



## Clinical trial results:

### A Phase 2b, Double-Blind, Randomized, Placebo-Controlled, Multicenter, Dose-Ranging Study to Evaluate the Efficacy and Safety Profile of PF-06700841 in Participants With Active Systemic Lupus Erythematosus (SLE)

#### Summary

|                          |                                  |
|--------------------------|----------------------------------|
| EudraCT number           | 2018-004175-12                   |
| Trial protocol           | BE HU GB CZ RO BG PT DE PL ES IT |
| Global end of trial date | 05 October 2023                  |

#### Results information

|                                |              |
|--------------------------------|--------------|
| Result version number          | v1 (current) |
| This version publication date  | 14 July 2024 |
| First version publication date | 14 July 2024 |

#### Trial information

##### Trial identification

|                       |          |
|-----------------------|----------|
| Sponsor protocol code | B7931028 |
|-----------------------|----------|

##### Additional study identifiers

|                                    |             |
|------------------------------------|-------------|
| ISRCTN number                      | -           |
| ClinicalTrials.gov id (NCT number) | NCT03845517 |
| 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., 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com |
| Scientific contact           | Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 001 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                       | 26 April 2024 |
| Is this the analysis of the primary completion data? | No            |

|                                  |                 |
|----------------------------------|-----------------|
| Global end of trial reached?     | Yes             |
| Global end of trial date         | 05 October 2023 |
| Was the trial ended prematurely? | No              |

Notes:

## General information about the trial

Main objective of the trial:

To evaluate the efficacy of 3 once daily (QD) dose levels of PF-06700841 compared to placebo in participants with active SLE.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Council for Harmonization (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trials participants were followed.

Background therapy: -

Evidence for comparator: -

|   |               |
|---|---------------|
| Actual start date of recruitment                          | 18 April 2019 |
| 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 | Argentina: 4          |
| Country: Number of subjects enrolled | Canada: 3             |
| Country: Number of subjects enrolled | Czechia: 6            |
| Country: Number of subjects enrolled | Germany: 1            |
| Country: Number of subjects enrolled | France: 2             |
| Country: Number of subjects enrolled | Hungary: 10           |
| Country: Number of subjects enrolled | Japan: 19             |
| Country: Number of subjects enrolled | Belgium: 3            |
| Country: Number of subjects enrolled | Spain: 8              |
| Country: Number of subjects enrolled | China: 4              |
| Country: Number of subjects enrolled | Portugal: 1           |
| Country: Number of subjects enrolled | Bulgaria: 25          |
| Country: Number of subjects enrolled | Colombia: 24          |
| Country: Number of subjects enrolled | Korea, Republic of: 5 |
| Country: Number of subjects enrolled | Poland: 25            |
| Country: Number of subjects enrolled | Serbia: 19            |
| Country: Number of subjects enrolled | Romania: 11           |
| Country: Number of subjects enrolled | Taiwan: 17            |
| Country: Number of subjects enrolled | Ukraine: 33           |
| Country: Number of subjects enrolled | United Kingdom: 5     |

|                                      |                   |
|--------------------------------------|-------------------|
| Country: Number of subjects enrolled | Mexico: 51        |
| Country: Number of subjects enrolled | United States: 70 |
| Country: Number of subjects enrolled | Greece: 4         |
| Worldwide total number of subjects   | 350               |
| EEA total number of subjects         | 96                |

Notes:

---

### Subjects enrolled per age group

|   |     |
|---|-----|
| In utero                                  | 0   |
| Preterm newborn - gestational age < 37 wk | 0   |
| Newborns (0-27 days)                      | 0   |
| Infants and toddlers (28 days-23 months)  | 0   |
| Children (2-11 years)                     | 0   |
| Adolescents (12-17 years)                 | 0   |
| Adults (18-64 years)                      | 341 |
| From 65 to 84 years                       | 9   |
| 85 years and over                         | 0   |

## Subject disposition

### Recruitment

Recruitment details:

A total of 350 participants with active SLE were enrolled and randomized in the study.

### Pre-assignment

Screening details:

The study was conducted at approximately 185 sites in the 24 countries from 18 April 2019 to 05 October 2023.

### Period 1

|                              |                                  |
|------------------------------|----------------------------------|
| Period 1 title               | Treatment Period (TP) (52 Weeks) |
| 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 |

Arm description:

Participants were randomised to receive placebo matched to PF-06700841 QD for 52 weeks. Participants were followed up for 4 weeks after last dose.

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

Dosage and administration details:

Participants received placebo matched to PF-06700841 QD for 52 weeks.

|                  |                   |
|------------------|-------------------|
| <b>Arm title</b> | PF-06700841 15 mg |
|------------------|-------------------|

Arm description:

Participants were randomised to receive PF-06700841 15 milligram (mg) tablets orally QD for 52 weeks. Participants were followed up for 4 weeks after last dose.

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

Dosage and administration details:

Participants received PF-06700841 15 mg QD for 52 weeks.

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

Arm description:

Participants were randomised to receive PF-06700841 30 mg tablets orally QD for 52 weeks. Participants were followed up for 4 weeks after last dose.

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

|  |                   |
|--|-------------------|
| Investigational medicinal product name                   | PF-06700841       |
| Investigational medicinal product code                   |                   |
| Other name   |                   |
| Pharmaceutical forms                                     | Tablet            |
| Routes of administration                                 | Oral use          |
| Dosage and administration details:                       |                   |
| Participants received PF-06700841 30 mg QD for 52 weeks. |                   |
| <b>Arm title</b>   | PF-06700841 45 mg |

Arm description:

Participants were randomised to receive PF-06700841 45 mg tablets orally QD for 52 weeks. Participants were followed up for 4 weeks after last dose.

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

Dosage and administration details:

Participants received PF-06700841 45 mg QD for 52 weeks.

| <b>Number of subjects in period 1</b> | Placebo | PF-06700841 15 mg | PF-06700841 30 mg |
|---------------------------------------|---------|-------------------|-------------------|
| Started                               | 100     | 50                | 101               |
| Completed                             | 68      | 36                | 78                |
| Not completed                         | 32      | 14                | 23                |
| Consent withdrawn by subject          | 4       | 6                 | 6                 |
| Adverse event, non-fatal              | 12      | 7                 | 10                |
| Death                                 | -       | -                 | 1                 |
| Pregnancy                             | 1       | -                 | -                 |
| Non-compliance with study drug        | 1       | -                 | -                 |
| Site Terminated by Sponsor            | 2       | -                 | -                 |
| Unspecified                           | 2       | -                 | -                 |
| Lost to follow-up                     | 2       | -                 | 1                 |
| Lack of efficacy                      | 8       | 1                 | 3                 |
| Physician's decision                  | -       | -                 | 1                 |
| Protocol deviation                    | -       | -                 | 1                 |

| <b>Number of subjects in period 1</b> | PF-06700841 45 mg |
|---------------------------------------|-------------------|
| Started                               | 99                |
| Completed                             | 71                |
| Not completed                         | 28                |
| Consent withdrawn by subject          | 5                 |
| Adverse event, non-fatal              | 17                |
| Death                                 | -                 |

|                                |   |
|--------------------------------|---|
| Pregnancy                      | 1 |
| Non-compliance with study drug | - |
| Site Terminated by Sponsor     | - |
| Unspecified                    | - |
| Lost to follow-up              | - |
| Lack of efficacy               | 4 |
| Physician's decision           | - |
| Protocol deviation             | 1 |

## Period 2

|                              |                                   |
|------------------------------|-----------------------------------|
| Period 2 title               | Follow-up Period (FU P) (4 Weeks) |
| Is this the baseline period? | No                                |
| Allocation method            | Not applicable                    |
| Blinding used                | Not blinded                       |

## Arms

|                              |         |
|------------------------------|---------|
| Are arms mutually exclusive? | No      |
| <b>Arm title</b>             | Placebo |

### Arm description:

Participants were randomised to receive placebo matched to PF-06700841 once daily (QD) for 52 weeks. Participants were followed up for 4 weeks after last dose.

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

### Dosage and administration details:

Participants received placebo matched to PF-06700841 QD for 52 weeks.

|                  |                   |
|------------------|-------------------|
| <b>Arm title</b> | PF-06700841 15 mg |
|------------------|-------------------|

### Arm description:

Participants were randomised to receive PF-06700841 15 milligram (mg) tablets orally QD for 52 weeks. Participants were followed up for 4 weeks after last dose.

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

### Dosage and administration details:

Participants received PF-06700841 15 mg QD for 52 weeks.

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

### Arm description:

Participants were randomised to receive PF-06700841 30 mg tablets orally QD for 52 weeks. Participants were followed up for 4 weeks after last dose.

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

|  |                   |
|--|-------------------|
| Investigational medicinal product name                   | PF-06700841       |
| Investigational medicinal product code                   |                   |
| Other name   |                   |
| Pharmaceutical forms                                     | Tablet            |
| Routes of administration                                 | Oral use          |
| Dosage and administration details:                       |                   |
| Participants received PF-06700841 30 mg QD for 52 weeks. |                   |
| <b>Arm title</b>   | PF-06700841 45 mg |

Arm description:

Participants were randomised to receive PF-06700841 45 mg tablets orally QD for 52 weeks. Participants were followed up for 4 weeks after last dose.

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

Dosage and administration details:

Participants received PF-06700841 45 mg QD for 52 weeks.

| <b>Number of subjects in period 2</b> | Placebo | PF-06700841 15 mg | PF-06700841 30 mg |
|---------------------------------------|---------|-------------------|-------------------|
| Started                               | 68      | 36                | 78                |
| Completed                             | 89      | 42                | 89                |
| Not completed                         | 11      | 8                 | 12                |
| Consent withdrawn by subject          | 3       | 5                 | 7                 |
| Adverse event, non-fatal              | 4       | 2                 | -                 |
| Death                                 | -       | -                 | 1                 |
| Pregnancy                             | 1       | -                 | -                 |
| Study terminated by sponsor           | -       | -                 | -                 |
| Unspecified                           | 1       | -                 | 1                 |
| Lost to follow-up                     | 2       | 1                 | 2                 |
| Physician's decision                  | -       | -                 | 1                 |
| Protocol deviation                    | -       | -                 | -                 |
| Joined                                | 32      | 14                | 23                |
| Continue to follow up                 | 32      | 14                | 23                |

| <b>Number of subjects in period 2</b> | PF-06700841 45 mg |
|---------------------------------------|-------------------|
| Started                               | 71                |
| Completed                             | 92                |
| Not completed                         | 7                 |
| Consent withdrawn by subject          | 1                 |
| Adverse event, non-fatal              | 2                 |

|                             |    |
|-----------------------------|----|
| Death                       | 1  |
| Pregnancy                   | -  |
| Study terminated by sponsor | 1  |
| Unspecified                 | -  |
| Lost to follow-up           | -  |
| Physician's decision        | 1  |
| Protocol deviation          | 1  |
| Joined                      | 28 |
| Continue to follow up       | 28 |



## Baseline characteristics

### Reporting groups

|  |                   |
|--|-------------------|
| Reporting group title  | Placebo           |
| Reporting group description:   |                   |
| Participants were randomised to receive placebo matched to PF-06700841 QD for 52 weeks. Participants were followed up for 4 weeks after last dose.               |                   |
| Reporting group title  | PF-06700841 15 mg |
| Reporting group description:   |                   |
| Participants were randomised to receive PF-06700841 15 milligram (mg) tablets orally QD for 52 weeks. Participants were followed up for 4 weeks after last dose. |                   |
| Reporting group title  | PF-06700841 30 mg |
| Reporting group description:   |                   |
| Participants were randomised to receive PF-06700841 30 mg tablets orally QD for 52 weeks. Participants were followed up for 4 weeks after last dose.             |                   |
| Reporting group title  | PF-06700841 45 mg |
| Reporting group description:   |                   |
| Participants were randomised to receive PF-06700841 45 mg tablets orally QD for 52 weeks. Participants were followed up for 4 weeks after last dose.             |                   |

| Reporting group values           | Placebo | PF-06700841 15 mg | PF-06700841 30 mg |
|----------------------------------|---------|-------------------|-------------------|
| Number of subjects               | 100     | 50                | 101               |
| Age categorical                  |         |                   |                   |
| Units: Participants              |         |                   |                   |
| Adults (18-64 years)             | 100     | 49                | 97                |
| From 65-84 years                 | 0       | 1                 | 4                 |
| Age Continuous                   |         |                   |                   |
| Units: Years                     |         |                   |                   |
| arithmetic mean                  | 42.5    | 41.5              | 42.8              |
| standard deviation               | ± 9.60  | ± 11.79           | ± 12.71           |
| Sex: Female, Male                |         |                   |                   |
| Units: Participants              |         |                   |                   |
| Female                           | 94      | 45                | 97                |
| Male                             | 6       | 5                 | 4                 |
| Race (NIH/OMB)                   |         |                   |                   |
| Units: Subjects                  |         |                   |                   |
| American Indian or Alaska Native | 2       | 0                 | 7                 |
| Asian                            | 14      | 9                 | 11                |
| Black or African American        | 6       | 4                 | 6                 |
| White                            | 71      | 31                | 69                |
| More than one race               | 2       | 0                 | 0                 |
| Unknown or Not Reported          | 5       | 6                 | 8                 |
| Ethnicity (NIH/OMB)              |         |                   |                   |
| Units: Subjects                  |         |                   |                   |
| Hispanic or Latino               | 29      | 17                | 34                |
| Not Hispanic or Latino           | 71      | 32                | 67                |
| Unknown or Not Reported          | 0       | 1                 | 0                 |

| Reporting group values | PF-06700841 45 mg | Total |  |
|------------------------|-------------------|-------|--|
| Number of subjects     | 99                | 350   |  |

|                                  |         |     |  |
|----------------------------------|---------|-----|--|
| Age categorical                  |         |     |  |
| Units: Participants              |         |     |  |
| Adults (18-64 years)             | 95      | 341 |  |
| From 65-84 years                 | 4       | 9   |  |
| Age Continuous                   |         |     |  |
| Units: Years                     |         |     |  |
| arithmetic mean                  | 41.0    |     |  |
| standard deviation               | ± 11.47 | -   |  |
| Sex: Female, Male                |         |     |  |
| Units: Participants              |         |     |  |
| Female                           | 91      | 327 |  |
| Male                             | 8       | 23  |  |
| Race (NIH/OMB)                   |         |     |  |
| Units: Subjects                  |         |     |  |
| American Indian or Alaska Native | 2       | 11  |  |
| Asian                            | 13      | 47  |  |
| Black or African American        | 7       | 23  |  |
| White                            | 68      | 239 |  |
| More than one race               | 0       | 2   |  |
| Unknown or Not Reported          | 9       | 28  |  |
| Ethnicity (NIH/OMB)              |         |     |  |
| Units: Subjects                  |         |     |  |
| Hispanic or Latino               | 35      | 115 |  |
| Not Hispanic or Latino           | 62      | 232 |  |
| Unknown or Not Reported          | 2       | 3   |  |

## End points

### End points reporting groups

|  |                   |
|--|-------------------|
| Reporting group title  | Placebo           |
| Reporting group description:<br>Participants were randomised to receive placebo matched to PF-06700841 QD for 52 weeks. Participants were followed up for 4 weeks after last dose.               |                   |
| Reporting group title  | PF-06700841 15 mg |
| Reporting group description:<br>Participants were randomised to receive PF-06700841 15 milligram (mg) tablets orally QD for 52 weeks. Participants were followed up for 4 weeks after last dose. |                   |
| Reporting group title  | PF-06700841 30 mg |
| Reporting group description:<br>Participants were randomised to receive PF-06700841 30 mg tablets orally QD for 52 weeks. Participants were followed up for 4 weeks after last dose.             |                   |
| Reporting group title  | PF-06700841 45 mg |
| Reporting group description:<br>Participants were randomised to receive PF-06700841 45 mg tablets orally QD for 52 weeks. Participants were followed up for 4 weeks after last dose.             |                   |
| Reporting group title  | Placebo           |
| Reporting group description:<br>Participants were randomised to receive placebo matched to PF-06700841 once daily (QD) for 52 weeks. Participants were followed up for 4 weeks after last dose.  |                   |
| Reporting group title  | PF-06700841 15 mg |
| Reporting group description:<br>Participants were randomised to receive PF-06700841 15 milligram (mg) tablets orally QD for 52 weeks. Participants were followed up for 4 weeks after last dose. |                   |
| Reporting group title  | PF-06700841 30 mg |
| Reporting group description:<br>Participants were randomised to receive PF-06700841 30 mg tablets orally QD for 52 weeks. Participants were followed up for 4 weeks after last dose.             |                   |
| Reporting group title  | PF-06700841 45 mg |
| Reporting group description:<br>Participants were randomised to receive PF-06700841 45 mg tablets orally QD for 52 weeks. Participants were followed up for 4 weeks after last dose.             |                   |

### Primary: Percentage of Participants Achieving SLE Responder Index (SRI) Change of 4 (SRI-4) at Week 52

|   |   |
|---|---|
| End point title   | Percentage of Participants Achieving SLE Responder Index (SRI) Change of 4 (SRI-4) at Week 52 |
| End point description:<br>SRI-4 components: SLEDAI-2K, BILAG 2004 and PhGA. Participants were classified as SRI-4 responders, if they met all of criteria compared with baseline: 1) $\geq 4$ point reduction in SLEDAI-2K score; 2) no new BILAG A organ domain score or 2 new BILAG B organ domain scores; 3) no worsening $< 0.3$ point increase in PhGA score. SLEDAI-2K: assesses improvement in disease activity (range: 0 to 105; higher score = higher severity). BILAG: assesses disease extent, severity in individual organ system (range: A [severe] to E [no disease]; higher score = less severity). PhGA: assesses worsening in participant's general health status (range: 0 [none] to 3 [severe]; higher score = higher severity). Full analysis set (FAS): all participants randomly assigned to study intervention and have received at least 1 dose of study intervention. Here "Number of Subjects Analyzed" signifies participants at Week 52 with Non-Responder Imputation (NRI) and Last Observation Carried Forward from Week 48 (LOCF48) applied. |   |
| End point type  | Primary   |
| End point timeframe:<br>Week 52   |   |

| <b>End point values</b>           | Placebo             | PF-06700841<br>15 mg | PF-06700841<br>30 mg | PF-06700841<br>45 mg |
|-----------------------------------|---------------------|----------------------|----------------------|----------------------|
| Subject group type                | Reporting group     | Reporting group      | Reporting group      | Reporting group      |
| Number of subjects analysed       | 96                  | 47                   | 99                   | 92                   |
| Units: Percentage of participants |                     |                      |                      |                      |
| number (confidence interval 95%)  | 64.6 (54.5 to 74.7) | 57.4 (42.2 to 72.6)  | 69.7 (60.1 to 79.3)  | 66.3 (56.1 to 76.5)  |

## Statistical analyses

|   |                                  |
|---|----------------------------------|
| <b>Statistical analysis title</b>       | Placebo versus PF-06700841 15 mg |
| Comparison groups                       | Placebo v PF-06700841 15 mg      |
| Number of subjects included in analysis | 143                              |
| Analysis specification                  | Pre-specified                    |
| Analysis type                           | superiority                      |
| P-value                                 | < 0.8076 <sup>[1]</sup>          |
| Method                                  | Cochran-Mantel-Haenszel          |
| Parameter estimate                      | Risk difference (RD)             |
| Point estimate                          | -7.5                             |
| Confidence interval                     |                                  |
| level                                   | 95 %                             |
| sides                                   | 2-sided                          |
| lower limit                             | -24.5                            |
| upper limit                             | 9.5                              |

Notes:

[1] - One sided p-value.

|   |                                  |
|---|----------------------------------|
| <b>Statistical analysis title</b>       | Placebo versus PF-06700841 45 mg |
| Comparison groups                       | PF-06700841 45 mg v Placebo      |
| Number of subjects included in analysis | 188                              |
| Analysis specification                  | Pre-specified                    |
| Analysis type                           | superiority                      |
| P-value                                 | < 0.401 <sup>[2]</sup>           |
| Method                                  | Cochran-Mantel-Haenszel          |
| Parameter estimate                      | Risk difference (RD)             |
| Point estimate                          | 1.7                              |
| Confidence interval                     |                                  |
| level                                   | 95 %                             |
| sides                                   | 2-sided                          |
| lower limit                             | -11.8                            |
| upper limit                             | 15.3                             |

Notes:

[2] - One sided p-value.

|                                   |                                  |
|-----------------------------------|----------------------------------|
| <b>Statistical analysis title</b> | Placebo versus PF-06700841 30 mg |
|-----------------------------------|----------------------------------|

|   |                             |
|---|-----------------------------|
| Comparison groups                       | PF-06700841 30 mg v Placebo |
| Number of subjects included in analysis | 195                         |
| Analysis specification                  | Pre-specified               |
| Analysis type                           | superiority                 |
| P-value                                 | < 0.2189 <sup>[3]</sup>     |
| Method                                  | Cochran-Mantel-Haenszel     |
| Parameter estimate                      | Risk difference (RD)        |
| Point estimate                          | 5.2                         |
| Confidence interval                     |                             |
| level                                   | 95 %                        |
| sides                                   | 2-sided                     |
| lower limit                             | -7.9                        |
| upper limit                             | 18.3                        |

Notes:

[3] - One sided p-value.

## Secondary: Percentage of Participants Achieving British Isles Lupus Assessment Group-Based Composite Lupus Assessment (BICLA) at Week 52

|                 |   |
|-----------------|---|
| End point title | Percentage of Participants Achieving British Isles Lupus Assessment Group-Based Composite Lupus Assessment (BICLA) at Week 52 |
|-----------------|---|

End point description:

BICLA included: BILAG-2004, SLEDAI-2K and PhGA. Participants were classified as responders, if they met all the following criteria: BILAG-2004 improvement (all A scores at baseline improved to B/C/D and all B scores improved to C or D); no worsening in disease activity (no new BILAG-2004 A scores or =<1 new B score); no worsening of total SLEDAI-2K score; no significant deterioration (<10 percent [%] worsening) in analogue PhGA. SLEDAI-2K: assesses improvement in disease activity (range: 0 to 105; higher score = higher severity). BILAG: assesses disease extent, severity in individual organ system (range: A [severe] to E [no disease]; higher score = less severity). PhGA: assesses worsening in participant's general health status (range: 0 [none] to 3 [severe]; higher score = higher severity). FAS was included. Here "Number of Subjects Analyzed" signifies participants at Week 52 with NRI and LOCF48 applied.

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

End point timeframe:

Week 52

| End point values                  | Placebo             | PF-06700841 15 mg   | PF-06700841 30 mg   | PF-06700841 45 mg   |
|-----------------------------------|---------------------|---------------------|---------------------|---------------------|
| Subject group type                | Reporting group     | Reporting group     | Reporting group     | Reporting group     |
| Number of subjects analysed       | 96                  | 47                  | 99                  | 92                  |
| Units: Percentage of participants |                     |                     |                     |                     |
| number (confidence interval 95%)  | 43.8 (33.3 to 54.2) | 42.6 (27.4 to 57.8) | 52.5 (42.2 to 62.9) | 53.3 (42.5 to 64.0) |

## Statistical analyses

|                            |                                  |
|----------------------------|----------------------------------|
| Statistical analysis title | Placebo versus PF-06700841 15 mg |
| Comparison groups          | Placebo v PF-06700841 15 mg      |

|   |                         |
|---|-------------------------|
| Number of subjects included in analysis | 143                     |
| Analysis specification                  | Pre-specified           |
| Analysis type                           |                         |
| P-value                                 | < 0.595 <sup>[4]</sup>  |
| Method                                  | Cochran-Mantel-Haenszel |
| Parameter estimate                      | Risk difference (RD)    |
| Point estimate                          | -2.1                    |
| Confidence interval                     |                         |
| level                                   | 95 %                    |
| sides                                   | 2-sided                 |
| lower limit                             | -19.1                   |
| upper limit                             | 14.9                    |

Notes:

[4] - One sided p-value.

|   |                                  |
|---|----------------------------------|
| <b>Statistical analysis title</b>       | Placebo versus PF-06700841 30 mg |
| Comparison groups                       | Placebo v PF-06700841 30 mg      |
| Number of subjects included in analysis | 195                              |
| Analysis specification                  | Pre-specified                    |
| Analysis type                           |                                  |
| P-value                                 | < 0.1125 <sup>[5]</sup>          |
| Method                                  | Cochran-Mantel-Haenszel          |
| Parameter estimate                      | Risk difference (RD)             |
| Point estimate                          | 8.6                              |
| Confidence interval                     |                                  |
| level                                   | 95 %                             |
| sides                                   | 2-sided                          |
| lower limit                             | -5.3                             |
| upper limit                             | 22.6                             |

Notes:

[5] - One sided p-value.

|   |                                  |
|---|----------------------------------|
| <b>Statistical analysis title</b>       | Placebo versus PF-06700841 45 mg |
| Comparison groups                       | Placebo v PF-06700841 45 mg      |
| Number of subjects included in analysis | 188                              |
| Analysis specification                  | Pre-specified                    |
| Analysis type                           |                                  |
| P-value                                 | < 0.0891 <sup>[6]</sup>          |
| Method                                  | Cochran-Mantel-Haenszel          |
| Parameter estimate                      | Risk difference (RD)             |
| Point estimate                          | 9.6                              |
| Confidence interval                     |                                  |
| level                                   | 95 %                             |
| sides                                   | 2-sided                          |
| lower limit                             | -4.4                             |
| upper limit                             | 23.6                             |

Notes:

[6] - One sided p-value.

---

## Secondary: Percentage of Participants Achieving Lupus Low Disease Activity State

---

## (LLDAS) at Week 52

|                 |  |
|-----------------|--|
| End point title | Percentage of Participants Achieving Lupus Low Disease Activity State (LLDAS) at Week 52 |
|-----------------|--|

### End point description:

LLDAS was defined as SLE disease activity index (SLEDAI-2k  $\leq 4$ , with no activity in major organ systems [renal, central nervous system, cardiopulmonary, vasculitis, fever]) and no haemolytic anaemia or gastrointestinal activity; no new lupus disease activity compared with the previous assessment; a Safety of Estrogens in Lupus Erythematosus National Assessment (SELENA)-SLEDAI PhGA (scale 0-3; higher scores = higher severity)  $\leq 1$ ; a current prednisolone (or equivalent) dose  $\leq 7.5$  milligram per day (mg/daily); and well tolerated standard maintenance doses of immunosuppressive drugs and approved biological agents. FAS included all participants randomly assigned to study intervention and have received at least 1 dose of study intervention. Data from participants from few sites were excluded from FAS. Here "Number of Subjects Analyzed" signifies participants at Week 52 with NRI applied.

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

### End point timeframe:

Week 52

| End point values                  | Placebo             | PF-06700841<br>15 mg | PF-06700841<br>30 mg | PF-06700841<br>45 mg |
|-----------------------------------|---------------------|----------------------|----------------------|----------------------|
| Subject group type                | Reporting group     | Reporting group      | Reporting group      | Reporting group      |
| Number of subjects analysed       | 93                  | 47                   | 97                   | 88                   |
| Units: Percentage of participants |                     |                      |                      |                      |
| number (confidence interval 95%)  | 22.6 (13.5 to 31.6) | 21.3 (8.5 to 34.0)   | 35.1 (25.0 to 45.1)  | 34.1 (23.6 to 44.6)  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Participants Achieving a Reduction in Prednisone (or Equivalent) Dose to $\leq 7.5$ mg/day and Sustained for 12 Weeks Prior to Week 52 in Participants on Prednisone $> 7.5$ mg/day (or Equivalent) at Baseline

|                 |   |
|-----------------|---|
| End point title | Percentage of Participants Achieving a Reduction in Prednisone (or Equivalent) Dose to $\leq 7.5$ mg/day and Sustained for 12 Weeks Prior to Week 52 in Participants on Prednisone $> 7.5$ mg/day (or Equivalent) at Baseline |
|-----------------|---|

### End point description:

In this outcome measure data is reported for participants who achieved a reduction in prednisone (or equivalent) dose to  $\leq 7.5$  mg/day and sustained for 12 Weeks prior at Week 52 and they also sustained this dose reduction for 12 weeks prior to Week 52 (Week 40 to Week 52). FAS included all participants randomly assigned to study intervention and have received at least 1 dose of study intervention. Number of participants in FAS with baseline Prednisone or equivalent  $> 7.5$  mg/day were analyzed. Here, "Number of Subjects Analyzed" signifies participants at Week 52 with NRI applied.

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

### End point timeframe:

Week 52 for achieving reduction in dose along with Week 42 to Week 52 for sustained dosing

| End point values                  | Placebo             | PF-06700841<br>15 mg | PF-06700841<br>30 mg | PF-06700841<br>45 mg |
|-----------------------------------|---------------------|----------------------|----------------------|----------------------|
| Subject group type                | Reporting group     | Reporting group      | Reporting group      | Reporting group      |
| Number of subjects analysed       | 53                  | 33                   | 46                   | 43                   |
| Units: Percentage of participants |                     |                      |                      |                      |
| number (confidence interval 95%)  | 26.4 (13.6 to 39.2) | 36.4 (18.4 to 54.3)  | 37.0 (21.9 to 52.0)  | 41.9 (26.0 to 57.8)  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Participants Achieving a SRI-4 Response With Prednisone Dose Reduced to $\leq 7.5$ mg/day and Sustained for 12 Weeks at Week 52 in Participants on Prednisone $> 7.5$ mg/day (or Equivalent) at Baseline

|                        |  |
|------------------------|--|
| End point title        | Percentage of Participants Achieving a SRI-4 Response With Prednisone Dose Reduced to $\leq 7.5$ mg/day and Sustained for 12 Weeks at Week 52 in Participants on Prednisone $> 7.5$ mg/day (or Equivalent) at Baseline   |
| End point description: | In this outcome measure data is reported for participants who achieved a reduction a SRI-4 response with prednisone dose reduced to $\leq 7.5$ mg/day and sustained for 12 weeks at Week 52. FAS included all participants randomly assigned to study intervention and have received at least 1 dose of study intervention. Number of participants in FAS with baseline Prednisone or equivalent $> 7.5$ mg/day were analyzed. Here, "Number of Subjects Analyzed" signifies participants at Week 52 with NRI applied. |
| End point type         | Secondary  |
| End point timeframe:   | 12 Weeks prior at Week 52 (Week 40 to Week 52)   |

| End point values                  | Placebo            | PF-06700841<br>15 mg | PF-06700841<br>30 mg | PF-06700841<br>45 mg |
|-----------------------------------|--------------------|----------------------|----------------------|----------------------|
| Subject group type                | Reporting group    | Reporting group      | Reporting group      | Reporting group      |
| Number of subjects analysed       | 53                 | 33                   | 46                   | 43                   |
| Units: Percentage of participants |                    |                      |                      |                      |
| number (confidence interval 95%)  | 20.8 (8.9 to 32.6) | 30.3 (13.1 to 47.5)  | 32.6 (18.0 to 47.2)  | 32.6 (17.4 to 47.7)  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Participants With $\geq 50\%$ Reduction in Cutaneous Lupus Erythematosus Disease Area and Severity Index Activity (CLASI-A) Score at Week 52 in Participants With Baseline CLASI-A Score $\geq 10$

|                 |  |
|-----------------|--|
| End point title | Percentage of Participants With $\geq 50\%$ Reduction in Cutaneous Lupus Erythematosus Disease Area and Severity Index Activity (CLASI-A) Score at Week 52 in Participants With Baseline CLASI-A Score $\geq 10$ |
|-----------------|--|



---

**End point description:**

CLASI is an validated measurement instrument for lupus erythematosus developed for use in clinical studies that consists of separate scores for the activity of the disease (CLASI-A). The CLASI activity score is calculated on the basis of erythema, scale/hyperkeratosis, mucous membrane involvement, acute hair loss and non-scarring alopecia. The CLASI activity score ranges from 0-70, with higher scores indicating more severe skin disease. Severity categories based on the CLASI activity score are as follows: mild (0-9), moderate (10-20), and severe (21-70). FAS included all participants randomly assigned to study intervention and have received at least 1 dose of study intervention. Number of participants in FAS with baseline CLASI-A score  $\geq 10$  were analyzed. Here, "Number of Subjects Analyzed" signifies participants at Week 52 with NRI applied.

---

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

---

End point timeframe:

Week 52

---

| End point values                  | Placebo                | PF-06700841<br>15 mg   | PF-06700841<br>30 mg   | PF-06700841<br>45 mg   |
|-----------------------------------|------------------------|------------------------|------------------------|------------------------|
| Subject group type                | Reporting group        | Reporting group        | Reporting group        | Reporting group        |
| Number of subjects analysed       | 23                     | 12                     | 27                     | 16                     |
| Units: Percentage of participants |                        |                        |                        |                        |
| number (confidence interval 95%)  | 73.9 (53.8 to<br>94.0) | 58.3 (26.3 to<br>90.4) | 77.8 (60.2 to<br>95.3) | 56.3 (28.8 to<br>83.7) |

---

**Statistical analyses**

No statistical analyses for this end point

---

---

**Secondary: Change From Baseline in Physical Health Domain Scores of Lupus Quality of Life (LupusQoL) at Week 52**

---

|                 |  |
|-----------------|--|
| End point title | Change From Baseline in Physical Health Domain Scores of Lupus Quality of Life (LupusQoL) at Week 52 |
|-----------------|--|

---

End point description:

The LupusQoL questionnaire is a validated questionnaire used to evaluate SLE -specific concepts of SLE as reported by participants. It consists of 34 items in 8 different domains: physical health, emotional health, body image, pain, planning, fatigue, intimate relationship, and burden to others; measured on a 5-point scale ranging from 0 (not at all) to 4 (very much). The individual domain scores are transformed to a 0 to 100 scale wherein higher scores indicate better quality of life. Physical health domain score of LupusQoL had score range from 0 to 100, where higher scores = better quality of life. FAS included all participants randomly assigned to study intervention and have received at least 1 dose of study intervention. Here, "Number of Subjects Analyzed" signifies participants evaluable for this outcome measure with observed data at the specified visit.

---

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

---

End point timeframe:

Baseline, Week 52

---

| End point values                             | Placebo                  | PF-06700841<br>15 mg     | PF-06700841<br>30 mg     | PF-06700841<br>45 mg      |
|--|--------------------------|--------------------------|--------------------------|---------------------------|
| Subject group type                           | Reporting group          | Reporting group          | Reporting group          | Reporting group           |
| Number of subjects analysed                  | 66                       | 36                       | 75                       | 64                        |
| Units: Units on a scale                      |                          |                          |                          |                           |
| least squares mean (confidence interval 95%) | 11.585 (7.475 to 15.695) | 10.892 (5.241 to 16.544) | 12.371 (8.464 to 16.278) | 14.875 (10.748 to 19.002) |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in Total Scores of Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F) at Week 52

|   |   |
|---|---|
| End point title   | Change From Baseline in Total Scores of Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F) at Week 52 |
| End point description:<br>The FACIT-F Scale is a participant completed questionnaire consisting of 13 items that assess fatigue. Participants responded to each item on a 5-point scale based on their experience of fatigue during the past 7 days (0 = not at all; 1 = a little bit; 2 = somewhat; 3 = quite a bit; 4 = very much). Instrument scoring yielded a range from 0 to 52 (negatively worded items were reversed during analysis), with higher scores representing better participant status (less fatigue). FAS included all participants randomly assigned to study intervention and have received at least 1 dose of study intervention. Here, "Number of Subjects Analyzed" signifies participants evaluable with observed data at Week 52. |   |
| End point type  | Secondary   |
| End point timeframe:<br>Baseline, Week 52   |   |

| End point values                             | Placebo          | PF-06700841<br>15 mg | PF-06700841<br>30 mg | PF-06700841<br>45 mg |
|--|------------------|----------------------|----------------------|----------------------|
| Subject group type                           | Reporting group  | Reporting group      | Reporting group      | Reporting group      |
| Number of subjects analysed                  | 66               | 36                   | 75                   | 64                   |
| Units: Units on a scale                      |                  |                      |                      |                      |
| least squares mean (confidence interval 95%) | 4.6 (2.5 to 6.6) | 7.4 (4.5 to 10.2)    | 5.8 (3.8 to 7.8)     | 7.6 (5.5 to 9.7)     |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in Body Image Domain Scores of LupusQoL at Week 52

|  |   |
|--|---|
| End point title  | Change From Baseline in Body Image Domain Scores of LupusQoL at Week 52 |
| End point description:<br>The LupusQoL questionnaire is a validated questionnaire used to evaluate SLE -specific concepts of SLE |   |

as reported by participants. It consists of 34 items in 8 different domains: physical health, emotional health, body image, pain, planning, fatigue, intimate relationship, and burden to others measured on a 5-point scale ranging from 0 (not at all) to 4 (very much). The individual domain scores are transformed to a 0 to 100 scale wherein higher scores indicate better quality of life. Body image domain score of LupusQoL had score range from 0 to 100, where higher scores = better quality of life. FAS included all participants randomly assigned to study intervention and have received at least 1 dose of study intervention. Here, "Number of Subjects Analyzed" signifies participants evaluable for this outcome measure with observed data at the specified visit.

|                      |           |
|----------------------|-----------|
| End point type       | Secondary |
| End point timeframe: |           |
| Baseline, Week 52    |           |

| End point values                             | Placebo                 | PF-06700841<br>15 mg     | PF-06700841<br>30 mg    | PF-06700841<br>45 mg      |
|--|-------------------------|--------------------------|-------------------------|---------------------------|
| Subject group type                           | Reporting group         | Reporting group          | Reporting group         | Reporting group           |
| Number of subjects analysed                  | 62                      | 32                       | 66                      | 50                        |
| Units: Units on a scale                      |                         |                          |                         |                           |
| least squares mean (confidence interval 95%) | 9.207 (4.352 to 14.062) | 10.935 (4.070 to 17.799) | 8.169 (3.448 to 12.890) | 15.599 (10.355 to 20.843) |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in Emotional Health Domain Scores of LupusQoL at Week 52

|                 |   |
|-----------------|---|
| End point title | Change From Baseline in Emotional Health Domain Scores of LupusQoL at Week 52 |
|-----------------|---|

End point description:

The LupusQoL questionnaire is a validated questionnaire used to evaluate SLE -specific concepts of SLE as reported by participants. It consists of 34 items in 8 different domains: physical health, emotional health, body image, pain, planning, fatigue, intimate relationship, and burden to others measured on a 5-point scale ranging from 0 (not at all) to 4 (very much). The individual domain scores are transformed to a 0 to 100 scale wherein higher scores indicate better quality of life. Emotional health domain score of LupusQoL had score range from 0 to 100, where higher scores = better quality of life. FAS included all participants randomly assigned to study intervention and have received at least 1 dose of study intervention. Here, "Number of Subjects Analyzed" signifies participants evaluable for this outcome measure with observed data at the specified visit.

|                      |           |
|----------------------|-----------|
| End point type       | Secondary |
| End point timeframe: |           |
| Baseline, Week 52    |           |

| End point values                             | Placebo                 | PF-06700841<br>15 mg     | PF-06700841<br>30 mg    | PF-06700841<br>45 mg     |
|--|-------------------------|--------------------------|-------------------------|--------------------------|
| Subject group type                           | Reporting group         | Reporting group          | Reporting group         | Reporting group          |
| Number of subjects analysed                  | 66                      | 36                       | 75                      | 64                       |
| Units: Units on a scale                      |                         |                          |                         |                          |
| least squares mean (confidence interval 95%) | 8.113 (4.132 to 12.093) | 10.469 (4.968 to 15.969) | 7.547 (3.749 to 11.346) | 11.823 (7.806 to 15.840) |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in Fatigue Domain Scores of LupusQoL at Week 52

|   |  |
|---|--|
| End point title   | Change From Baseline in Fatigue Domain Scores of LupusQoL at Week 52 |
| End point description:<br>The LupusQoL questionnaire is a validated questionnaire used to evaluate SLE -specific concepts of SLE as reported by participants. It consists of 34 items in 8 different domains: physical health, emotional health, body image, pain, planning, fatigue, intimate relationship, and burden to others measured on a 5-point scale ranging from 0 (not at all) to 4 (very much). The individual domain scores are transformed to a 0 to 100 scale wherein higher scores indicate better quality of life. Fatigue domain score of LupusQoL had score range from 0 to 100, where higher scores = better quality of life. FAS included all participants randomly assigned to study intervention and have received at least 1 dose of study intervention. Here, "Number of Subjects Analyzed" signifies participants evaluable for this outcome measure with observed data at the specified visit. |  |
| End point type  | Secondary  |
| End point timeframe:<br>Baseline, Week 52   |  |

| End point values                             | Placebo                  | PF-06700841<br>15 mg     | PF-06700841<br>30 mg     | PF-06700841<br>45 mg      |
|--|--------------------------|--------------------------|--------------------------|---------------------------|
| Subject group type                           | Reporting group          | Reporting group          | Reporting group          | Reporting group           |
| Number of subjects analysed                  | 66                       | 36                       | 75                       | 64                        |
| Units: Units on a scale                      |                          |                          |                          |                           |
| least squares mean (confidence interval 95%) | 10.317 (5.951 to 14.683) | 11.893 (5.892 to 17.894) | 11.701 (7.550 to 15.853) | 16.443 (12.036 to 20.850) |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in Pain Domain Scores of LupusQoL at Week 52

|  |   |
|--|---|
| End point title  | Change From Baseline in Pain Domain Scores of LupusQoL at Week 52 |
| End point description:<br>The LupusQoL questionnaire is a validated questionnaire used to evaluate SLE -specific concepts of SLE as reported by participants. It consists of 34 items in 8 different domains: physical health, emotional |   |

health, body image, pain, planning, fatigue, intimate relationship, and burden to others measured on a 5-point scale ranging from 0 (not at all) to 4 (very much). The individual domain scores are transformed to a 0 to 100 scale wherein higher scores indicate better quality of life. Pain domain score of LupusQoL had score range from 0 to 100, where higher scores = better quality of life. FAS included all participants randomly assigned to study intervention and have received at least 1 dose of study intervention. Here, "Number of Subjects Analyzed" signifies participants evaluable for this outcome measure with observed data at the specified visit.

|                      |           |
|----------------------|-----------|
| End point type       | Secondary |
| End point timeframe: |           |
| Baseline, Week 52    |           |

| End point values                             | Placebo                   | PF-06700841<br>15 mg     | PF-06700841<br>30 mg      | PF-06700841<br>45 mg      |
|--|---------------------------|--------------------------|---------------------------|---------------------------|
| Subject group type                           | Reporting group           | Reporting group          | Reporting group           | Reporting group           |
| Number of subjects analysed                  | 66                        | 36                       | 75                        | 64                        |
| Units: Units on a scale                      |                           |                          |                           |                           |
| least squares mean (confidence interval 95%) | 15.065 (10.470 to 19.659) | 15.480 (9.132 to 21.828) | 16.855 (12.488 to 21.223) | 24.418 (19.790 to 29.047) |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in Planning Domain Scores of LupusQoL at Week 52

|                 |   |
|-----------------|---|
| End point title | Change From Baseline in Planning Domain Scores of LupusQoL at Week 52 |
|-----------------|---|

End point description:

The LupusQoL questionnaire is a validated questionnaire used to evaluate SLE -specific concepts of SLE as reported by participants. It consists of 34 items in 8 different domains: physical health, emotional health, body image, pain, planning, fatigue, intimate relationship, and burden to others measured on a 5-point scale ranging from 0 (not at all) to 4 (very much). The individual domain scores are transformed to a 0 to 100 scale wherein higher scores indicate better quality of life. Planning domain score of LupusQoL had score range from 0 to 100, where higher scores = better quality of life. FAS included all participants randomly assigned to study intervention and have received at least 1 dose of study intervention. Here, "Number of Subjects Analyzed" signifies participants evaluable for this outcome measure with observed data at the specified visit.

|                      |           |
|----------------------|-----------|
| End point type       | Secondary |
| End point timeframe: |           |
| Baseline, Week 52    |           |

| End point values                             | Placebo                  | PF-06700841<br>15 mg     | PF-06700841<br>30 mg     | PF-06700841<br>45 mg      |
|--|--------------------------|--------------------------|--------------------------|---------------------------|
| Subject group type                           | Reporting group          | Reporting group          | Reporting group          | Reporting group           |
| Number of subjects analysed                  | 66                       | 36                       | 75                       | 64                        |
| Units: Units on a scale                      |                          |                          |                          |                           |
| least squares mean (confidence interval 95%) | 14.168 (9.423 to 18.912) | 12.013 (5.487 to 18.538) | 10.335 (5.826 to 14.843) | 20.310 (15.523 to 25.097) |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Change From Baseline in Burden to Others Domain Scores of LupusQoL at Week 52

|                 |   |
|-----------------|---|
| End point title | Change From Baseline in Burden to Others Domain Scores of LupusQoL at Week 52 |
|-----------------|---|

End point description:

The LupusQoL questionnaire is a validated questionnaire used to evaluate SLE -specific concepts of SLE as reported by participants. It consists of 34 items in 8 different domains: physical health, emotional health, body image, pain, planning, fatigue, intimate relationship, and burden to others measured on a 5-point scale ranging from 0 (not at all) to 4 (very much). The individual domain scores are transformed to a 0 to 100 scale wherein higher scores indicate better quality of life. Burden to others domain score of LupusQoL had score range from 0 to 100, where higher scores = better quality of life. FAS included all participants randomly assigned to study intervention and have received at least 1 dose of study intervention. Here, "Number of Subjects Analyzed" signifies participants evaluable for this outcome measure with observed data at the specified visit.

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

End point timeframe:

Baseline, Week 52

| End point values                             | Placebo                  | PF-06700841<br>15 mg      | PF-06700841<br>30 mg     | PF-06700841<br>45 mg      |
|--|--------------------------|---------------------------|--------------------------|---------------------------|
| Subject group type                           | Reporting group          | Reporting group           | Reporting group          | Reporting group           |
| Number of subjects analysed                  | 66                       | 36                        | 75                       | 64                        |
| Units: Units on a scale                      |                          |                           |                          |                           |
| least squares mean (confidence interval 95%) | 12.535 (7.227 to 17.842) | 17.739 (10.412 to 25.065) | 11.560 (6.500 to 16.621) | 18.878 (13.523 to 24.233) |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Incidence Rate of Severe Flare Event

|                 |                                      |
|-----------------|--------------------------------------|
| End point title | Incidence Rate of Severe Flare Event |
|-----------------|--------------------------------------|

End point description:

Incidence rate was defined as the number of participants with events per 100 participant-years. FAS included all participants randomly assigned to study intervention and have received at least 1 dose of study intervention.

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

End point timeframe:

Week 52

| End point values                              | Placebo              | PF-06700841<br>15 mg | PF-06700841<br>30 mg | PF-06700841<br>45 mg |
|---|----------------------|----------------------|----------------------|----------------------|
| Subject group type                            | Reporting group      | Reporting group      | Reporting group      | Reporting group      |
| Number of subjects analysed                   | 96                   | 47                   | 100                  | 97                   |
| Units: Participants per 100 participant-years |                      |                      |                      |                      |
| number (confidence interval 95%)              | 8.32 (3.35 to 17.15) | 6.92 (1.43 to 20.23) | 3.24 (0.67 to 9.46)  | 6.95 (2.55 to 15.13) |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in Intimate Relationship Domain Scores of LupusQoL at Week 52

|                 |  |
|-----------------|--|
| End point title | Change From Baseline in Intimate Relationship Domain Scores of LupusQoL at Week 52 |
|-----------------|--|

End point description:

The LupusQoL questionnaire is a validated questionnaire used to evaluate SLE -specific concepts of SLE as reported by participants. It consists of 34 items in 8 different domains: physical health, emotional health, body image, pain, planning, fatigue, intimate relationship, and burden to others measured on a 5-point scale ranging from 0 (not at all) to 4 (very much). The individual domain scores are transformed to a 0 to 100 scale wherein higher scores indicate better quality of life. Intimate relationship domain score of LupusQoL had score range from 0 to 100, where higher scores = better quality of life. FAS included all participants randomly assigned to study intervention and have received at least 1 dose of study intervention. Here, "Number of Subjects Analyzed" signifies participants evaluable for this outcome measure with observed data at the specified visit.

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

End point timeframe:

Baseline, Week 52

| End point values                             | Placebo                  | PF-06700841<br>15 mg     | PF-06700841<br>30 mg    | PF-06700841<br>45 mg     |
|--|--------------------------|--------------------------|-------------------------|--------------------------|
| Subject group type                           | Reporting group          | Reporting group          | Reporting group         | Reporting group          |
| Number of subjects analysed                  | 56                       | 25                       | 59                      | 42                       |
| Units: Units on a scale                      |                          |                          |                         |                          |
| least squares mean (confidence interval 95%) | 12.430 (6.842 to 18.019) | 12.625 (4.112 to 21.139) | 6.494 (0.960 to 12.027) | 15.363 (9.078 to 21.647) |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Number of Participants With Treatment-Emergent Adverse Events (AE)

|   |  |
|---|--|
| End point title   | Number of Participants With Treatment-Emergent Adverse Events (AE) |
| End point description:<br>An AE was any untoward medical occurrence in a participant who received study intervention without regard to possibility of causal relationship. TEAEs are events from first dose of study intervention to 4 weeks after last dose of study intervention that were absent before treatment or that worsened relative to pre-treatment state. An SAE was an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial or prolonged inpatient hospitalization; life-threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly. AEs included both SAEs and all non-SAEs. Safety analysis set included all participants who were randomly assigned to study intervention and who took at least 1 dose of study intervention. |  |
| End point type  | Secondary  |
| End point timeframe:<br>Day 1 of dosing up to 4 weeks after last dose of study drug (maximum treatment was up to 52 weeks, follow-up up to 56 weeks)  |  |

| End point values            | Placebo         | PF-06700841<br>15 mg | PF-06700841<br>30 mg | PF-06700841<br>45 mg |
|-----------------------------|-----------------|----------------------|----------------------|----------------------|
| Subject group type          | Reporting group | Reporting group      | Reporting group      | Reporting group      |
| Number of subjects analysed | 100             | 50                   | 101                  | 99                   |
| Units: Participants         | 80              | 38                   | 88                   | 83                   |

## Statistical analyses

No statistical analyses for this end point

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

|  |   |
|--|---|
| End point title  | Number of Participants With Serious Adverse Events (SAEs) |
| End point description:<br>An AE was any untoward medical occurrence in a participant who received study intervention without regard to possibility of causal relationship. An SAE was an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial or prolonged inpatient hospitalization; life-threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly. Safety analysis set included all participants who were randomly assigned to study intervention and who took at least 1 dose of study intervention. |   |
| End point type   | Secondary   |
| End point timeframe:<br>Day 1 of dosing up to 4 weeks after last dose of study drug (maximum treatment was up to 52 weeks, follow-up up to 56 weeks)   |   |

| End point values            | Placebo         | PF-06700841<br>15 mg | PF-06700841<br>30 mg | PF-06700841<br>45 mg |
|-----------------------------|-----------------|----------------------|----------------------|----------------------|
| Subject group type          | Reporting group | Reporting group      | Reporting group      | Reporting group      |
| Number of subjects analysed | 100             | 50                   | 101                  | 99                   |
| Units: Participants         | 8               | 4                    | 8                    | 9                    |



## Statistical analyses

No statistical analyses for this end point

### Secondary: Number of Participants With Adverse Events Leading to Discontinuation From Study

|                 |  |
|-----------------|--|
| End point title | Number of Participants With Adverse Events Leading to Discontinuation From Study |
|-----------------|--|

End point description:

An AE was any untoward medical occurrence in a participant who received study intervention without regard to possibility of causal relationship. In this endpoint, participants with adverse events leading to discontinuation from study were reported. Safety analysis set included all participants who were randomly assigned to study intervention and who took at least 1 dose of study intervention.

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

End point timeframe:

Day 1 of dosing up to 4 weeks after last dose of study drug (maximum treatment was up to 52 weeks, follow-up up to 56 weeks)

| End point values            | Placebo         | PF-06700841<br>15 mg | PF-06700841<br>30 mg | PF-06700841<br>45 mg |
|-----------------------------|-----------------|----------------------|----------------------|----------------------|
| Subject group type          | Reporting group | Reporting group      | Reporting group      | Reporting group      |
| Number of subjects analysed | 100             | 50                   | 101                  | 99                   |
| Units: Participants         | 6               | 2                    | 1                    | 3                    |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Number of Participants With Clinically Significant Electrocardiogram (ECG) Abnormalities

|                 |  |
|-----------------|--|
| End point title | Number of Participants With Clinically Significant Electrocardiogram (ECG) Abnormalities |
|-----------------|--|

End point description:

Clinical significance in ECG abnormalities was judged by investigator. Safety analysis set (SAS) included all participants who were randomly assigned to study intervention and who took at least 1 dose of study intervention.

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

End point timeframe:

Day 1 of dosing up to 4 weeks after last dose of study drug (maximum treatment was up to 52 weeks, follow-up up to 56 weeks)

| End point values            | Placebo         | PF-06700841<br>15 mg | PF-06700841<br>30 mg | PF-06700841<br>45 mg |
|-----------------------------|-----------------|----------------------|----------------------|----------------------|
| Subject group type          | Reporting group | Reporting group      | Reporting group      | Reporting group      |
| Number of subjects analysed | 100             | 50                   | 101                  | 99                   |
| Units: Participants         | 0               | 0                    | 0                    | 0                    |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Number of Participants With Clinically Significant Vital Signs Abnormalities

|   |  |
|---|--|
| End point title   | Number of Participants With Clinically Significant Vital Signs Abnormalities |
| End point description:<br>Vital signs included blood pressure, pulse rate, respiratory rate, and temperature. Clinical significance in vital signs abnormalities was judged by investigator. Safety analysis set included all participants who were randomly assigned to study intervention and who took at least 1 dose of study intervention. |  |
| End point type  | Secondary  |
| End point timeframe:<br>Day 1 of dosing up to 4 weeks after last dose of study drug (maximum treatment was up to 52 weeks, follow-up up to 56 weeks)  |  |

| End point values            | Placebo         | PF-06700841<br>15 mg | PF-06700841<br>30 mg | PF-06700841<br>45 mg |
|-----------------------------|-----------------|----------------------|----------------------|----------------------|
| Subject group type          | Reporting group | Reporting group      | Reporting group      | Reporting group      |
| Number of subjects analysed | 100             | 50                   | 101                  | 99                   |
| Units: Participants         | 0               | 0                    | 0                    | 0                    |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Number of Participants With Laboratory Test Abnormalities

|  |   |
|--|---|
| End point title  | Number of Participants With Laboratory Test Abnormalities |
| End point description:<br>Hematology (Hemoglobin[hgb],hematocrit,erythrocytes[ery]:<0.8*lower limit of normal[LLN];reticulocytes,reticulocytes/ery:<0.5*LLN,>1.5*upper LN[ULN];ery mean corpuscular volume[EMC], EMC hgb:<0.9*LLN,>1.5*ULN;EMC hgb concentration:<0.9*LLN;platelet:<0.5*LLN;leukocytes[leu]:<0.6*LLN,>1.5*ULN;lymphocytes, lymphocytes/leu, neutrophils, neutrophils/leu:<0.8* LLN,>1.2*ULN;basophils, basophils/leu, eosinophils, eosinophils/leu, monocytes, monocytes/leu:>1.2*ULN;activated partial thromboplastin time[PTT], PTT, prothrombin time:>1.1*ULN);Clinical chemistry(Total/direct/indirect bilirubin, glucose-fasting:>1.5*ULN; aspartate aminotransferase[AT], alanine AT:>3.0*ULN; protein, albumin, HDL cholesterol:<0.8*LLN;urea nitrogen, creatinine, triglyceride, cholesterol:>1.3*ULN;urate,LDL cholesterol:>1.2*ULN;potassium:<0.9*LLN,>1.1*ULN;calcium, bicarbonate:<0.9*LLN;creatinine kinase:>2.0*ULN);Urinalysis (pH<4.5;glucose, protein, hgb, ketones, nitrite, leu esterase, |   |
| End point type   | Secondary   |

---

End point timeframe:

Day 1 of dosing up to 4 weeks after last dose of study drug (maximum treatment was up to 52 weeks, follow-up up to 56 weeks)

---

| <b>End point values</b>     | Placebo         | PF-06700841<br>15 mg | PF-06700841<br>30 mg | PF-06700841<br>45 mg |
|-----------------------------|-----------------|----------------------|----------------------|----------------------|
| Subject group type          | Reporting group | Reporting group      | Reporting group      | Reporting group      |
| Number of subjects analysed | 100             | 50                   | 101                  | 99                   |
| Units: Participants         | 96              | 48                   | 99                   | 97                   |

### Statistical analyses

---

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Day 1 of dosing up to 4 weeks after last dose of study drug (maximum up to 56 weeks)

Adverse event reporting additional description:

Same event may appear as AE and SAE, what is presented are distinct events. Event may be categorised as serious in 1 participant and as non-serious in another participant or 1 participant may have experienced both serious and non-serious event during study.

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

### Dictionary used

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

|                    |      |
|--------------------|------|
| Dictionary version | 26.0 |
|--------------------|------|

### Reporting groups

|                       |         |
|-----------------------|---------|
| Reporting group title | Placebo |
|-----------------------|---------|

Reporting group description:

Participants were randomized to receive placebo matched to PF-06700841 QD for 52 weeks. Participants were followed up for 4 weeks after last dose.

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

Reporting group description:

Participants were randomized to receive PF-06700841 30 mg tablets orally QD for 52 weeks. Participants were followed up for 4 weeks after last dose.

|                       |                   |
|-----------------------|-------------------|
| Reporting group title | PF-06700841 45 mg |
|-----------------------|-------------------|

Reporting group description:

Participants were randomized to receive PF-06700841 45 mg tablets orally QD for 52 weeks. Participants were followed up for 4 weeks after last dose.

|                       |                   |
|-----------------------|-------------------|
| Reporting group title | PF-06700841 15 mg |
|-----------------------|-------------------|

Reporting group description:

Participants were randomized to receive PF-06700841 15 mg tablets orally QD for 52 weeks. Participants were followed up for 4 weeks after last dose.

| Serious adverse events  | Placebo         | PF-06700841 30 mg | PF-06700841 45 mg |
|---|-----------------|-------------------|-------------------|
| Total subjects affected by serious adverse events                   |                 |                   |                   |
| subjects affected / exposed   | 8 / 100 (8.00%) | 8 / 101 (7.92%)   | 9 / 99 (9.09%)    |
| number of deaths (all causes)                                       | 0               | 1                 | 1                 |
| number of deaths resulting from adverse events                      | 0               | 1                 | 1                 |
| Investigations  |                 |                   |                   |
| Transaminases increased   |                 |                   |                   |
| subjects affected / exposed   | 0 / 100 (0.00%) | 0 / 101 (0.00%)   | 1 / 99 (1.01%)    |
| occurrences causally related to treatment / all                     | 0 / 0           | 0 / 0             | 0 / 1             |
| deaths causally related to treatment / all                          | 0 / 0           | 0 / 0             | 0 / 0             |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |                 |                   |                   |
| Invasive breast carcinoma   |                 |                   |                   |

|  |                 |                 |                |
|--|-----------------|-----------------|----------------|
| subjects affected / exposed                          | 0 / 100 (0.00%) | 0 / 101 (0.00%) | 0 / 99 (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          |
| Cutaneous T-cell lymphoma                            |                 |                 |                |
| subjects affected / exposed                          | 0 / 100 (0.00%) | 0 / 101 (0.00%) | 1 / 99 (1.01%) |
| occurrences causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 1          |
| deaths causally related to treatment / all           | 0 / 0           | 0 / 0           | 0 / 0          |
| Vascular disorders                                   |                 |                 |                |
| Circulatory collapse                                 |                 |                 |                |
| subjects affected / exposed                          | 0 / 100 (0.00%) | 1 / 101 (0.99%) | 0 / 99 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0           | 0 / 1           | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0           | 0 / 1           | 0 / 0          |
| Nervous system disorders                             |                 |                 |                |
| Lupus encephalitis                                   |                 |                 |                |
| subjects affected / exposed                          | 0 / 100 (0.00%) | 0 / 101 (0.00%) | 1 / 99 (1.01%) |
| occurrences causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 1          |
| deaths causally related to treatment / all           | 0 / 0           | 0 / 0           | 0 / 0          |
| Thalamic stroke                                      |                 |                 |                |
| subjects affected / exposed                          | 0 / 100 (0.00%) | 0 / 101 (0.00%) | 0 / 99 (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 |                 |                 |                |
| Non-cardiac chest pain                               |                 |                 |                |
| subjects affected / exposed                          | 0 / 100 (0.00%) | 1 / 101 (0.99%) | 0 / 99 (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          |
| Immune system disorders                              |                 |                 |                |
| Hypersensitivity                                     |                 |                 |                |
| subjects affected / exposed                          | 0 / 100 (0.00%) | 1 / 101 (0.99%) | 1 / 99 (1.01%) |
| occurrences causally related to treatment / all      | 0 / 0           | 1 / 1           | 2 / 2          |
| deaths causally related to treatment / all           | 0 / 0           | 0 / 0           | 0 / 0          |
| Gastrointestinal disorders                           |                 |                 |                |
| Intestinal strangulation                             |                 |                 |                |

|   |                 |                 |                |
|---|-----------------|-----------------|----------------|
| subjects affected / exposed                     | 0 / 100 (0.00%) | 1 / 101 (0.99%) | 0 / 99 (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          |
| Haemorrhoids                                    |                 |                 |                |
| subjects affected / exposed                     | 1 / 100 (1.00%) | 0 / 101 (0.00%) | 0 / 99 (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          |
| Respiratory, thoracic and mediastinal disorders |                 |                 |                |
| Lupus pleurisy                                  |                 |                 |                |
| subjects affected / exposed                     | 0 / 100 (0.00%) | 0 / 101 (0.00%) | 0 / 99 (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          |
| Hepatobiliary disorders                         |                 |                 |                |
| Cholecystitis acute                             |                 |                 |                |
| subjects affected / exposed                     | 1 / 100 (1.00%) | 0 / 101 (0.00%) | 0 / 99 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0          |
| Renal and urinary disorders                     |                 |                 |                |
| Ureterolithiasis                                |                 |                 |                |
| subjects affected / exposed                     | 0 / 100 (0.00%) | 0 / 101 (0.00%) | 1 / 99 (1.01%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0          |
| Renal colic                                     |                 |                 |                |
| subjects affected / exposed                     | 1 / 100 (1.00%) | 0 / 101 (0.00%) | 0 / 99 (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          |
| Lupus nephritis                                 |                 |                 |                |
| subjects affected / exposed                     | 1 / 100 (1.00%) | 0 / 101 (0.00%) | 0 / 99 (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          |
| Musculoskeletal and connective tissue disorders |                 |                 |                |
| Systemic lupus erythematosus                    |                 |                 |                |

|   |                 |                 |                |
|---|-----------------|-----------------|----------------|
| subjects affected / exposed                     | 2 / 100 (2.00%) | 1 / 101 (0.99%) | 2 / 99 (2.02%) |
| occurrences causally related to treatment / all | 1 / 2           | 0 / 1           | 1 / 2          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0          |
| Osteonecrosis                                   |                 |                 |                |
| subjects affected / exposed                     | 0 / 100 (0.00%) | 1 / 101 (0.99%) | 0 / 99 (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          |
| Infections and infestations                     |                 |                 |                |
| Bacteraemia                                     |                 |                 |                |
| subjects affected / exposed                     | 0 / 100 (0.00%) | 0 / 101 (0.00%) | 1 / 99 (1.01%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0          |
| COVID-19  |                 |                 |                |
| subjects affected / exposed                     | 0 / 100 (0.00%) | 1 / 101 (0.99%) | 1 / 99 (1.01%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 1          |
| Upper respiratory tract infection               |                 |                 |                |
| subjects affected / exposed                     | 1 / 100 (1.00%) | 0 / 101 (0.00%) | 0 / 99 (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 / 100 (0.00%) | 1 / 101 (0.99%) | 0 / 99 (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          |
| Periorbital cellulitis                          |                 |                 |                |
| subjects affected / exposed                     | 1 / 100 (1.00%) | 0 / 101 (0.00%) | 0 / 99 (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          |
| Gastroenteritis                                 |                 |                 |                |
| subjects affected / exposed                     | 0 / 100 (0.00%) | 0 / 101 (0.00%) | 0 / 99 (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          |
| COVID-19 pneumonia                              |                 |                 |                |

|   |                 |                 |                |
|---|-----------------|-----------------|----------------|
| subjects affected / exposed                     | 0 / 100 (0.00%) | 0 / 101 (0.00%) | 1 / 99 (1.01%) |
| 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>                                       | PF-06700841 15 mg |  |  |
| Total subjects affected by serious adverse events                   |                   |  |  |
| subjects affected / exposed   | 4 / 50 (8.00%)    |  |  |
| number of deaths (all causes)                                       | 0                 |  |  |
| number of deaths resulting from adverse events                      | 0                 |  |  |
| Investigations  |                   |  |  |
| Transaminases increased   |                   |  |  |
| subjects affected / exposed   | 0 / 50 (0.00%)    |  |  |
| occurrences causally related to treatment / all                     | 0 / 0             |  |  |
| deaths causally related to treatment / all                          | 0 / 0             |  |  |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |                   |  |  |
| Invasive breast carcinoma   |                   |  |  |
| subjects affected / exposed   | 1 / 50 (2.00%)    |  |  |
| occurrences causally related to treatment / all                     | 0 / 1             |  |  |
| deaths causally related to treatment / all                          | 0 / 0             |  |  |
| Cutaneous T-cell lymphoma   |                   |  |  |
| subjects affected / exposed   | 0 / 50 (0.00%)    |  |  |
| occurrences causally related to treatment / all                     | 0 / 0             |  |  |
| deaths causally related to treatment / all                          | 0 / 0             |  |  |
| Vascular disorders  |                   |  |  |
| Circulatory collapse  |                   |  |  |
| subjects affected / exposed   | 0 / 50 (0.00%)    |  |  |
| occurrences causally related to treatment / all                     | 0 / 0             |  |  |
| deaths causally related to treatment / all                          | 0 / 0             |  |  |
| Nervous system disorders  |                   |  |  |
| Lupus encephalitis  |                   |  |  |
| subjects affected / exposed   | 0 / 50 (0.00%)    |  |  |
| occurrences causally related to treatment / all                     | 0 / 0             |  |  |
| deaths causally related to treatment / all                          | 0 / 0             |  |  |
| Thalamic stroke   |                   |  |  |



|  |                |  |  |
|--|----------------|--|--|
| subjects affected / exposed                          | 1 / 50 (2.00%) |  |  |
| occurrences causally related to treatment / all      | 0 / 1          |  |  |
| deaths causally related to treatment / all           | 0 / 0          |  |  |
| General disorders and administration site conditions |                |  |  |
| Non-cardiac chest pain                               |                |  |  |
| subjects affected / exposed                          | 0 / 50 (0.00%) |  |  |
| occurrences causally related to treatment / all      | 0 / 0          |  |  |
| deaths causally related to treatment / all           | 0 / 0          |  |  |
| Immune system disorders                              |                |  |  |
| Hypersensitivity                                     |                |  |  |
| subjects affected / exposed                          | 0 / 50 (0.00%) |  |  |
| occurrences causally related to treatment / all      | 0 / 0          |  |  |
| deaths causally related to treatment / all           | 0 / 0          |  |  |
| Gastrointestinal disorders                           |                |  |  |
| Intestinal strangulation                             |                |  |  |
| subjects affected / exposed                          | 0 / 50 (0.00%) |  |  |
| occurrences causally related to treatment / all      | 0 / 0          |  |  |
| deaths causally related to treatment / all           | 0 / 0          |  |  |
| Haemorrhoids   |                |  |  |
| subjects affected / exposed                          | 0 / 50 (0.00%) |  |  |
| occurrences causally related to treatment / all      | 0 / 0          |  |  |
| deaths causally related to treatment / all           | 0 / 0          |  |  |
| Respiratory, thoracic and mediastinal disorders      |                |  |  |
| Lupus pleurisy                                       |                |  |  |
| subjects affected / exposed                          | 1 / 50 (2.00%) |  |  |
| occurrences causally related to treatment / all      | 0 / 1          |  |  |
| deaths causally related to treatment / all           | 0 / 0          |  |  |
| Hepatobiliary disorders                              |                |  |  |
| Cholecystitis acute                                  |                |  |  |
| subjects affected / exposed                          | 0 / 50 (0.00%) |  |  |
| occurrences causally related to treatment / all      | 0 / 0          |  |  |
| deaths causally related to treatment / all           | 0 / 0          |  |  |
| Renal and urinary disorders                          |                |  |  |
| Ureterolithiasis                                     |                |  |  |

|   |                |  |  |
|---|----------------|--|--|
| subjects affected / exposed                     | 0 / 50 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Renal colic                                     |                |  |  |
| subjects affected / exposed                     | 0 / 50 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Lupus nephritis                                 |                |  |  |
| subjects affected / exposed                     | 0 / 50 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Musculoskeletal and connective tissue disorders |                |  |  |
| Systemic lupus erythematosus                    |                |  |  |
| subjects affected / exposed                     | 0 / 50 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Osteonecrosis                                   |                |  |  |
| subjects affected / exposed                     | 0 / 50 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Infections and infestations                     |                |  |  |
| Bacteraemia                                     |                |  |  |
| subjects affected / exposed                     | 0 / 50 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| COVID-19  |                |  |  |
| subjects affected / exposed                     | 0 / 50 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Upper respiratory tract infection               |                |  |  |
| subjects affected / exposed                     | 0 / 50 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |

|   |                |  |  |
|---|----------------|--|--|
| Pneumonia                                       |                |  |  |
| subjects affected / exposed                     | 0 / 50 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Periorbital cellulitis                          |                |  |  |
| subjects affected / exposed                     | 0 / 50 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Gastroenteritis                                 |                |  |  |
| subjects affected / exposed                     | 1 / 50 (2.00%) |  |  |
| occurrences causally related to treatment / all | 1 / 1          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| COVID-19 pneumonia                              |                |  |  |
| subjects affected / exposed                     | 0 / 50 (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           | PF-06700841 30 mg | PF-06700841 45 mg |
|---|-------------------|-------------------|-------------------|
| Total subjects affected by non-serious adverse events |                   |                   |                   |
| subjects affected / exposed                           | 47 / 100 (47.00%) | 53 / 101 (52.48%) | 47 / 99 (47.47%)  |
| Investigations  |                   |                   |                   |
| Blood creatine phosphokinase increased                |                   |                   |                   |
| subjects affected / exposed                           | 1 / 100 (1.00%)   | 1 / 101 (0.99%)   | 4 / 99 (4.04%)    |
| occurrences (all)                                     | 1                 | 1                 | 5                 |
| Nervous system disorders                              |                   |                   |                   |
| Headache  |                   |                   |                   |
| subjects affected / exposed                           | 5 / 100 (5.00%)   | 17 / 101 (16.83%) | 9 / 99 (9.09%)    |
| occurrences (all)                                     | 6                 | 20                | 9                 |
| General disorders and administration site conditions  |                   |                   |                   |
| Fatigue   |                   |                   |                   |
| subjects affected / exposed                           | 0 / 100 (0.00%)   | 6 / 101 (5.94%)   | 2 / 99 (2.02%)    |
| occurrences (all)                                     | 0                 | 6                 | 2                 |
| Gastrointestinal disorders                            |                   |                   |                   |

|                                   |                   |                   |                  |
|-----------------------------------|-------------------|-------------------|------------------|
| Diarrhoea                         |                   |                   |                  |
| subjects affected / exposed       | 5 / 100 (5.00%)   | 7 / 101 (6.93%)   | 6 / 99 (6.06%)   |
| occurrences (all)                 | 5                 | 11                | 6                |
| Nausea                            |                   |                   |                  |
| subjects affected / exposed       | 5 / 100 (5.00%)   | 3 / 101 (2.97%)   | 7 / 99 (7.07%)   |
| occurrences (all)                 | 5                 | 3                 | 9                |
| Vomiting                          |                   |                   |                  |
| subjects affected / exposed       | 1 / 100 (1.00%)   | 4 / 101 (3.96%)   | 4 / 99 (4.04%)   |
| occurrences (all)                 | 1                 | 4                 | 4                |
| Infections and infestations       |                   |                   |                  |
| Cystitis                          |                   |                   |                  |
| subjects affected / exposed       | 3 / 100 (3.00%)   | 2 / 101 (1.98%)   | 2 / 99 (2.02%)   |
| occurrences (all)                 | 3                 | 2                 | 3                |
| Nasopharyngitis                   |                   |                   |                  |
| subjects affected / exposed       | 7 / 100 (7.00%)   | 6 / 101 (5.94%)   | 8 / 99 (8.08%)   |
| occurrences (all)                 | 10                | 8                 | 9                |
| Oral candidiasis                  |                   |                   |                  |
| subjects affected / exposed       | 0 / 100 (0.00%)   | 0 / 101 (0.00%)   | 6 / 99 (6.06%)   |
| occurrences (all)                 | 0                 | 0                 | 7                |
| Upper respiratory tract infection |                   |                   |                  |
| subjects affected / exposed       | 7 / 100 (7.00%)   | 11 / 101 (10.89%) | 8 / 99 (8.08%)   |
| occurrences (all)                 | 7                 | 12                | 11               |
| Urinary tract infection           |                   |                   |                  |
| subjects affected / exposed       | 11 / 100 (11.00%) | 10 / 101 (9.90%)  | 11 / 99 (11.11%) |
| occurrences (all)                 | 13                | 11                | 12               |
| COVID-19                          |                   |                   |                  |
| subjects affected / exposed       | 17 / 100 (17.00%) | 11 / 101 (10.89%) | 10 / 99 (10.10%) |
| occurrences (all)                 | 17                | 11                | 10               |

|   |                   |  |  |
|---|-------------------|--|--|
| <b>Non-serious adverse events</b>                     | PF-06700841 15 mg |  |  |
| Total subjects affected by non-serious adverse events |                   |  |  |
| subjects affected / exposed                           | 19 / 50 (38.00%)  |  |  |
| Investigations  |                   |  |  |
| Blood creatine phosphokinase increased                |                   |  |  |
| subjects affected / exposed                           | 3 / 50 (6.00%)    |  |  |
| occurrences (all)                                     | 3                 |  |  |
| Nervous system disorders                              |                   |  |  |

|  |   |  |  |
|--|---|--|--|
| Headache<br>subjects affected / exposed<br>occurrences (all)   | 4 / 50 (8.00%)<br>5   |  |  |
| General disorders and administration<br>site conditions<br>Fatigue<br>subjects affected / exposed<br>occurrences (all)   | 0 / 50 (0.00%)<br>0   |  |  |
| Gastrointestinal disorders<br>Diarrhoea<br>subjects affected / exposed<br>occurrences (all)<br><br>Nausea<br>subjects affected / exposed<br>occurrences (all)<br><br>Vomiting<br>subjects affected / exposed<br>occurrences (all)  | 1 / 50 (2.00%)<br>1<br><br>4 / 50 (8.00%)<br>4<br><br>3 / 50 (6.00%)<br>3   |  |  |
| Infections and infestations<br>Cystitis<br>subjects affected / exposed<br>occurrences (all)<br><br>Nasopharyngitis<br>subjects affected / exposed<br>occurrences (all)<br><br>Oral candidiasis<br>subjects affected / exposed<br>occurrences (all)<br><br>Upper respiratory tract infection<br>subjects affected / exposed<br>occurrences (all)<br><br>Urinary tract infection<br>subjects affected / exposed<br>occurrences (all)<br><br>COVID-19<br>subjects affected / exposed<br>occurrences (all) | 3 / 50 (6.00%)<br>8<br><br>5 / 50 (10.00%)<br>5<br><br>0 / 50 (0.00%)<br>0<br><br>1 / 50 (2.00%)<br>1<br><br>1 / 50 (2.00%)<br>2<br><br>9 / 50 (18.00%)<br>10 |  |  |



## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date              | Amendment  |
|-------------------|--|
| 02 March 2021     | The following modifications were made to PA4 as a result of the updated PF-06700841 Investigational Brochure (IB). The following changes were added and/or modified to the overview of the MoA and the safety profile of the product: Section 2.2.2. Clinical Overview Added study C2501007, an ongoing study in hidradenitis suppurativa. Updated to include additional guidance to the sites to encourage randomized participants to remain in the study at least through to the end of the double-blind period to complete safety and efficacy assessments.   |
| 28 September 2021 | The overall rationale for B7931028 protocol amendment 6 is to address the Quantiferon gold test results which are not negative. The amendment will allow specific safety monitoring to be put into place to allow participants with latent TB (not active TB) to be eligible for the B7931028 study provided the protocol criteria can be met. China is having the biggest impact on enrolling participants into the study because of this eligibility criteria; however, once the next global protocol amendment is required, this language will be added as well.  |
| 06 June 2022      | The overall rationale for B7931028 Protocol Amendment 7 is to decrease the sample size for the study from 448 participants to 350 participants, and to allow eligibility of participants with latent TB (positive quantiferon gold tests) who agree to receiving treatment with INH and Vitamin B6. This amendment also included the administrative changes made in Protocol Amendment 5 (requested during the EU Voluntary Harmonization Procedure (VHP) review of Amendment 4, countries submitting their initial clinical trial application with Amendment 5 (Italy and Argentina), and to any country requiring new protocol amendments to be submitted (Taiwan); and Protocol Amendment 6 (China only amendment) to be globally implemented. Furthermore, this change will allow specific safety monitoring to be put into place to allow participants with latent TB (not active TB) to be eligible for the study provided the protocol inclusion/exclusion criteria can be met. |
| 15 June 2023      | The driver for B7931028 Protocol Amendment 8 is to modify the key secondary endpoint of 'time to first severe SLE flare' and replace it with an exploratory endpoint of 'BICLA response at Week 52'. 'Time to first severe SLE flare' will remain as a secondary endpoint, just not the 'key' secondary endpoint and the data will be summarized as a secondary endpoint. The estimands for the associated endpoints have been updated to reflect these changes. E2, has been updated to align with the revised 'Key' secondary endpoint of 'BICLA response at Week 52' as was E7, the estimand for 'time to first severe SLE flare'.  |

Notes:

### Interruptions (globally)

Were there any global interruptions to the trial? No

## Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

For the PF-06700841 30 mg, there was a total of 1 death which was reported in both on-treatment and follow-up phases in subject disposition section.

Notes: