



## Clinical trial results:

### A Phase 2, Dose-Escalation, Placebo-Controlled Study of the Safety of INCB054707 in Participants With Hidradenitis Suppurativa

#### Summary

|                          |                |
|--------------------------|----------------|
| EudraCT number           | 2018-000827-15 |
| Trial protocol           | DK             |
| Global end of trial date | 13 August 2019 |

#### Results information

|                                |                |
|--------------------------------|----------------|
| Result version number          | v1 (current)   |
| This version publication date  | 28 August 2020 |
| First version publication date | 28 August 2020 |

#### Trial information

##### Trial identification

|                       |                |
|-----------------------|----------------|
| Sponsor protocol code | INCB 54707-203 |
|-----------------------|----------------|

##### Additional study identifiers

|                                    |             |
|------------------------------------|-------------|
| ISRCTN number                      | -           |
| ClinicalTrials.gov id (NCT number) | NCT03607487 |
| WHO universal trial number (UTN)   | -           |

Notes:

#### Sponsors

|                              |                                                                                         |
|------------------------------|-----------------------------------------------------------------------------------------|
| Sponsor organisation name    | Incyte Corporation                                                                      |
| Sponsor organisation address | 1801 Augustine Cutoff, Wilmington, United States, 19803                                 |
| Public contact               | Incyte Corporation Call Center, Incyte Corporation, +44 18554633463, medinfo@incyte.com |
| Scientific contact           | Incyte Corporation Call Center, Incyte Corporation, +44 18554633463, medinfo@incyte.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                       | 13 August 2019 |
| Is this the analysis of the primary completion data? | No             |
| Global end of trial reached?                         | Yes            |
| Global end of trial date                             | 13 August 2019 |
| Was the trial ended prematurely?                     | No             |

Notes:

## General information about the trial

Main objective of the trial:

The purpose of this study is to evaluate the safety of INCB054707 over an 8-week treatment period in men and women with moderate to severe hidradenitis suppurativa.

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

|                                                           |                   |
|-----------------------------------------------------------|-------------------|
| Actual start date of recruitment                          | 18 September 2018 |
| Long term follow-up planned                               | No                |
| Independent data monitoring committee (IDMC) involvement? | No                |

Notes:

## Population of trial subjects

### Subjects enrolled per country

|                                      |            |
|--------------------------------------|------------|
| Country: Number of subjects enrolled | Canada: 33 |
| Country: Number of subjects enrolled | Germany: 2 |
| Worldwide total number of subjects   | 35         |
| EEA total number of subjects         | 2          |

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)                      | 35 |
| From 65 to 84 years                       | 0  |
| 85 years and over                         | 0  |

## Subject disposition

### Recruitment

Recruitment details:

The study was conducted at 9 different sites in Canada, 2 different sites in Germany and 1 site in Denmark.

### Pre-assignment

Screening details:

A total of 43 participants were screened for enrollment in the study, 8 did not meet the eligibility criteria. A total of 35 participants were randomized to one of the treatment groups.

### Period 1

|                              |                                |
|------------------------------|--------------------------------|
| Period 1 title               | Overall Study (overall period) |
| Is this the baseline period? | Yes                            |
| Allocation method            | Not applicable                 |
| Blinding used                | Not blinded                    |

### Arms

|                              |         |
|------------------------------|---------|
| Are arms mutually exclusive? | Yes     |
| <b>Arm title</b>             | Placebo |

Arm description:

Placebo was administered QD over an 8 week treatment period.

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

Dosage and administration details:

Placebo was administered QD over an 8 week treatment period.

|                  |                     |
|------------------|---------------------|
| <b>Arm title</b> | INCB054707 at 30 mg |
|------------------|---------------------|

Arm description:

INCB054707 was administered at 30 mg QD over an 8 week treatment period.

|                                        |              |
|----------------------------------------|--------------|
| Arm type                               | Experimental |
| Investigational medicinal product name | INCB054707   |
| Investigational medicinal product code |              |
| Other name                             |              |
| Pharmaceutical forms                   | Tablet       |
| Routes of administration               | Oral use     |

Dosage and administration details:

INCB054707 was administered at 30 mg QD over an 8 week treatment period.

|                  |                     |
|------------------|---------------------|
| <b>Arm title</b> | INCB054707 at 60 mg |
|------------------|---------------------|

Arm description:

INCB054707 was administered at 60 mg QD over an 8 week treatment period.

|                                        |              |
|----------------------------------------|--------------|
| Arm type                               | Experimental |
| Investigational medicinal product name | INCB054707   |
| Investigational medicinal product code |              |
| Other name                             |              |
| Pharmaceutical forms                   | Tablet       |
| Routes of administration               | Oral use     |

Dosage and administration details:

INCB054707 was administered at 60 mg QD over an 8 week treatment period.

|                                                                                              |                     |
|----------------------------------------------------------------------------------------------|---------------------|
| <b>Arm title</b>                                                                             | INCB054707 at 90 mg |
| Arm description:<br>INCB054707 was administered at 90 mg QD over an 8 week treatment period. |                     |
| Arm type                                                                                     | Experimental        |
| Investigational medicinal product name                                                       | INCB054707          |
| Investigational medicinal product code                                                       |                     |
| Other name                                                                                   |                     |
| Pharmaceutical forms                                                                         | Tablet              |
| Routes of administration                                                                     | Oral use            |

Dosage and administration details:

INCB054707 was administered at 90 mg QD over an 8 week treatment period.

| <b>Number of subjects in period 1</b> | Placebo | INCB054707 at 30 mg | INCB054707 at 60 mg |
|---------------------------------------|---------|---------------------|---------------------|
| Started                               | 9       | 9                   | 9                   |
| Completed                             | 7       | 9                   | 9                   |
| Not completed                         | 2       | 0                   | 0                   |
| Consent withdrawn by subject          | 2       | -                   | -                   |

| <b>Number of subjects in period 1</b> | INCB054707 at 90 mg |
|---------------------------------------|---------------------|
| Started                               | 8                   |
| Completed                             | 7                   |
| Not completed                         | 1                   |
| Consent withdrawn by subject          | 1                   |

## Baseline characteristics

### Reporting groups

|                                                                                                          |                     |
|----------------------------------------------------------------------------------------------------------|---------------------|
| Reporting group title                                                                                    | Placebo             |
| Reporting group description:<br>Placebo was administered QD over an 8 week treatment period.             |                     |
| Reporting group title                                                                                    | INCB054707 at 30 mg |
| Reporting group description:<br>INCB054707 was administered at 30 mg QD over an 8 week treatment period. |                     |
| Reporting group title                                                                                    | INCB054707 at 60 mg |
| Reporting group description:<br>INCB054707 was administered at 60 mg QD over an 8 week treatment period. |                     |
| Reporting group title                                                                                    | INCB054707 at 90 mg |
| Reporting group description:<br>INCB054707 was administered at 90 mg QD over an 8 week treatment period. |                     |

| Reporting group values                             | Placebo | INCB054707 at 30 mg | INCB054707 at 60 mg |
|----------------------------------------------------|---------|---------------------|---------------------|
| Number of subjects                                 | 9       | 9                   | 9                   |
| Age categorical<br>Units: Subjects                 |         |                     |                     |
| In utero                                           | 0       | 0                   | 0                   |
| Preterm newborn infants (gestational age < 37 wks) | 0       | 0                   | 0                   |
| Newborns (0-27 days)                               | 0       | 0                   | 0                   |
| Infants and toddlers (28 days-23 months)           | 0       | 0                   | 0                   |
| Children (2-11 years)                              | 0       | 0                   | 0                   |
| Adolescents (12-17 years)                          | 0       | 0                   | 0                   |
| Adults (18-64 years)                               | 9       | 9                   | 9                   |
| From 65-84 years                                   | 0       | 0                   | 0                   |
| 85 years and over                                  | 0       | 0                   | 0                   |
| Age Continuous<br>Units: years                     |         |                     |                     |
| arithmetic mean                                    | 40.3    | 41.0                | 42.2                |
| standard deviation                                 | ± 16.70 | ± 11.53             | ± 11.96             |
| Sex: Female, Male<br>Units: Participants           |         |                     |                     |
| Female                                             | 8       | 7                   | 8                   |
| Male                                               | 1       | 2                   | 1                   |
| Race/Ethnicity, Customized<br>Units: Subjects      |         |                     |                     |
| White/Caucasian                                    | 8       | 7                   | 9                   |
| Black/African-American                             | 0       | 0                   | 0                   |
| American-Indian/Alaska Native                      | 0       | 2                   | 0                   |
| Other                                              | 1       | 0                   | 0                   |
| Race/Ethnicity, Customized<br>Units: Subjects      |         |                     |                     |
| Hispanic or Latino                                 | 0       | 1                   | 0                   |
| Not Hispanic or Latino                             | 9       | 7                   | 9                   |

|              |   |   |   |
|--------------|---|---|---|
| Not Reported | 0 | 1 | 0 |
|--------------|---|---|---|

| Reporting group values                             | INCB054707 at 90 mg | Total |  |
|----------------------------------------------------|---------------------|-------|--|
| Number of subjects                                 | 8                   | 35    |  |
| Age categorical<br>Units: Subjects                 |                     |       |  |
| In utero                                           | 0                   | 0     |  |
| Preterm newborn infants (gestational age < 37 wks) | 0                   | 0     |  |
| Newborns (0-27 days)                               | 0                   | 0     |  |
| Infants and toddlers (28 days-23 months)           | 0                   | 0     |  |
| Children (2-11 years)                              | 0                   | 0     |  |
| Adolescents (12-17 years)                          | 0                   | 0     |  |
| Adults (18-64 years)                               | 8                   | 35    |  |
| From 65-84 years                                   | 0                   | 0     |  |
| 85 years and over                                  | 0                   | 0     |  |
| Age Continuous<br>Units: years                     |                     |       |  |
| arithmetic mean                                    | 42.8                |       |  |
| standard deviation                                 | ± 14.62             | -     |  |
| Sex: Female, Male<br>Units: Participants           |                     |       |  |
| Female                                             | 5                   | 28    |  |
| Male                                               | 3                   | 7     |  |
| Race/Ethnicity, Customized<br>Units: Subjects      |                     |       |  |
| White/Caucasian                                    | 7                   | 31    |  |
| Black/African-American                             | 1                   | 1     |  |
| American-Indian/Alaska Native                      | 0                   | 2     |  |
| Other                                              | 0                   | 1     |  |
| Race/Ethnicity, Customized<br>Units: Subjects      |                     |       |  |
| Hispanic or Latino                                 | 0                   | 1     |  |
| Not Hispanic or Latino                             | 8                   | 33    |  |
| Not Reported                                       | 0                   | 1     |  |

## End points

### End points reporting groups

|                                                                                                                                                                    |                     |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Reporting group title                                                                                                                                              | Placebo             |
| Reporting group description:<br>Placebo was administered QD over an 8 week treatment period.                                                                       |                     |
| Reporting group title                                                                                                                                              | INCB054707 at 30 mg |
| Reporting group description:<br>INCB054707 was administered at 30 mg QD over an 8 week treatment period.                                                           |                     |
| Reporting group title                                                                                                                                              | INCB054707 at 60 mg |
| Reporting group description:<br>INCB054707 was administered at 60 mg QD over an 8 week treatment period.                                                           |                     |
| Reporting group title                                                                                                                                              | INCB054707 at 90 mg |
| Reporting group description:<br>INCB054707 was administered at 90 mg QD over an 8 week treatment period.                                                           |                     |
| Subject analysis set title                                                                                                                                         | INCB54707           |
| Subject analysis set type                                                                                                                                          | Per protocol        |
| Subject analysis set description:<br>INCB54707 was administered at either 30,60, or 90 mg. All samples from different dose groups were combined for this analysis. |                     |

### Primary: Number of treatment-emergent adverse events (TEAEs)

|                                                                                                                                                                        |                                                                    |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------|
| End point title                                                                                                                                                        | Number of treatment-emergent adverse events (TEAEs) <sup>[1]</sup> |
| End point description:<br>TEAE is defined as any adverse event either reported for the first time or worsening of a pre-existing event after first dose of study drug. |                                                                    |
| End point type                                                                                                                                                         | Primary                                                            |
| End point timeframe:<br>Up to 12 weeks                                                                                                                                 |                                                                    |

Notes:

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

Justification: There is no hypothesis testing for this endpoint , descriptive analysis is provided.

| End point values            | Placebo         | INCB054707 at 30 mg | INCB054707 at 60 mg | INCB054707 at 90 mg |
|-----------------------------|-----------------|---------------------|---------------------|---------------------|
| Subject group type          | Reporting group | Reporting group     | Reporting group     | Reporting group     |
| Number of subjects analysed | 9               | 9                   | 9                   | 8                   |
| Units: Participants         |                 |                     |                     |                     |
| No TEAE                     | 5               | 1                   | 3                   | 1                   |
| Grade 1 TEAE                | 2               | 6                   | 4                   | 1                   |
| Grade 2 TEAE                | 2               | 2                   | 2                   | 3                   |
| Grade 3 TEAE                | 0               | 0                   | 0                   | 3                   |
| Grade 4 TEAE                | 0               | 0                   | 0                   | 0                   |

### Statistical analyses

No statistical analyses for this end point

**Secondary: Apparent oral clearance of INCB054707**

|                 |                                       |
|-----------------|---------------------------------------|
| End point title | Apparent oral clearance of INCB054707 |
|-----------------|---------------------------------------|

End point description:

To determine the systemic exposure to INCB054707. Dependent upon the final compartmental model describing INCB054707.

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

End point timeframe:

Predose Day 1, Week 4, and 8, Postdose Day1, week 2,4,6, and 8

| End point values                     | INCB54707            |  |  |  |
|--------------------------------------|----------------------|--|--|--|
| Subject group type                   | Subject analysis set |  |  |  |
| Number of subjects analysed          | 26                   |  |  |  |
| Units: L/hr                          |                      |  |  |  |
| arithmetic mean (standard deviation) | 5.27 (± 2.89)        |  |  |  |

**Statistical analyses**

No statistical analyses for this end point

**Secondary: Apparent oral volume of distribution of INCB054707**

|                 |                                                    |
|-----------------|----------------------------------------------------|
| End point title | Apparent oral volume of distribution of INCB054707 |
|-----------------|----------------------------------------------------|

End point description:

To determine the systemic exposure to INCB054707. Dependent upon the final compartmental model describing INCB054707.

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

End point timeframe:

Predose Day 1, Week 4, and 8, Postdose Day1, week 2,4,6, and 8

| End point values                     | INCB54707            |  |  |  |
|--------------------------------------|----------------------|--|--|--|
| Subject group type                   | Subject analysis set |  |  |  |
| Number of subjects analysed          | 26                   |  |  |  |
| Units: Liters                        |                      |  |  |  |
| arithmetic mean (standard deviation) | 239 (± 85.7)         |  |  |  |

**Statistical analyses**

No statistical analyses for this end point

**Secondary: Proportion of participants achieving a Hidradenitis Suppurativa Clinical Response (HiSCR) at each visit**

|                 |                                                                 |
|-----------------|-----------------------------------------------------------------|
| End point title | Proportion of participants achieving a Hidradenitis Suppurativa |
|-----------------|-----------------------------------------------------------------|

End point description:

HiSCR defined as at least 50% reduction in abscess and inflammatory nodule (AN) count with no increase in abscess count and no increase in draining fistula count relative to baseline.

End point type Secondary

End point timeframe:

From screening up to 12 weeks

| End point values            | Placebo         | INCB054707 at 30 mg | INCB054707 at 60 mg | INCB054707 at 90 mg |
|-----------------------------|-----------------|---------------------|---------------------|---------------------|
| Subject group type          | Reporting group | Reporting group     | Reporting group     | Reporting group     |
| Number of subjects analysed | 9               | 9                   | 9                   | 8                   |
| Units: Participants         |                 |                     |                     |                     |
| Week 1 Yes                  | 1               | 1                   | 4                   | 2                   |
| Week 1 No                   | 6               | 8                   | 5                   | 5                   |
| Week 2 Yes                  | 1               | 6                   | 5                   | 4                   |
| Week 2 No                   | 6               | 3                   | 4                   | 4                   |
| Week 4 Yes                  | 3               | 5                   | 5                   | 5                   |
| Week 4 No                   | 4               | 4                   | 4                   | 3                   |
| Week 6 Yes                  | 3               | 3                   | 6                   | 6                   |
| Week 6 No                   | 4               | 6                   | 3                   | 2                   |
| Week 8 Yes                  | 4               | 5                   | 5                   | 7                   |
| Week 8 No                   | 3               | 4                   | 4                   | 1                   |
| Early Termination Yes       | 0               | 0                   | 0                   | 0                   |
| Early Termination No        | 1               | 0                   | 0                   | 0                   |
| Follow Up Yes               | 3               | 3                   | 1                   | 4                   |
| Follow Up No                | 4               | 6                   | 8                   | 3                   |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Proportion of participants achieving an AN count of 0 to 2 at each visit

End point title Proportion of participants achieving an AN count of 0 to 2 at each visit

End point description:

AN defined as abscess and inflammatory nodule count.

End point type Secondary

End point timeframe:

Up to 12 weeks

| End point values            | Placebo         | INCB054707 at 30 mg | INCB054707 at 60 mg | INCB054707 at 90 mg |
|-----------------------------|-----------------|---------------------|---------------------|---------------------|
| Subject group type          | Reporting group | Reporting group     | Reporting group     | Reporting group     |
| Number of subjects analysed | 9               | 9                   | 9                   | 8                   |
| Units: Participants         |                 |                     |                     |                     |
| Baseline Yes                | 0               | 0                   | 0                   | 1                   |
| Baseline No                 | 9               | 9                   | 9                   | 7                   |
| Week 1 Yes                  | 0               | 0                   | 2                   | 2                   |
| Week 1 No                   | 7               | 9                   | 7                   | 5                   |
| Week 2 Yes                  | 0               | 3                   | 5                   | 4                   |
| Week 2 No                   | 7               | 6                   | 4                   | 4                   |
| Week 4 Yes                  | 2               | 3                   | 6                   | 5                   |
| Week 4 No                   | 5               | 6                   | 3                   | 3                   |
| Week 6 Yes                  | 3               | 2                   | 5                   | 5                   |
| Week 6 No                   | 4               | 7                   | 4                   | 3                   |
| Week 8 Yes                  | 4               | 4                   | 4                   | 5                   |
| Week 8 No                   | 3               | 5                   | 5                   | 3                   |
| Early Termination Yes       | 0               | 0                   | 0                   | 0                   |
| Early Termination No        | 1               | 0                   | 0                   | 0                   |
| Follow Up Yes               | 1               | 3                   | 0                   | 4                   |
| Follow Up No                | 6               | 6                   | 9                   | 3                   |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Mean change from baseline in the Hidradenitis Suppurativa Pain Numeric Rating Scale (HS Pain NRS) scores at each visit

|                        |                                                                                                                        |
|------------------------|------------------------------------------------------------------------------------------------------------------------|
| End point title        | Mean change from baseline in the Hidradenitis Suppurativa Pain Numeric Rating Scale (HS Pain NRS) scores at each visit |
| End point description: | An 11-point scale used to assess the worst skin pain and the average skin pain due to HS.                              |
| End point type         | Secondary                                                                                                              |
| End point timeframe:   | From baseline up to 12 weeks                                                                                           |

| End point values                     | Placebo         | INCB054707 at 30 mg | INCB054707 at 60 mg | INCB054707 at 90 mg |
|--------------------------------------|-----------------|---------------------|---------------------|---------------------|
| Subject group type                   | Reporting group | Reporting group     | Reporting group     | Reporting group     |
| Number of subjects analysed          | 9               | 9                   | 9                   | 8                   |
| Units: Units on a scale              |                 |                     |                     |                     |
| arithmetic mean (standard deviation) |                 |                     |                     |                     |
| Mean change from Baseline to Week 1  | 0.2 (± 1.39)    | -0.8 (± 1.13)       | -0.3 (± 1.06)       | -1.5 (± 1.04)       |
| Mean change from Baseline to Week 2  | -0.1 (± 1.49)   | -1.5 (± 1.18)       | -1.1 (± 0.91)       | -3.3 (± 3.06)       |
| Mean change from Baseline to Week 4  | -0.3 (± 2.09)   | -2.0 (± 2.02)       | -1.4 (± 1.56)       | -3.6 (± 3.30)       |
| Mean change from Baseline to Week 6  | 0.0 (± 3.49)    | -0.9 (± 0.90)       | -2.0 (± 1.55)       | -3.4 (± 3.05)       |
| Mean change from Baseline to Week 8  | 0.3 (± 2.77)    | -2.2 (± 2.18)       | -1.4 (± 1.44)       | -3.1 (± 3.28)       |

|                                        |                   |                    |                    |                    |
|----------------------------------------|-------------------|--------------------|--------------------|--------------------|
| Mean change from Baseline to Follow Up | 2.6 ( $\pm$ 2.62) | -2.7 ( $\pm$ 2.20) | -0.8 ( $\pm$ 0.97) | -1.2 ( $\pm$ 1.91) |
|----------------------------------------|-------------------|--------------------|--------------------|--------------------|

## Statistical analyses

No statistical analyses for this end point

## Secondary: Mean change from baseline in the modified Sartorius scale score

|                                                               |                                                                 |
|---------------------------------------------------------------|-----------------------------------------------------------------|
| End point title                                               | Mean change from baseline in the modified Sartorius scale score |
| End point description:<br>Scale measuring the severity of HS. |                                                                 |
| End point type                                                | Secondary                                                       |
| End point timeframe:<br>From baseline up to week 8            |                                                                 |

| End point values                     | Placebo              | INCB054707 at 30 mg  | INCB054707 at 60 mg  | INCB054707 at 90 mg  |
|--------------------------------------|----------------------|----------------------|----------------------|----------------------|
| Subject group type                   | Reporting group      | Reporting group      | Reporting group      | Reporting group      |
| Number of subjects analysed          | 7                    | 9                    | 9                    | 8                    |
| Units: Units on a scale              |                      |                      |                      |                      |
| arithmetic mean (standard deviation) |                      |                      |                      |                      |
| Week 8                               | -36.4 ( $\pm$ 35.83) | -41.9 ( $\pm$ 36.84) | -59.2 ( $\pm$ 48.48) | -54.6 ( $\pm$ 55.42) |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Mean change from baseline in the number of draining fistulas count at each visit.

|                                                                                                                                 |                                                                                   |
|---------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|
| End point title                                                                                                                 | Mean change from baseline in the number of draining fistulas count at each visit. |
| End point description:<br>Defined as fistulas that drain serous or purulent fluid, either spontaneously or by gentle palpation. |                                                                                   |
| End point type                                                                                                                  | Secondary                                                                         |
| End point timeframe:<br>From baseline up to 12 weeks                                                                            |                                                                                   |

| End point values                     | Placebo         | INCB054707 at 30 mg | INCB054707 at 60 mg | INCB054707 at 90 mg |
|--------------------------------------|-----------------|---------------------|---------------------|---------------------|
| Subject group type                   | Reporting group | Reporting group     | Reporting group     | Reporting group     |
| Number of subjects analysed          | 7               | 9                   | 9                   | 7                   |
| Units: Number of Fistulas            |                 |                     |                     |                     |
| arithmetic mean (standard deviation) |                 |                     |                     |                     |
| Week 1                               | -0.1 (± 0.38)   | -0.1 (± 1.27)       | -0.8 (± 2.39)       | -0.3 (± 0.49)       |
| Week 2                               | 0.0 (± 1.53)    | -0.9 (± 1.05)       | -2.1 (± 3.48)       | -0.8 (± 2.19)       |
| Week 4                               | -0.9 (± 2.79)   | -0.6 (± 1.01)       | -2.0 (± 3.57)       | -0.9 (± 2.53)       |
| Week 6                               | -1.3 (± 2.69)   | -0.4 (± 1.74)       | -2.1 (± 3.30)       | -0.6 (± 2.72)       |
| Week 8                               | -1.0 (± 3.06)   | -0.3 (± 1.66)       | -2.0 (± 3.35)       | -0.6 (± 3.85)       |
| Follow Up                            | -0.4 (± 3.10)   | 0.1 (± 1.69)        | -2.2 (± 3.19)       | -1.3 (± 3.86)       |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Proportion of participants at each category of Hurley Stage

|                 |                                                             |
|-----------------|-------------------------------------------------------------|
| End point title | Proportion of participants at each category of Hurley Stage |
|-----------------|-------------------------------------------------------------|

End point description:

The Hurley classification is a static score and was originally designed for selection of the appropriate treatment modality in a certain body region. The assessor determines the Hurley stage in each affected anatomical region. If more than 1 stage is present in the same region, the worst stage in that region is documented. The participant will be assigned an overall Hurley stage classification corresponding to the stage of the worst involved anatomical region. The definition of each Hurley stage is as follows:

Stage I : Abscess formation, single or multiple, without sinus tracts and cicatrization (scarring).

Stage II : One or more widely separated recurrent abscesses with tract formation and cicatrization (scarring).

Stage III : Multiple interconnected tracts and abscesses across the entire area, with diffuse or near diffuse involvement.

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

End point timeframe:

Baseline and Week 8

| End point values            | Placebo         | INCB054707 at 30 mg | INCB054707 at 60 mg | INCB054707 at 90 mg |
|-----------------------------|-----------------|---------------------|---------------------|---------------------|
| Subject group type          | Reporting group | Reporting group     | Reporting group     | Reporting group     |
| Number of subjects analysed | 9               | 9                   | 9                   | 8                   |
| Units: Participants         |                 |                     |                     |                     |
| Baseline Stage I            | 0               | 0                   | 0                   | 0                   |
| Week 8 Stage I              | 1               | 3                   | 3                   | 0                   |
| Baseline Stage II           | 4               | 9                   | 5                   | 7                   |
| Week 8 Stage II             | 3               | 6                   | 5                   | 7                   |
| Baseline Stage III          | 5               | 0                   | 4                   | 1                   |
| Week 8 Stage III            | 3               | 0                   | 0                   | 0                   |
| Baseline No HS              | 0               | 0                   | 0                   | 0                   |
| Week 8 No HS                | 0               | 0                   | 1                   | 1                   |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Proportions of participants in each HS Patient Global Impression of Change (PGIC) category during the treatment period

|                 |                                                                                                                        |
|-----------------|------------------------------------------------------------------------------------------------------------------------|
| End point title | Proportions of participants in each HS Patient Global Impression of Change (PGIC) category during the treatment period |
|-----------------|------------------------------------------------------------------------------------------------------------------------|

End point description:

The HS-PGIC consists of 1 self-administered item that assesses change in the severity of skin in the HS area. The participant will answer the following: Since your last visit, your HS is: (1) very much improved, (2) much improved, (3) minimally improved, (4) no change, (5) minimally worse, (6) much worse, or (7) very much worse.

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

End point timeframe:

Up to 12 weeks

| End point values            | Placebo         | INCB054707 at 30 mg | INCB054707 at 60 mg | INCB054707 at 90 mg |
|-----------------------------|-----------------|---------------------|---------------------|---------------------|
| Subject group type          | Reporting group | Reporting group     | Reporting group     | Reporting group     |
| Number of subjects analysed | 9               | 9                   | 9                   | 8                   |
| Units: participants         |                 |                     |                     |                     |
| Week 1 1                    | 0               | 0                   | 0                   | 0                   |
| Week 2 1                    | 0               | 1                   | 0                   | 0                   |
| Week 4 1                    | 0               | 1                   | 2                   | 0                   |
| Week 6 1                    | 0               | 0                   | 1                   | 0                   |
| Week 8 1                    | 0               | 0                   | 0                   | 1                   |
| Early Termination 1         | 0               | 0                   | 0                   | 0                   |
| Follow Up 1                 | 0               | 0                   | 0                   | 0                   |
| Week 1 2                    | 0               | 1                   | 0                   | 0                   |
| Week 2 2                    | 0               | 1                   | 2                   | 3                   |
| Week 4 2                    | 0               | 1                   | 1                   | 3                   |
| Week 6 2                    | 1               | 1                   | 1                   | 2                   |
| Week 8 2                    | 0               | 3                   | 1                   | 0                   |
| Early Termination 2         | 0               | 0                   | 0                   | 0                   |
| Follow Up 2                 | 0               | 1                   | 0                   | 0                   |
| Week 1 3                    | 0               | 3                   | 3                   | 3                   |
| Week 2 3                    | 3               | 4                   | 3                   | 1                   |
| Week 4 3                    | 3               | 2                   | 1                   | 1                   |
| Week 6 3                    | 3               | 2                   | 3                   | 2                   |
| Week 8 3                    | 1               | 1                   | 3                   | 1                   |
| Early Termination 3         | 0               | 0                   | 0                   | 0                   |
| Follow Up 3                 | 1               | 1                   | 0                   | 0                   |

|                     |   |   |   |   |
|---------------------|---|---|---|---|
| Week 1 4            | 4 | 2 | 4 | 2 |
| Week 2 4            | 1 | 2 | 3 | 3 |
| Week 4 4            | 2 | 2 | 2 | 2 |
| Week 6 4            | 1 | 4 | 1 | 4 |
| Week 8 4            | 5 | 3 | 4 | 2 |
| Early Termination 4 | 1 | 0 | 0 | 0 |
| Follow Up 4         | 1 | 2 | 2 | 1 |
| Week 1 5            | 3 | 3 | 1 | 2 |
| Week 2 5            | 3 | 1 | 1 | 1 |
| Week 4 5            | 2 | 1 | 2 | 2 |
| Week 6 5            | 2 | 1 | 3 | 0 |
| Week 8 5            | 1 | 1 | 1 | 3 |
| Early Termination 5 | 0 | 0 | 0 | 0 |
| Follow Up 5         | 3 | 2 | 2 | 3 |
| Week 1 6            | 0 | 0 | 1 | 0 |
| Week 2 6            | 0 | 0 | 0 | 0 |
| Week 4 6            | 0 | 1 | 1 | 0 |
| Week 6 6            | 0 | 1 | 0 | 0 |
| Week 8 6            | 0 | 1 | 0 | 1 |
| Early Termination 6 | 0 | 0 | 0 | 0 |
| Follow Up 6         | 2 | 3 | 4 | 0 |
| Week 1 7            | 0 | 0 | 0 | 0 |
| Week 2 7            | 0 | 0 | 0 | 0 |
| Week 4 7            | 0 | 1 | 0 | 0 |
| Week 6 7            | 0 | 0 | 0 | 0 |
| Week 8 7            | 0 | 0 | 0 | 0 |
| Early Termination 7 | 0 | 0 | 0 | 0 |
| Follow Up 7         | 0 | 0 | 1 | 3 |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Actual measurements in HS-PGIC at each visit

|                                                                                                                                                                                                                                                                                                                                            |                                              |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------|
| End point title                                                                                                                                                                                                                                                                                                                            | Actual measurements in HS-PGIC at each visit |
| End point description:                                                                                                                                                                                                                                                                                                                     |                                              |
| The HS-PGIC consists of 1 self-administered item that assesses change in the severity of skin in the HS area. The participant will answer the following: Since your last visit, your HS is: (1) very much improved, (2) much improved, (3) minimally improved, (4) no change, (5) minimally worse, (6) much worse, or (7) very much worse. |                                              |
| End point type                                                                                                                                                                                                                                                                                                                             | Secondary                                    |
| End point timeframe:                                                                                                                                                                                                                                                                                                                       |                                              |
| Up to 12 weeks                                                                                                                                                                                                                                                                                                                             |                                              |

| End point values            | Placebo         | INCB054707 at 30 mg | INCB054707 at 60 mg | INCB054707 at 90 mg |
|-----------------------------|-----------------|---------------------|---------------------|---------------------|
| Subject group type          | Reporting group | Reporting group     | Reporting group     | Reporting group     |
| Number of subjects analysed | 9               | 9                   | 9                   | 8                   |
| Units: participants         |                 |                     |                     |                     |
| Week 1 1                    | 0               | 0                   | 0                   | 0                   |
| Week 2 1                    | 0               | 1                   | 0                   | 0                   |
| Week 4 1                    | 0               | 1                   | 2                   | 0                   |
| Week 6 1                    | 0               | 0                   | 1                   | 0                   |
| Week 8 1                    | 0               | 0                   | 0                   | 1                   |
| Early Termination 1         | 0               | 0                   | 0                   | 0                   |
| Follow Up 1                 | 0               | 0                   | 0                   | 0                   |
| Week 1 2                    | 0               | 1                   | 0                   | 0                   |
| Week 2 2                    | 0               | 1                   | 2                   | 3                   |
| Week 4 2                    | 0               | 1                   | 1                   | 3                   |
| Week 6 2                    | 1               | 1                   | 1                   | 2                   |
| Week 8 2                    | 0               | 3                   | 1                   | 0                   |
| Early Termination 2         | 0               | 0                   | 0                   | 0                   |
| Follow Up 2                 | 0               | 1                   | 0                   | 0                   |
| Week 1 3                    | 0               | 3                   | 3                   | 3                   |
| Week 2 3                    | 3               | 4                   | 3                   | 1                   |
| Week 4 3                    | 3               | 2                   | 1                   | 1                   |
| Week 6 3                    | 3               | 2                   | 3                   | 2                   |
| Week 8 3                    | 1               | 1                   | 3                   | 1                   |
| Early Termination 3         | 0               | 0                   | 0                   | 0                   |
| Follow Up 3                 | 1               | 1                   | 0                   | 0                   |
| Week 1 4                    | 4               | 2                   | 4                   | 2                   |
| Week 2 4                    | 1               | 2                   | 3                   | 3                   |
| Week 4 4                    | 2               | 2                   | 2                   | 2                   |
| Week 6 4                    | 1               | 4                   | 1                   | 4                   |
| Week 8 4                    | 5               | 3                   | 4                   | 2                   |
| Early Termination 4         | 1               | 0                   | 0                   | 0                   |
| Follow Up 4                 | 1               | 2                   | 2                   | 1                   |
| Week 1 5                    | 3               | 3                   | 1                   | 2                   |
| Week 2 5                    | 3               | 1                   | 1                   | 1                   |
| Week 4 5                    | 2               | 1                   | 2                   | 2                   |
| Week 6 5                    | 2               | 1                   | 3                   | 0                   |
| Week 8 5                    | 1               | 1                   | 1                   | 3                   |
| Early Termination 5         | 0               | 0                   | 0                   | 0                   |
| Follow Up 5                 | 3               | 2                   | 2                   | 3                   |
| Week 1 6                    | 0               | 0                   | 1                   | 0                   |
| Week 2 6                    | 0               | 0                   | 0                   | 0                   |
| Week 4 6                    | 0               | 1                   | 1                   | 0                   |
| Week 6 6                    | 0               | 1                   | 0                   | 0                   |
| Week 8 6                    | 0               | 1                   | 0                   | 1                   |
| Early Termination 6         | 0               | 0                   | 0                   | 0                   |
| Follow Up 6                 | 2               | 3                   | 4                   | 0                   |
| Week 1 7                    | 0               | 0                   | 0                   | 0                   |
| Week 2 7                    | 0               | 0                   | 0                   | 0                   |
| Week 4 7                    | 0               | 1                   | 0                   | 0                   |
| Week 6 7                    | 0               | 0                   | 0                   | 0                   |
| Week 8 7                    | 0               | 0                   | 0                   | 0                   |

|                     |   |   |   |   |
|---------------------|---|---|---|---|
| Early Termination 7 | 0 | 0 | 0 | 0 |
| Follow Up 7         | 0 | 0 | 1 | 3 |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Proportion of participants with change from baseline Hurley Stage

|                 |                                                                   |
|-----------------|-------------------------------------------------------------------|
| End point title | Proportion of participants with change from baseline Hurley Stage |
|-----------------|-------------------------------------------------------------------|

End point description:

The Hurley classification is a static score and was originally designed for selection of the appropriate treatment modality in a certain body region. The assessor determines the Hurley stage in each affected anatomical region. If more than 1 stage is present in the same region, the worst stage in that region is documented. The participant will be assigned an overall Hurley stage classification corresponding to the stage of the worst involved anatomical region. The definition of each Hurley stage is as follows:

Stage I : Abscess formation, single or multiple, without sinus tracts and cicatrization (scarring).

Stage II : One or more widely separated recurrent abscesses with tract formation and cicatrization (scarring).

Stage III : Multiple interconnected tracts and abscesses across the entire area, with diffuse or near diffuse involvement.

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

End point timeframe:

Baseline and Week 8

| End point values            | Placebo         | INCB054707 at 30 mg | INCB054707 at 60 mg | INCB054707 at 90 mg |
|-----------------------------|-----------------|---------------------|---------------------|---------------------|
| Subject group type          | Reporting group | Reporting group     | Reporting group     | Reporting group     |
| Number of subjects analysed | 9               | 9                   | 9                   | 8                   |
| Units: Participants         |                 |                     |                     |                     |
| Baseline Stage I            | 0               | 0                   | 0                   | 0                   |
| Week 8 Stage I              | 1               | 3                   | 3                   | 0                   |
| Baseline Stage II           | 4               | 9                   | 5                   | 7                   |
| Week 8 Stage II             | 3               | 6                   | 5                   | 7                   |
| Baseline Stage III          | 5               | 0                   | 4                   | 1                   |
| Week 8 Stage III            | 3               | 0                   | 0                   | 0                   |
| Baseline No HS              | 0               | 0                   | 0                   | 0                   |
| Week 8 No HS                | 0               | 0                   | 1                   | 1                   |
| Baseline Missing            | 0               | 0                   | 0                   | 0                   |
| Week 8 Missing              | 2               | 0                   | 0                   | 0                   |

## Statistical analyses



## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Up to 12 weeks

Adverse event reporting additional description:

AE additional description

|                 |            |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

### Dictionary used

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

|                    |    |
|--------------------|----|
| Dictionary version | 20 |
|--------------------|----|

### Reporting groups

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

Reporting group description:

Placebo

|                       |                  |
|-----------------------|------------------|
| Reporting group title | INCB054707 30 mg |
|-----------------------|------------------|

Reporting group description:

INCB054707 30 mg

|                       |                  |
|-----------------------|------------------|
| Reporting group title | INCB054707 60 mg |
|-----------------------|------------------|

Reporting group description:

INCB054707 60 mg

|                       |                  |
|-----------------------|------------------|
| Reporting group title | INCB054707 90 mg |
|-----------------------|------------------|

Reporting group description:

INCB054707 90 mg

|                       |       |
|-----------------------|-------|
| Reporting group title | Total |
|-----------------------|-------|

Reporting group description:

Total

| Serious adverse events                            | Placebo       | INCB054707 30 mg | INCB054707 60 mg |
|---------------------------------------------------|---------------|------------------|------------------|
| Total subjects affected by serious adverse events |               |                  |                  |
| subjects affected / exposed                       | 0 / 9 (0.00%) | 0 / 9 (0.00%)    | 0 / 9 (0.00%)    |
| number of deaths (all causes)                     | 0             | 0                | 0                |
| number of deaths resulting from adverse events    | 0             | 0                | 0                |

| Serious adverse events                            | INCB054707 90 mg | Total          |  |
|---------------------------------------------------|------------------|----------------|--|
| Total subjects affected by serious adverse events |                  |                |  |
| subjects affected / exposed                       | 0 / 8 (0.00%)    | 0 / 35 (0.00%) |  |
| number of deaths (all causes)                     | 0                | 0              |  |
| number of deaths resulting from adverse events    | 0                | 0              |  |

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

| <b>Non-serious adverse events</b>                                   | Placebo        | INCB054707 30 mg | INCB054707 60 mg |
|---------------------------------------------------------------------|----------------|------------------|------------------|
| Total subjects affected by non-serious adverse events               |                |                  |                  |
| subjects affected / exposed                                         | 4 / 9 (44.44%) | 8 / 9 (88.89%)   | 6 / 9 (66.67%)   |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |                |                  |                  |
| Basal cell carcinoma                                                |                |                  |                  |
| subjects affected / exposed                                         | 0 / 9 (0.00%)  | 0 / 9 (0.00%)    | 1 / 9 (11.11%)   |
| occurrences (all)                                                   | 0              | 0                | 1                |
| Surgical and medical procedures                                     |                |                  |                  |
| Endodontic procedure                                                |                |                  |                  |
| subjects affected / exposed                                         | 0 / 9 (0.00%)  | 0 / 9 (0.00%)    | 1 / 9 (11.11%)   |
| occurrences (all)                                                   | 0              | 0                | 1                |
| General disorders and administration site conditions                |                |                  |                  |
| Chest pain                                                          |                |                  |                  |
| subjects affected / exposed                                         | 0 / 9 (0.00%)  | 0 / 9 (0.00%)    | 0 / 9 (0.00%)    |
| occurrences (all)                                                   | 0              | 0                | 0                |
| Exercise tolerance decreased                                        |                |                  |                  |
| subjects affected / exposed                                         | 1 / 9 (11.11%) | 0 / 9 (0.00%)    | 0 / 9 (0.00%)    |
| occurrences (all)                                                   | 1              | 0                | 0                |
| Fatigue                                                             |                |                  |                  |
| subjects affected / exposed                                         | 1 / 9 (11.11%) | 1 / 9 (11.11%)   | 2 / 9 (22.22%)   |
| occurrences (all)                                                   | 1              | 1                | 2                |
| Oedema peripheral                                                   |                |                  |                  |
| subjects affected / exposed                                         | 0 / 9 (0.00%)  | 1 / 9 (11.11%)   | 0 / 9 (0.00%)    |
| occurrences (all)                                                   | 0              | 1                | 0                |
| Pain                                                                |                |                  |                  |
| subjects affected / exposed                                         | 0 / 9 (0.00%)  | 0 / 9 (0.00%)    | 0 / 9 (0.00%)    |
| occurrences (all)                                                   | 0              | 0                | 0                |
| Pyrexia                                                             |                |                  |                  |
| subjects affected / exposed                                         | 0 / 9 (0.00%)  | 0 / 9 (0.00%)    | 0 / 9 (0.00%)    |
| occurrences (all)                                                   | 0              | 0                | 0                |
| Vessel puncture site haemorrhage                                    |                |                  |                  |
| subjects affected / exposed                                         | 1 / 9 (11.11%) | 1 / 9 (11.11%)   | 0 / 9 (0.00%)    |
| occurrences (all)                                                   | 1              | 1                | 0                |
| Reproductive system and breast                                      |                |                  |                  |

|                                                 |                |                |               |
|-------------------------------------------------|----------------|----------------|---------------|
| disorders                                       |                |                |               |
| Polymenorrhoea                                  |                |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 1 / 9 (11.11%) | 0 / 9 (0.00%) |
| occurrences (all)                               | 0              | 1              | 0             |
| Respiratory, thoracic and mediastinal disorders |                |                |               |
| Cough                                           |                |                |               |
| subjects affected / exposed                     | 1 / 9 (11.11%) | 0 / 9 (0.00%)  | 0 / 9 (0.00%) |
| occurrences (all)                               | 1              | 0              | 0             |
| Oropharyngeal pain                              |                |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 1 / 9 (11.11%) | 0 / 9 (0.00%) |
| occurrences (all)                               | 0              | 1              | 0             |
| Psychiatric disorders                           |                |                |               |
| Insomnia                                        |                |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 1 / 9 (11.11%) | 0 / 9 (0.00%) |
| occurrences (all)                               | 0              | 1              | 0             |
| Restlessness                                    |                |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 9 (0.00%)  | 0 / 9 (0.00%) |
| occurrences (all)                               | 0              | 0              | 0             |
| Sleep disorder                                  |                |                |               |
| subjects affected / exposed                     | 1 / 9 (11.11%) | 0 / 9 (0.00%)  | 0 / 9 (0.00%) |
| occurrences (all)                               | 1              | 0              | 0             |
| Injury, poisoning and procedural complications  |                |                |               |
| Animal bite                                     |                |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 1 / 9 (11.11%) | 0 / 9 (0.00%) |
| occurrences (all)                               | 0              | 1              | 0             |
| Fall                                            |                |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 1 / 9 (11.11%) | 0 / 9 (0.00%) |
| occurrences (all)                               | 0              | 1              | 0             |
| Rib fracture                                    |                |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 9 (0.00%)  | 0 / 9 (0.00%) |
| occurrences (all)                               | 0              | 0              | 0             |
| Cardiac disorders                               |                |                |               |
| Palpitations                                    |                |                |               |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 1 / 9 (11.11%) | 0 / 9 (0.00%) |
| occurrences (all)                               | 0              | 1              | 0             |
| Nervous system disorders                        |                |                |               |

|                                                                                                              |                     |                     |                     |
|--------------------------------------------------------------------------------------------------------------|---------------------|---------------------|---------------------|
| Disturbance in attention<br>subjects affected / exposed<br>occurrences (all)                                 | 0 / 9 (0.00%)<br>0  | 0 / 9 (0.00%)<br>0  | 1 / 9 (11.11%)<br>1 |
| Dizziness<br>subjects affected / exposed<br>occurrences (all)                                                | 1 / 9 (11.11%)<br>1 | 0 / 9 (0.00%)<br>0  | 0 / 9 (0.00%)<br>0  |
| Headache<br>subjects affected / exposed<br>occurrences (all)                                                 | 2 / 9 (22.22%)<br>2 | 0 / 9 (0.00%)<br>0  | 2 / 9 (22.22%)<br>3 |
| Hypoaesthesia<br>subjects affected / exposed<br>occurrences (all)                                            | 0 / 9 (0.00%)<br>0  | 1 / 9 (11.11%)<br>1 | 0 / 9 (0.00%)<br>0  |
| Migraine<br>subjects affected / exposed<br>occurrences (all)                                                 | 0 / 9 (0.00%)<br>0  | 0 / 9 (0.00%)<br>0  | 1 / 9 (11.11%)<br>2 |
| Sinus headache<br>subjects affected / exposed<br>occurrences (all)                                           | 0 / 9 (0.00%)<br>0  | 0 / 9 (0.00%)<br>0  | 1 / 9 (11.11%)<br>1 |
| Blood and lymphatic system disorders<br>Thrombocytopenia<br>subjects affected / exposed<br>occurrences (all) | 0 / 9 (0.00%)<br>0  | 0 / 9 (0.00%)<br>0  | 0 / 9 (0.00%)<br>0  |
| Gastrointestinal disorders<br>Abdominal distension<br>subjects affected / exposed<br>occurrences (all)       | 0 / 9 (0.00%)<br>0  | 0 / 9 (0.00%)<br>0  | 1 / 9 (11.11%)<br>1 |
| Abdominal pain<br>subjects affected / exposed<br>occurrences (all)                                           | 1 / 9 (11.11%)<br>1 | 1 / 9 (11.11%)<br>1 | 0 / 9 (0.00%)<br>0  |
| Abdominal pain upper<br>subjects affected / exposed<br>occurrences (all)                                     | 0 / 9 (0.00%)<br>0  | 1 / 9 (11.11%)<br>1 | 0 / 9 (0.00%)<br>0  |
| Constipation<br>subjects affected / exposed<br>occurrences (all)                                             | 1 / 9 (11.11%)<br>1 | 0 / 9 (0.00%)<br>0  | 1 / 9 (11.11%)<br>2 |
| Diarrhoea                                                                                                    |                     |                     |                     |

|                                                 |                |                |                |
|-------------------------------------------------|----------------|----------------|----------------|
| subjects affected / exposed                     | 2 / 9 (22.22%) | 1 / 9 (11.11%) | 0 / 9 (0.00%)  |
| occurrences (all)                               | 2              | 1              | 0              |
| Dyspepsia                                       |                |                |                |
| subjects affected / exposed                     | 1 / 9 (11.11%) | 0 / 9 (0.00%)  | 0 / 9 (0.00%)  |
| occurrences (all)                               | 1              | 0              | 0              |
| Food poisoning                                  |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 1 / 9 (11.11%) | 0 / 9 (0.00%)  |
| occurrences (all)                               | 0              | 1              | 0              |
| Nausea                                          |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 9 (0.00%)  | 0 / 9 (0.00%)  |
| occurrences (all)                               | 0              | 0              | 0              |
| Rectal haemorrhage                              |                |                |                |
| subjects affected / exposed                     | 1 / 9 (11.11%) | 0 / 9 (0.00%)  | 0 / 9 (0.00%)  |
| occurrences (all)                               | 1              | 0              | 0              |
| Skin and subcutaneous tissue disorders          |                |                |                |
| Acne                                            |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 9 (0.00%)  | 0 / 9 (0.00%)  |
| occurrences (all)                               | 0              | 0              | 0              |
| Acne cystic                                     |                |                |                |
| subjects affected / exposed                     | 1 / 9 (11.11%) | 0 / 9 (0.00%)  | 0 / 9 (0.00%)  |
| occurrences (all)                               | 1              | 0              | 0              |
| Seborrhoeic dermatitis                          |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 1 / 9 (11.11%) | 0 / 9 (0.00%)  |
| occurrences (all)                               | 0              | 1              | 0              |
| Telangiectasia                                  |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 9 (0.00%)  | 1 / 9 (11.11%) |
| occurrences (all)                               | 0              | 0              | 1              |
| Musculoskeletal and connective tissue disorders |                |                |                |
| Arthralgia                                      |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 1 / 9 (11.11%) | 0 / 9 (0.00%)  |
| occurrences (all)                               | 0              | 1              | 0              |
| Back pain                                       |                |                |                |
| subjects affected / exposed                     | 0 / 9 (0.00%)  | 0 / 9 (0.00%)  | 1 / 9 (11.11%) |
| occurrences (all)                               | 0              | 0              | 1              |
| Torticollis                                     |                |                |                |

|                                                  |                     |                    |                    |
|--------------------------------------------------|---------------------|--------------------|--------------------|
| subjects affected / exposed<br>occurrences (all) | 1 / 9 (11.11%)<br>1 | 0 / 9 (0.00%)<br>0 | 0 / 9 (0.00%)<br>0 |
| Infections and infestations                      |                     |                    |                    |
| Folliculitis                                     |                     |                    |                    |
| subjects affected / exposed                      | 1 / 9 (11.11%)      | 2 / 9 (22.22%)     | 1 / 9 (11.11%)     |
| occurrences (all)                                | 1                   | 2                  | 1                  |
| Gastroenteritis                                  |                     |                    |                    |
| subjects affected / exposed                      | 0 / 9 (0.00%)       | 0 / 9 (0.00%)      | 2 / 9 (22.22%)     |
| occurrences (all)                                | 0                   | 0                  | 2                  |
| Influenza                                        |                     |                    |                    |
| subjects affected / exposed                      | 0 / 9 (0.00%)       | 1 / 9 (11.11%)     | 0 / 9 (0.00%)      |
| occurrences (all)                                | 0                   | 1                  | 0                  |
| Nasopharyngitis                                  |                     |                    |                    |
| subjects affected / exposed                      | 1 / 9 (11.11%)      | 1 / 9 (11.11%)     | 2 / 9 (22.22%)     |
| occurrences (all)                                | 1                   | 1                  | 2                  |
| Oral herpes                                      |                     |                    |                    |
| subjects affected / exposed                      | 1 / 9 (11.11%)      | 1 / 9 (11.11%)     | 0 / 9 (0.00%)      |
| occurrences (all)                                | 1                   | 1                  | 0                  |
| Sinusitis                                        |                     |                    |                    |
| subjects affected / exposed                      | 0 / 9 (0.00%)       | 0 / 9 (0.00%)      | 0 / 9 (0.00%)      |
| occurrences (all)                                | 0                   | 0                  | 0                  |
| Tinea pedis                                      |                     |                    |                    |
| subjects affected / exposed                      | 0 / 9 (0.00%)       | 1 / 9 (11.11%)     | 0 / 9 (0.00%)      |
| occurrences (all)                                | 0                   | 1                  | 0                  |
| Tonsillitis                                      |                     |                    |                    |
| subjects affected / exposed                      | 0 / 9 (0.00%)       | 1 / 9 (11.11%)     | 0 / 9 (0.00%)      |
| occurrences (all)                                | 0                   | 1                  | 0                  |
| Upper respiratory tract infection                |                     |                    |                    |
| subjects affected / exposed                      | 0 / 9 (0.00%)       | 0 / 9 (0.00%)      | 0 / 9 (0.00%)      |
| occurrences (all)                                | 0                   | 0                  | 0                  |
| Metabolism and nutrition disorders               |                     |                    |                    |
| Decreased appetite                               |                     |                    |                    |
| subjects affected / exposed                      | 0 / 9 (0.00%)       | 0 / 9 (0.00%)      | 1 / 9 (11.11%)     |
| occurrences (all)                                | 0                   | 0                  | 1                  |
| Hypertriglyceridaemia                            |                     |                    |                    |

|                             |               |                |               |
|-----------------------------|---------------|----------------|---------------|
| subjects affected / exposed | 0 / 9 (0.00%) | 1 / 9 (11.11%) | 0 / 9 (0.00%) |
| occurrences (all)           | 0             | 1              | 0             |
| Hypoglycaemia               |               |                |               |
| subjects affected / exposed | 0 / 9 (0.00%) | 1 / 9 (11.11%) | 0 / 9 (0.00%) |
| occurrences (all)           | 0             | 1              | 0             |

| <b>Non-serious adverse events</b>                                   | INCB054707 90 mg | Total            |  |
|---------------------------------------------------------------------|------------------|------------------|--|
| Total subjects affected by non-serious adverse events               |                  |                  |  |
| subjects affected / exposed                                         | 7 / 8 (87.50%)   | 25 / 35 (71.43%) |  |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |                  |                  |  |
| Basal cell carcinoma                                                |                  |                  |  |
| subjects affected / exposed                                         | 0 / 8 (0.00%)    | 1 / 35 (2.86%)   |  |
| occurrences (all)                                                   | 0                | 1                |  |
| Surgical and medical procedures                                     |                  |                  |  |
| Endodontic procedure                                                |                  |                  |  |
| subjects affected / exposed                                         | 0 / 8 (0.00%)    | 1 / 35 (2.86%)   |  |
| occurrences (all)                                                   | 0                | 1                |  |
| General disorders and administration site conditions                |                  |                  |  |
| Chest pain                                                          |                  |                  |  |
| subjects affected / exposed                                         | 1 / 8 (12.50%)   | 1 / 35 (2.86%)   |  |
| occurrences (all)                                                   | 1                | 1                |  |
| Exercise tolerance decreased                                        |                  |                  |  |
| subjects affected / exposed                                         | 0 / 8 (0.00%)    | 1 / 35 (2.86%)   |  |
| occurrences (all)                                                   | 0                | 1                |  |
| Fatigue                                                             |                  |                  |  |
| subjects affected / exposed                                         | 3 / 8 (37.50%)   | 7 / 35 (20.00%)  |  |
| occurrences (all)                                                   | 3                | 7                |  |
| Oedema peripheral                                                   |                  |                  |  |
| subjects affected / exposed                                         | 0 / 8 (0.00%)    | 1 / 35 (2.86%)   |  |
| occurrences (all)                                                   | 0                | 1                |  |
| Pain                                                                |                  |                  |  |
| subjects affected / exposed                                         | 1 / 8 (12.50%)   | 1 / 35 (2.86%)   |  |
| occurrences (all)                                                   | 1                | 1                |  |
| Pyrexia                                                             |                  |                  |  |
| subjects affected / exposed                                         | 1 / 8 (12.50%)   | 1 / 35 (2.86%)   |  |
| occurrences (all)                                                   | 1                | 1                |  |

|                                                                                                                                                                                                                                                           |                                                                         |                                                                           |  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------|---------------------------------------------------------------------------|--|
| Vessel puncture site haemorrhage<br>subjects affected / exposed<br>occurrences (all)                                                                                                                                                                      | 0 / 8 (0.00%)<br>0                                                      | 2 / 35 (5.71%)<br>2                                                       |  |
| Reproductive system and breast disorders<br>Polymenorrhoea<br>subjects affected / exposed<br>occurrences (all)                                                                                                                                            | 0 / 8 (0.00%)<br>0                                                      | 1 / 35 (2.86%)<br>1                                                       |  |
| Respiratory, thoracic and mediastinal disorders<br>Cough<br>subjects affected / exposed<br>occurrences (all)<br><br>Oropharyngeal pain<br>subjects affected / exposed<br>occurrences (all)                                                                | 0 / 8 (0.00%)<br>0<br><br>0 / 8 (0.00%)<br>0                            | 1 / 35 (2.86%)<br>1<br><br>1 / 35 (2.86%)<br>1                            |  |
| Psychiatric disorders<br>Insomnia<br>subjects affected / exposed<br>occurrences (all)<br><br>Restlessness<br>subjects affected / exposed<br>occurrences (all)<br><br>Sleep disorder<br>subjects affected / exposed<br>occurrences (all)                   | 0 / 8 (0.00%)<br>0<br><br>1 / 8 (12.50%)<br>2<br><br>0 / 8 (0.00%)<br>0 | 1 / 35 (2.86%)<br>1<br><br>1 / 35 (2.86%)<br>2<br><br>1 / 35 (2.86%)<br>1 |  |
| Injury, poisoning and procedural complications<br>Animal bite<br>subjects affected / exposed<br>occurrences (all)<br><br>Fall<br>subjects affected / exposed<br>occurrences (all)<br><br>Rib fracture<br>subjects affected / exposed<br>occurrences (all) | 0 / 8 (0.00%)<br>0<br><br>0 / 8 (0.00%)<br>0<br><br>1 / 8 (12.50%)<br>1 | 1 / 35 (2.86%)<br>1<br><br>1 / 35 (2.86%)<br>1<br><br>1 / 35 (2.86%)<br>1 |  |
| Cardiac disorders                                                                                                                                                                                                                                         |                                                                         |                                                                           |  |

|                                                                              |                     |                      |  |
|------------------------------------------------------------------------------|---------------------|----------------------|--|
| Palpitations<br>subjects affected / exposed<br>occurrences (all)             | 0 / 8 (0.00%)<br>0  | 1 / 35 (2.86%)<br>1  |  |
| Nervous system disorders                                                     |                     |                      |  |
| Disturbance in attention<br>subjects affected / exposed<br>occurrences (all) | 1 / 8 (12.50%)<br>2 | 2 / 35 (5.71%)<br>3  |  |
| Dizziness<br>subjects affected / exposed<br>occurrences (all)                | 0 / 8 (0.00%)<br>0  | 1 / 35 (2.86%)<br>1  |  |
| Headache<br>subjects affected / exposed<br>occurrences (all)                 | 2 / 8 (25.00%)<br>4 | 6 / 35 (17.14%)<br>9 |  |
| Hypoaesthesia<br>subjects affected / exposed<br>occurrences (all)            | 0 / 8 (0.00%)<br>0  | 1 / 35 (2.86%)<br>1  |  |
| Migraine<br>subjects affected / exposed<br>occurrences (all)                 | 0 / 8 (0.00%)<br>0  | 1 / 35 (2.86%)<br>2  |  |
| Sinus headache<br>subjects affected / exposed<br>occurrences (all)           | 0 / 8 (0.00%)<br>0  | 1 / 35 (2.86%)<br>1  |  |
| Blood and lymphatic system disorders                                         |                     |                      |  |
| Thrombocytopenia<br>subjects affected / exposed<br>occurrences (all)         | 4 / 8 (50.00%)<br>4 | 4 / 35 (11.43%)<br>4 |  |
| Gastrointestinal disorders                                                   |                     |                      |  |
| Abdominal distension<br>subjects affected / exposed<br>occurrences (all)     | 0 / 8 (0.00%)<br>0  | 1 / 35 (2.86%)<br>1  |  |
| Abdominal pain<br>subjects affected / exposed<br>occurrences (all)           | 0 / 8 (0.00%)<br>0  | 2 / 35 (5.71%)<br>2  |  |
| Abdominal pain upper<br>subjects affected / exposed<br>occurrences (all)     | 0 / 8 (0.00%)<br>0  | 1 / 35 (2.86%)<br>1  |  |
| Constipation                                                                 |                     |                      |  |

|                                                 |                |                |  |
|-------------------------------------------------|----------------|----------------|--|
| subjects affected / exposed                     | 0 / 8 (0.00%)  | 2 / 35 (5.71%) |  |
| occurrences (all)                               | 0              | 3              |  |
| Diarrhoea                                       |                |                |  |
| subjects affected / exposed                     | 0 / 8 (0.00%)  | 3 / 35 (8.57%) |  |
| occurrences (all)                               | 0              | 3              |  |
| Dyspepsia                                       |                |                |  |
| subjects affected / exposed                     | 0 / 8 (0.00%)  | 1 / 35 (2.86%) |  |
| occurrences (all)                               | 0              | 1              |  |
| Food poisoning                                  |                |                |  |
| subjects affected / exposed                     | 0 / 8 (0.00%)  | 1 / 35 (2.86%) |  |
| occurrences (all)                               | 0              | 1              |  |
| Nausea                                          |                |                |  |
| subjects affected / exposed                     | 1 / 8 (12.50%) | 1 / 35 (2.86%) |  |
| occurrences (all)                               | 1              | 1              |  |
| Rectal haemorrhage                              |                |                |  |
| subjects affected / exposed                     | 0 / 8 (0.00%)  | 1 / 35 (2.86%) |  |
| occurrences (all)                               | 0              | 1              |  |
| Skin and subcutaneous tissue disorders          |                |                |  |
| Acne                                            |                |                |  |
| subjects affected / exposed                     | 1 / 8 (12.50%) | 1 / 35 (2.86%) |  |
| occurrences (all)                               | 1              | 1              |  |
| Acne cystic                                     |                |                |  |
| subjects affected / exposed                     | 0 / 8 (0.00%)  | 1 / 35 (2.86%) |  |
| occurrences (all)                               | 0              | 1              |  |
| Seborrhoeic dermatitis                          |                |                |  |
| subjects affected / exposed                     | 0 / 8 (0.00%)  | 1 / 35 (2.86%) |  |
| occurrences (all)                               | 0              | 1              |  |
| Telangiectasia                                  |                |                |  |
| subjects affected / exposed                     | 0 / 8 (0.00%)  | 1 / 35 (2.86%) |  |
| occurrences (all)                               | 0              | 1              |  |
| Musculoskeletal and connective tissue disorders |                |                |  |
| Arthralgia                                      |                |                |  |
| subjects affected / exposed                     | 1 / 8 (12.50%) | 2 / 35 (5.71%) |  |
| occurrences (all)                               | 1              | 2              |  |
| Back pain                                       |                |                |  |

|                                    |                |                 |  |
|------------------------------------|----------------|-----------------|--|
| subjects affected / exposed        | 0 / 8 (0.00%)  | 1 / 35 (2.86%)  |  |
| occurrences (all)                  | 0              | 1               |  |
| Torticollis                        |                |                 |  |
| subjects affected / exposed        | 0 / 8 (0.00%)  | 1 / 35 (2.86%)  |  |
| occurrences (all)                  | 0              | 1               |  |
| Infections and infestations        |                |                 |  |
| Folliculitis                       |                |                 |  |
| subjects affected / exposed        | 0 / 8 (0.00%)  | 4 / 35 (11.43%) |  |
| occurrences (all)                  | 0              | 4               |  |
| Gastroenteritis                    |                |                 |  |
| subjects affected / exposed        | 0 / 8 (0.00%)  | 2 / 35 (5.71%)  |  |
| occurrences (all)                  | 0              | 2               |  |
| Influenza                          |                |                 |  |
| subjects affected / exposed        | 0 / 8 (0.00%)  | 1 / 35 (2.86%)  |  |
| occurrences (all)                  | 0              | 1               |  |
| Nasopharyngitis                    |                |                 |  |
| subjects affected / exposed        | 0 / 8 (0.00%)  | 4 / 35 (11.43%) |  |
| occurrences (all)                  | 0              | 4               |  |
| Oral herpes                        |                |                 |  |
| subjects affected / exposed        | 0 / 8 (0.00%)  | 2 / 35 (5.71%)  |  |
| occurrences (all)                  | 0              | 2               |  |
| Sinusitis                          |                |                 |  |
| subjects affected / exposed        | 1 / 8 (12.50%) | 1 / 35 (2.86%)  |  |
| occurrences (all)                  | 1              | 1               |  |
| Tinea pedis                        |                |                 |  |
| subjects affected / exposed        | 0 / 8 (0.00%)  | 1 / 35 (2.86%)  |  |
| occurrences (all)                  | 0              | 1               |  |
| Tonsillitis                        |                |                 |  |
| subjects affected / exposed        | 0 / 8 (0.00%)  | 1 / 35 (2.86%)  |  |
| occurrences (all)                  | 0              | 1               |  |
| Upper respiratory tract infection  |                |                 |  |
| subjects affected / exposed        | 1 / 8 (12.50%) | 1 / 35 (2.86%)  |  |
| occurrences (all)                  | 1              | 1               |  |
| Metabolism and nutrition disorders |                |                 |  |
| Decreased appetite                 |                |                 |  |

|                             |               |                |  |
|-----------------------------|---------------|----------------|--|
| subjects affected / exposed | 0 / 8 (0.00%) | 1 / 35 (2.86%) |  |
| occurrences (all)           | 0             | 1              |  |
| Hypertriglyceridaemia       |               |                |  |
| subjects affected / exposed | 0 / 8 (0.00%) | 1 / 35 (2.86%) |  |
| occurrences (all)           | 0             | 1              |  |
| Hypoglycaemia               |               |                |  |
| subjects affected / exposed | 0 / 8 (0.00%) | 1 / 35 (2.86%) |  |
| occurrences (all)           | 0             | 1              |  |

## **More information**

### **Substantial protocol amendments (globally)**

Were there any global substantial amendments to the protocol? No

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### **Interruptions (globally)**

Were there any global interruptions to the trial? No

### **Limitations and caveats**

None reported