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
Arm title	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.

Arm title	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.

Arm title	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.

Arm title	INCB054707 at 90 mg

Arm description:
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.

Number of subjects in period 1	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	-	-

Number of subjects in period 1	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:	
Placebo was administered QD over an 8 week treatment period.	
Reporting group title	INCB054707 at 30 mg
Reporting group description:	
INCB054707 was administered at 30 mg QD over an 8 week treatment period.	
Reporting group title	INCB054707 at 60 mg
Reporting group description:	
INCB054707 was administered at 60 mg QD over an 8 week treatment period.	
Reporting group title	INCB054707 at 90 mg
Reporting group description:	
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 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 Units: years			
arithmetic mean	40.3	41.0	42.2
standard deviation	± 16.70	± 11.53	± 11.96
Sex: Female, Male Units: Participants			
Female	8	7	8
Male	1	2	1
Race/Ethnicity, Customized 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 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 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 Units: years			
arithmetic mean	42.8		
standard deviation	± 14.62	-	
Sex: Female, Male Units: Participants			
Female	5	28	
Male	3	7	
Race/Ethnicity, Customized Units: Subjects			
White/Caucasian	7	31	
Black/African-American	1	1	
American-Indian/Alaska Native	0	2	
Other	0	1	
Race/Ethnicity, Customized 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:	
Placebo was administered QD over an 8 week treatment period.	
Reporting group title	INCB054707 at 30 mg
Reporting group description:	
INCB054707 was administered at 30 mg QD over an 8 week treatment period.	
Reporting group title	INCB054707 at 60 mg
Reporting group description:	
INCB054707 was administered at 60 mg QD over an 8 week treatment period.	
Reporting group title	INCB054707 at 90 mg
Reporting group description:	
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:	
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)[1]
End point description:	
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:	
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

	Clinical Response (HiSCR) at each visit

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 (± 2.62)	-2.7 (± 2.20)	-0.8 (± 0.97)	-1.2 (± 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:	
Scale measuring the severity of HS.	
End point type	Secondary
End point timeframe:	
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 (± 35.83)	-41.9 (± 36.84)	-59.2 (± 48.48)	-54.6 (± 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:	
Defined as fistulas that drain serous or purulent fluid, either spontaneously or by gentle palpation.	
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	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

No statistical analyses for this end point

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 %

Non-serious adverse events	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			
subjects affected / exposed	0 / 9 (0.00%)	0 / 9 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Dizziness			
subjects affected / exposed	1 / 9 (11.11%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Headache			
subjects affected / exposed	2 / 9 (22.22%)	0 / 9 (0.00%)	2 / 9 (22.22%)
occurrences (all)	2	0	3
Hypoaesthesia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 9 (11.11%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Migraine			
subjects affected / exposed	0 / 9 (0.00%)	0 / 9 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	2
Sinus headache			
subjects affected / exposed	0 / 9 (0.00%)	0 / 9 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Thrombocytopenia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 9 (0.00%)	0 / 9 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Abdominal pain			
subjects affected / exposed	1 / 9 (11.11%)	1 / 9 (11.11%)	0 / 9 (0.00%)
occurrences (all)	1	1	0
Abdominal pain upper			
subjects affected / exposed	0 / 9 (0.00%)	1 / 9 (11.11%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Constipation			
subjects affected / exposed	1 / 9 (11.11%)	0 / 9 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	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	1 / 9 (11.11%)	0 / 9 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	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

Non-serious adverse events	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			
subjects affected / exposed	0 / 8 (0.00%)	2 / 35 (5.71%)	
occurrences (all)	0	2	
Reproductive system and breast disorders			
Polymenorrhoea			
subjects affected / exposed	0 / 8 (0.00%)	1 / 35 (2.86%)	
occurrences (all)	0	1	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 8 (0.00%)	1 / 35 (2.86%)	
occurrences (all)	0	1	
Oropharyngeal pain			
subjects affected / exposed	0 / 8 (0.00%)	1 / 35 (2.86%)	
occurrences (all)	0	1	
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 35 (2.86%)	
occurrences (all)	0	1	
Restlessness			
subjects affected / exposed	1 / 8 (12.50%)	1 / 35 (2.86%)	
occurrences (all)	2	2	
Sleep disorder			
subjects affected / exposed	0 / 8 (0.00%)	1 / 35 (2.86%)	
occurrences (all)	0	1	
Injury, poisoning and procedural complications			
Animal bite			
subjects affected / exposed	0 / 8 (0.00%)	1 / 35 (2.86%)	
occurrences (all)	0	1	
Fall			
subjects affected / exposed	0 / 8 (0.00%)	1 / 35 (2.86%)	
occurrences (all)	0	1	
Rib fracture			
subjects affected / exposed	1 / 8 (12.50%)	1 / 35 (2.86%)	
occurrences (all)	1	1	
Cardiac disorders			

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

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported