subjects affected / exposed                           | 0 / 9 (0.00%)                                  | 0 / 39 (0.00%)                         | 0 / 37 (0.00%)                         |
| occurrences (all)                                     | 0                                              | 0                                      | 0                                      |
| Respiratory, thoracic and mediastinal disorders       |                                                |                                        |                                        |

|                                                                                            |                                               |                     |                     |
|--------------------------------------------------------------------------------------------|-----------------------------------------------|---------------------|---------------------|
| Cough<br>subjects affected / exposed<br>occurrences (all)                                  | 0 / 9 (0.00%)<br>0                            | 0 / 39 (0.00%)<br>0 | 0 / 37 (0.00%)<br>0 |
| Rhinorrhoea<br>subjects affected / exposed<br>occurrences (all)                            | 1 / 9 (11.11%)<br>1                           | 0 / 39 (0.00%)<br>0 | 0 / 37 (0.00%)<br>0 |
| Psychiatric disorders                                                                      |                                               |                     |                     |
| Anxiety<br>subjects affected / exposed<br>occurrences (all)                                | 1 / 9 (11.11%)<br>1                           | 0 / 39 (0.00%)<br>0 | 0 / 37 (0.00%)<br>0 |
| Irritable mood                                                                             | Additional description: Irritability          |                     |                     |
| subjects affected / exposed<br>occurrences (all)                                           | 1 / 9 (11.11%)<br>1                           | 0 / 39 (0.00%)<br>0 | 0 / 37 (0.00%)<br>0 |
| Investigations                                                                             |                                               |                     |                     |
| Blood creatine phosphokinase increased<br>subjects affected / exposed<br>occurrences (all) | 0 / 9 (0.00%)<br>0                            | 3 / 39 (7.69%)<br>4 | 3 / 37 (8.11%)<br>3 |
| Blood urine present<br>subjects affected / exposed<br>occurrences (all)                    | 0 / 9 (0.00%)<br>0                            | 2 / 39 (5.13%)<br>2 | 0 / 37 (0.00%)<br>0 |
| Urine protein, quantitative                                                                | Additional description: Protein urine present |                     |                     |
| subjects affected / exposed<br>occurrences (all)                                           | 0 / 9 (0.00%)<br>0                            | 2 / 39 (5.13%)<br>2 | 0 / 37 (0.00%)<br>0 |
| Nervous system disorders                                                                   |                                               |                     |                     |
| Headache<br>subjects affected / exposed<br>occurrences (all)                               | 0 / 9 (0.00%)<br>0                            | 2 / 39 (5.13%)<br>2 | 1 / 37 (2.70%)<br>1 |
| Sciatica<br>subjects affected / exposed<br>occurrences (all)                               | 1 / 9 (11.11%)<br>1                           | 0 / 39 (0.00%)<br>0 | 0 / 37 (0.00%)<br>0 |
| Blood and lymphatic system disorders                                                       |                                               |                     |                     |
| Anaemia<br>subjects affected / exposed<br>occurrences (all)                                | 1 / 9 (11.11%)<br>1                           | 2 / 39 (5.13%)<br>2 | 0 / 37 (0.00%)<br>0 |
| Ear and labyrinth disorders                                                                |                                               |                     |                     |

|                                                                             |                                           |                     |                     |
|-----------------------------------------------------------------------------|-------------------------------------------|---------------------|---------------------|
| Hearing loss unilateral<br>subjects affected / exposed<br>occurrences (all) | 0 / 9 (0.00%)<br>0                        | 0 / 39 (0.00%)<br>0 | 0 / 37 (0.00%)<br>0 |
| Eye disorders                                                               |                                           |                     |                     |
| Visual field tests abnormal                                                 | Additional description: Visual impairment |                     |                     |
| subjects affected / exposed                                                 | 0 / 9 (0.00%)                             | 0 / 39 (0.00%)      | 0 / 37 (0.00%)      |
| occurrences (all)                                                           | 0                                         | 0                   | 0                   |
| Gastrointestinal disorders                                                  |                                           |                     |                     |
| Abdominal pain                                                              |                                           |                     |                     |
| subjects affected / exposed                                                 | 0 / 9 (0.00%)                             | 2 / 39 (5.13%)      | 1 / 37 (2.70%)      |
| occurrences (all)                                                           | 0                                         | 2                   | 2                   |
| Anal exam abnormal                                                          | Additional description: Anal fissure      |                     |                     |
| subjects affected / exposed                                                 | 0 / 9 (0.00%)                             | 0 / 39 (0.00%)      | 0 / 37 (0.00%)      |
| occurrences (all)                                                           | 0                                         | 0                   | 0                   |
| Ulcerative colitis                                                          |                                           |                     |                     |
| subjects affected / exposed                                                 | 1 / 9 (11.11%)                            | 6 / 39 (15.38%)     | 2 / 37 (5.41%)      |
| occurrences (all)                                                           | 1                                         | 6                   | 2                   |
| Diarrhoea                                                                   |                                           |                     |                     |
| subjects affected / exposed                                                 | 0 / 9 (0.00%)                             | 0 / 39 (0.00%)      | 2 / 37 (5.41%)      |
| occurrences (all)                                                           | 0                                         | 0                   | 2                   |
| Nausea                                                                      |                                           |                     |                     |
| subjects affected / exposed                                                 | 0 / 9 (0.00%)                             | 0 / 39 (0.00%)      | 2 / 37 (5.41%)      |
| occurrences (all)                                                           | 0                                         | 0                   | 2                   |
| Flatulence                                                                  |                                           |                     |                     |
| subjects affected / exposed                                                 | 0 / 9 (0.00%)                             | 0 / 39 (0.00%)      | 0 / 37 (0.00%)      |
| occurrences (all)                                                           | 0                                         | 0                   | 0                   |
| Dyspepsia                                                                   |                                           |                     |                     |
| subjects affected / exposed                                                 | 0 / 9 (0.00%)                             | 1 / 39 (2.56%)      | 0 / 37 (0.00%)      |
| occurrences (all)                                                           | 0                                         | 1                   | 0                   |
| Skin and subcutaneous tissue disorders                                      |                                           |                     |                     |
| Acne                                                                        |                                           |                     |                     |
| subjects affected / exposed                                                 | 0 / 9 (0.00%)                             | 1 / 39 (2.56%)      | 0 / 37 (0.00%)      |
| occurrences (all)                                                           | 0                                         | 1                   | 0                   |
| Alopecia                                                                    |                                           |                     |                     |
| subjects affected / exposed                                                 | 0 / 9 (0.00%)                             | 0 / 39 (0.00%)      | 1 / 37 (2.70%)      |
| occurrences (all)                                                           | 0                                         | 0                   | 1                   |
| Dermatitis atopic                                                           |                                           |                     |                     |

|                                                 |                                                 |                 |                 |
|-------------------------------------------------|-------------------------------------------------|-----------------|-----------------|
| subjects affected / exposed                     | 0 / 9 (0.00%)                                   | 0 / 39 (0.00%)  | 0 / 37 (0.00%)  |
| occurrences (all)                               | 0                                               | 0               | 0               |
| Rash                                            |                                                 |                 |                 |
| subjects affected / exposed                     | 0 / 9 (0.00%)                                   | 0 / 39 (0.00%)  | 0 / 37 (0.00%)  |
| occurrences (all)                               | 0                                               | 0               | 0               |
| Musculoskeletal and connective tissue disorders |                                                 |                 |                 |
| Arthralgia                                      |                                                 |                 |                 |
| subjects affected / exposed                     | 0 / 9 (0.00%)                                   | 4 / 39 (10.26%) | 1 / 37 (2.70%)  |
| occurrences (all)                               | 0                                               | 5               | 1               |
| Arthritis                                       |                                                 |                 |                 |
| subjects affected / exposed                     | 0 / 9 (0.00%)                                   | 0 / 39 (0.00%)  | 0 / 37 (0.00%)  |
| occurrences (all)                               | 0                                               | 0               | 0               |
| Contracture of palmar fascia                    | Additional description: Dupuytren's contracture |                 |                 |
| subjects affected / exposed                     | 0 / 9 (0.00%)                                   | 0 / 39 (0.00%)  | 0 / 37 (0.00%)  |
| occurrences (all)                               | 0                                               | 0               | 0               |
| Osteoarthritis                                  |                                                 |                 |                 |
| subjects affected / exposed                     | 0 / 9 (0.00%)                                   | 1 / 39 (2.56%)  | 0 / 37 (0.00%)  |
| occurrences (all)                               | 0                                               | 1               | 0               |
| Pain                                            | Additional description: Pain in extremity       |                 |                 |
| subjects affected / exposed                     | 0 / 9 (0.00%)                                   | 0 / 39 (0.00%)  | 0 / 37 (0.00%)  |
| occurrences (all)                               | 0                                               | 0               | 0               |
| Infections and infestations                     |                                                 |                 |                 |
| Nasopharyngitis                                 |                                                 |                 |                 |
| subjects affected / exposed                     | 1 / 9 (11.11%)                                  | 2 / 39 (5.13%)  | 5 / 37 (13.51%) |
| occurrences (all)                               | 2                                               | 3               | 7               |
| COVID-19                                        |                                                 |                 |                 |
| subjects affected / exposed                     | 0 / 9 (0.00%)                                   | 2 / 39 (5.13%)  | 0 / 37 (0.00%)  |
| occurrences (all)                               | 0                                               | 2               | 0               |
| Conjunctivitis                                  |                                                 |                 |                 |
| subjects affected / exposed                     | 0 / 9 (0.00%)                                   | 0 / 39 (0.00%)  | 0 / 37 (0.00%)  |
| occurrences (all)                               | 0                                               | 0               | 0               |
| Herpes zoster                                   |                                                 |                 |                 |
| subjects affected / exposed                     | 0 / 9 (0.00%)                                   | 1 / 39 (2.56%)  | 0 / 37 (0.00%)  |
| occurrences (all)                               | 0                                               | 1               | 0               |
| Influenza                                       |                                                 |                 |                 |

|                                    |               |                |                |
|------------------------------------|---------------|----------------|----------------|
| subjects affected / exposed        | 0 / 9 (0.00%) | 0 / 39 (0.00%) | 1 / 37 (2.70%) |
| occurrences (all)                  | 0             | 0              | 1              |
| Urinary tract infection            |               |                |                |
| subjects affected / exposed        | 0 / 9 (0.00%) | 1 / 39 (2.56%) | 0 / 37 (0.00%) |
| occurrences (all)                  | 0             | 1              | 0              |
| Metabolism and nutrition disorders |               |                |                |
| Hypermatraemia                     |               |                |                |
| subjects affected / exposed        | 0 / 9 (0.00%) | 0 / 39 (0.00%) | 0 / 37 (0.00%) |
| occurrences (all)                  | 0             | 0              | 0              |

|                                                       |                                                |  |  |
|-------------------------------------------------------|------------------------------------------------|--|--|
| <b>Non-serious adverse events</b>                     | Pooling Placebo<br>During Chronic              |  |  |
| Total subjects affected by non-serious adverse events |                                                |  |  |
| subjects affected / exposed                           | 15 / 37 (40.54%)                               |  |  |
| Vascular disorders                                    |                                                |  |  |
| Hypertension                                          |                                                |  |  |
| subjects affected / exposed                           | 0 / 37 (0.00%)                                 |  |  |
| occurrences (all)                                     | 0                                              |  |  |
| General disorders and administration site conditions  |                                                |  |  |
| Feeling hot                                           |                                                |  |  |
| subjects affected / exposed                           | 0 / 37 (0.00%)                                 |  |  |
| occurrences (all)                                     | 0                                              |  |  |
| Feeling bad                                           | Additional description: Influenza like illness |  |  |
| subjects affected / exposed                           | 0 / 37 (0.00%)                                 |  |  |
| occurrences (all)                                     | 0                                              |  |  |
| Oedema peripheral                                     |                                                |  |  |
| subjects affected / exposed                           | 0 / 37 (0.00%)                                 |  |  |
| occurrences (all)                                     | 0                                              |  |  |
| Pyrexia                                               |                                                |  |  |
| subjects affected / exposed                           | 1 / 37 (2.70%)                                 |  |  |
| occurrences (all)                                     | 1                                              |  |  |
| Swelling face                                         |                                                |  |  |
| subjects affected / exposed                           | 0 / 37 (0.00%)                                 |  |  |
| occurrences (all)                                     | 0                                              |  |  |
| Respiratory, thoracic and mediastinal disorders       |                                                |  |  |
| Cough                                                 |                                                |  |  |

|                                        |                                               |  |  |
|----------------------------------------|-----------------------------------------------|--|--|
| subjects affected / exposed            | 0 / 37 (0.00%)                                |  |  |
| occurrences (all)                      | 0                                             |  |  |
| Rhinorrhoea                            |                                               |  |  |
| subjects affected / exposed            | 0 / 37 (0.00%)                                |  |  |
| occurrences (all)                      | 0                                             |  |  |
| Psychiatric disorders                  |                                               |  |  |
| Anxiety                                |                                               |  |  |
| subjects affected / exposed            | 0 / 37 (0.00%)                                |  |  |
| occurrences (all)                      | 0                                             |  |  |
| Irritable mood                         | Additional description: Irritability          |  |  |
| subjects affected / exposed            | 0 / 37 (0.00%)                                |  |  |
| occurrences (all)                      | 0                                             |  |  |
| Investigations                         |                                               |  |  |
| Blood creatine phosphokinase increased |                                               |  |  |
| subjects affected / exposed            | 0 / 37 (0.00%)                                |  |  |
| occurrences (all)                      | 0                                             |  |  |
| Blood urine present                    |                                               |  |  |
| subjects affected / exposed            | 0 / 37 (0.00%)                                |  |  |
| occurrences (all)                      | 0                                             |  |  |
| Urine protein, quantitative            | Additional description: Protein urine present |  |  |
| subjects affected / exposed            | 0 / 37 (0.00%)                                |  |  |
| occurrences (all)                      | 0                                             |  |  |
| Nervous system disorders               |                                               |  |  |
| Headache                               |                                               |  |  |
| subjects affected / exposed            | 1 / 37 (2.70%)                                |  |  |
| occurrences (all)                      | 1                                             |  |  |
| Sciatica                               |                                               |  |  |
| subjects affected / exposed            | 0 / 37 (0.00%)                                |  |  |
| occurrences (all)                      | 0                                             |  |  |
| Blood and lymphatic system disorders   |                                               |  |  |
| Anaemia                                |                                               |  |  |
| subjects affected / exposed            | 2 / 37 (5.41%)                                |  |  |
| occurrences (all)                      | 2                                             |  |  |
| Ear and labyrinth disorders            |                                               |  |  |
| Hearing loss unilateral                |                                               |  |  |

|                                                  |                                           |  |  |
|--------------------------------------------------|-------------------------------------------|--|--|
| subjects affected / exposed<br>occurrences (all) | 0 / 37 (0.00%)<br>0                       |  |  |
| Eye disorders                                    |                                           |  |  |
| Visual field tests abnormal                      | Additional description: Visual impairment |  |  |
| subjects affected / exposed<br>occurrences (all) | 0 / 37 (0.00%)<br>0                       |  |  |
| Gastrointestinal disorders                       |                                           |  |  |
| Abdominal pain                                   |                                           |  |  |
| subjects affected / exposed<br>occurrences (all) | 1 / 37 (2.70%)<br>1                       |  |  |
| Anal exam abnormal                               | Additional description: Anal fissure      |  |  |
| subjects affected / exposed<br>occurrences (all) | 0 / 37 (0.00%)<br>0                       |  |  |
| Ulcerative colitis                               |                                           |  |  |
| subjects affected / exposed<br>occurrences (all) | 8 / 37 (21.62%)<br>8                      |  |  |
| Diarrhoea                                        |                                           |  |  |
| subjects affected / exposed<br>occurrences (all) | 0 / 37 (0.00%)<br>0                       |  |  |
| Nausea                                           |                                           |  |  |
| subjects affected / exposed<br>occurrences (all) | 0 / 37 (0.00%)<br>0                       |  |  |
| Flatulence                                       |                                           |  |  |
| subjects affected / exposed<br>occurrences (all) | 0 / 37 (0.00%)<br>0                       |  |  |
| Dyspepsia                                        |                                           |  |  |
| subjects affected / exposed<br>occurrences (all) | 0 / 37 (0.00%)<br>0                       |  |  |
| Skin and subcutaneous tissue disorders           |                                           |  |  |
| Acne                                             |                                           |  |  |
| subjects affected / exposed<br>occurrences (all) | 0 / 37 (0.00%)<br>0                       |  |  |
| Alopecia                                         |                                           |  |  |
| subjects affected / exposed<br>occurrences (all) | 0 / 37 (0.00%)<br>0                       |  |  |
| Dermatitis atopic                                |                                           |  |  |



|                                                 |                                                 |  |  |
|-------------------------------------------------|-------------------------------------------------|--|--|
| subjects affected / exposed                     | 0 / 37 (0.00%)                                  |  |  |
| occurrences (all)                               | 0                                               |  |  |
| Rash                                            |                                                 |  |  |
| subjects affected / exposed                     | 0 / 37 (0.00%)                                  |  |  |
| occurrences (all)                               | 0                                               |  |  |
| Musculoskeletal and connective tissue disorders |                                                 |  |  |
| Arthralgia                                      |                                                 |  |  |
| subjects affected / exposed                     | 1 / 37 (2.70%)                                  |  |  |
| occurrences (all)                               | 1                                               |  |  |
| Arthritis                                       |                                                 |  |  |
| subjects affected / exposed                     | 0 / 37 (0.00%)                                  |  |  |
| occurrences (all)                               | 0                                               |  |  |
| Contracture of palmar fascia                    | Additional description: Dupuytren's contracture |  |  |
| subjects affected / exposed                     | 0 / 37 (0.00%)                                  |  |  |
| occurrences (all)                               | 0                                               |  |  |
| Osteoarthritis                                  |                                                 |  |  |
| subjects affected / exposed                     | 0 / 37 (0.00%)                                  |  |  |
| occurrences (all)                               | 0                                               |  |  |
| Pain                                            | Additional description: Pain in extremity       |  |  |
| subjects affected / exposed                     | 0 / 37 (0.00%)                                  |  |  |
| occurrences (all)                               | 0                                               |  |  |
| Infections and infestations                     |                                                 |  |  |
| Nasopharyngitis                                 |                                                 |  |  |
| subjects affected / exposed                     | 4 / 37 (10.81%)                                 |  |  |
| occurrences (all)                               | 5                                               |  |  |
| COVID-19                                        |                                                 |  |  |
| subjects affected / exposed                     | 0 / 37 (0.00%)                                  |  |  |
| occurrences (all)                               | 0                                               |  |  |
| Conjunctivitis                                  |                                                 |  |  |
| subjects affected / exposed                     | 0 / 37 (0.00%)                                  |  |  |
| occurrences (all)                               | 0                                               |  |  |
| Herpes zoster                                   |                                                 |  |  |
| subjects affected / exposed                     | 0 / 37 (0.00%)                                  |  |  |
| occurrences (all)                               | 0                                               |  |  |
| Influenza                                       |                                                 |  |  |

|                                                                                                          |                     |  |  |
|----------------------------------------------------------------------------------------------------------|---------------------|--|--|
| subjects affected / exposed<br>occurrences (all)                                                         | 1 / 37 (2.70%)<br>1 |  |  |
| Urinary tract infection<br>subjects affected / exposed<br>occurrences (all)                              | 2 / 37 (5.41%)<br>2 |  |  |
| Metabolism and nutrition disorders<br>Hypermatraemia<br>subjects affected / exposed<br>occurrences (all) | 0 / 37 (0.00%)<br>0 |  |  |

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date            | Amendment                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
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| 27 October 2016 | <p>In the Schedule of Activities, Section 6 Study Procedures, and Section 7.2.12 Audiogram, added audiogram assessments at regular intervals. In the Schedule of Activities and Section 6 Study Procedures, added Serum Cystatin C (and eGFR) at all time points. In the Schedule of Activities, Section 6.5 Guidelines for Monitoring and Discontinuations, Section 7.2.2 Creatinine and Cystatin C, and Section 8.4.3 Potential Cases of Decreased eGFR, removed statement that a creatinine increase above the ULN will trigger a reflex test for serum cystatin-C in order to facilitate both serum cystatin-C based, and serum creatinine based eGFR calculation. Section 7.2.2 Creatinine and Cystatin C, clarified that creatinine elevations above the ULN will be followed until resolution or baseline. In the Schedule of Activities and Section 6 Study Procedures, added that the screening urinalysis will include a spot urine albumin/creatinine ratio. In the Schedule of Activities, Section 5.3, Subject Compliance, Section 5.5, Administration, and Section 6, Study Procedures, removed reference to subject dosing diary. In the Schedule of Activities, Section 2, Study Objectives and Endpoints, Section 6 Study Procedures, and Section 7.3.5 Ulcerative Colitis Endoscopic Index of Severity, added UCEIS evaluation at same time points as Mayo score. Changes were made in Section 4.1, 4.2 to provide updates in inclusion and exclusion criterion. Section 5.8.1, Oral Corticosteroids, removed requirement for subject to record oral corticosteroids on a daily diary. Section 6.5, Guidelines for Monitoring and Discontinuations, added that treatment with investigational product will be discontinued and subject withdrawn from the study if there is an AST or ALT elevation <math>\geq 3</math> times the upper limit of normal with an INR <math>&gt; 1.5</math>.</p> |
| 14 March 2017   | <p>Changes were made in Section 4.1, 4.2 to provide updates in inclusion and exclusion criterion. Section 5.2, Breaking the Blind is revised to state that discussion with a member of the study team in advance of unblinding is not required. Section 5.8.3, Prohibited Medications revised to prohibit any live (attenuated) vaccines from 30 days prior to baseline and through the end of study (Week 36). Section 5.8.4, Vaccinations is added. Section 6.5, Guidelines for Monitoring and Discontinuations revised to state that an absolute neutrophil count <math>&lt; 1.0 \times 10^9/L</math> (<math>&lt; 1000/mm^3</math>) or platelet count <math>&lt; 75 \times 10^9/L</math> (<math>&lt; 75,000/mm^3</math>) or lymphocyte count <math>&lt; 500/mm^3</math> (<math>&lt; 0.5 \times 10^9/L</math>) must be repeated as soon as feasible and within 3 days. Section 6.5, Guidelines for Monitoring and Discontinuations, added criteria to state that subjects who are inadequately responding to investigational product in the opinion of the investigator should be withdrawn from the study. Section 7.2.13, Electrocardiogram revised to include a statement defining QTc prolongations. Section 9.5, Interim Analysis is revised to incorporate futility stopping guidelines and remove reference to re-estimation of sample size.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |

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| 05 April 2017  | <p>Changes were made in Section 1.2.1 to provide clarification for Non-Clinical Pharmacokinetics and Metabolism of PF-06651600. Changes were made in Section 4.1 and 4.2 to provide clarification and update for inclusion and exclusion criterion. Section 5.5, Administration, revised to note that for study visit days (ie, baseline, Weeks 2, 4, 8, 12, 16, 20, and 24), to highlight that on visits where dosing is at the clinic, subjects are to take the dose at the clinic and from their current blister card or bottle. Section 6.1, Screening, Section 6.2.1, Baseline/(Week 0, Day 1), Section 7.3.1, Endoscopy and Schedule of Activities footnote w, revised to clarify that the stool frequency, rectal bleeding and centrally read endoscopy subscores from the screening endoscopy and the PGA obtained at baseline are used to determine eligibility. Section 7.4.6, Stool Samples for Microbiome Analysis revised to indicate sequencing of DNA present in the stool will be performed to better understand disease activity and response to therapy. During this process some human DNA may be inadvertently sequenced, but will not be used for the final microbiome analysis. Appendix 8, France Appendix added to capture operational items not included in the mandatory contract format for France (ie, French "Contrat Unique"). Administrative changes and sentence revisions made throughout the document.</p> |
| 06 March 2018  | <p>Changes were made in Section 4.2 Exclusion Criterion to provide clarification, consistency within protocol and remove redundancy. Section 7.2.12 Audiogram Testing: Clarification was provided that results of the audiogram test must be available by the time of the following clinic visit. Gene expression analysis was moved from Section 7.6.1 to Section 7.4.7 of the protocol. Several additional minor editorial changes were made to protocol language for the purposes of improving clarity and readability and for maintaining consistency throughout the document.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 16 August 2018 | <p>Changes were made in Background and rationale to align with Investigator Brochure. In Protocol Summary, Schedule of Activities (SoA), Section 1 Introduction, Section 2 Study Objectives and Endpoints, Section 3 Study Design, Section 6 Study Procedures, and Section 9 Data Analysis/Statistical Methods, placebo treatment has been removed from the chronic dosing period. Various changes were made to SoA footnote to provide clarification of specific examinations.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |

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| 17 September 2020 | <p>Changes were made in protocol summary, Schedule of Activities, Section 6.1, Section 7 and Section 7.3.6 To provide guidance on study conduct during public emergencies including COVID-19. Schedule of Activities Footnote "d" and Section 7.2.11</p> <p>updated to clarify that breast and external genitalia examination as a part of physical exam is optional, but skin examination should include a visual examination of the breast and external genitalia to assess rashes. Changes were made in Section 1.3, 1.4, 4.3.1 to align with Investigator Brochure. Section 2: Objectives and Endpoints listed separately for the Induction and Chronic dosing periods. Safety Endpoints for Induction and Chronic dosing periods updated to include laboratory abnormalities, vital signs and 12-lead ECG. Section 4.1 Inclusion criteria #6, Section 5.8.2 and Appendix 1: Updated to reference Steroid conversion table in Appendix 9. Section 4.2: Exclusion criterion #14 updated to exclude re-testing of a positive IGRA test even though protocol states that all screening labs with abnormal results may be repeated within the screening window to confirm abnormal results. Section 5.4.2: Updated to include reference to Appendix 10 on alternative measures during public emergencies. Section 6.5 (Guidelines for Monitoring and Discontinuations): Added Lymphocytes &lt;800/mm<sup>3</sup>; &lt;0.8 x 10<sup>9</sup>/L and CK &gt;3x ULN as additional labs to monitor. Section 7.2.6 updated to allow central lab to replace QuantiFERON®-TB Gold test (QFT-G), QuantiFERON®-TB Gold In-Tube test (QFT-GIT) and T-SPOT® TB test with other acceptable QFT tests. Section 7.2.12 updated to indicate that audiogram results maybe reviewed by an external audiologist. Section 7.3.1: updated to indicate that a Colonoscopy should not be performed at the Early Termination (ET) visit if the previous colonoscopy was less than 8 weeks prior to this.</p> |
| 18 November 2020  | <p>Changes were made in protocol summary, Sections 1.3.2, 1.4.1, 1.4.2, 2.1- 2.2, 3.1, 4.2, 6.5, 7.3.3, 7.3.4, 9.1, 9.2.1 and 9.2.3 with the rational of clarity and to correct grammatical errors and typographical errors, to align with the updated Investigator Brochure, and regulatory request.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |

Notes:

## Interruptions (globally)

Were there any global interruptions to the trial? No

## Limitations and caveats

None reported