Clinical trial results:
A Multi-center, Randomized, Double-blind, Placebo-controlled, Parallel Group, Phase 2 Study to Evaluate Clinical Efficacy and Safety of Deucravacitinib (BMS-986165) in Participants with Alopecia Areata

Summary

EudraCT number	2020-000113-33
Trial protocol	FR
Global end of trial date	16 May 2024

Results information

Result version number	v1 (current)
This version publication date	30 May 2025
First version publication date	30 May 2025

Trial information

Trial identification

Sponsor protocol code	IM011-134

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Bristol-Myers Squibb
Sponsor organisation address	Chaussée de la Hulpe 185, Brussels, Belgium, 1170
Public contact	Global Submission Management, Clinical Trials, Bristol-Myers Squibb International Corporation, mg-gsm-ct@bms.com
Scientific contact	Bristol-Myers Squibb Study Director, Bristol-Myers Squibb, mg-gsm-ct@bms.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	12 June 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	16 May 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Change from baseline in SALT score at Week 24

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	08 November 2022
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Canada: 35
Country: Number of subjects enrolled	France: 16
Country: Number of subjects enrolled	Japan: 12
Country: Number of subjects enrolled	Poland: 8
Country: Number of subjects enrolled	United States: 19
Country: Number of subjects enrolled	Australia: 4
Worldwide total number of subjects	94
EEA total number of subjects	24

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)	93
From 65 to 84 years	1
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Study was terminated due to change in business objectives.

Pre-assignment

Screening details:

94 participants randomized and treated in Placebo controlled period. the 31 participants in the placebo cohort, were re-randomized into the active treatment period (ATP) cohort.

Period 1

Period 1 title	Placebo-Controlled (Day 1 to Week 24)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Investigator, Subject

Arms

Are arms mutually exclusive?	Yes
Arm title	Deucravacitinib 6 mg QD

Arm description:

Participants with alopecia areata received deucravacitinib 6 mg tablet orally once daily (QD) from Day 1 to Week 24 in Placebo-controlled Period.

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

Dosage and administration details:

6 mg QD

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Placebo

Arm title	Deucravacitinib 6 mg BID

Arm description:

Participants with alopecia areata received deucravacitinib 6 mg tablet orally twice daily (BID) from Day 1 to Week 24 in Placebo-controlled Period.

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

Dosage and administration details:

Placebo

Investigational medicinal product name	Deucravacitinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

6 mg BID

Arm title	Placebo

Arm description:

Participants with alopecia areata received placebo tablet orally twice daily (BID) from Day 1 to Week 24 in Placebo-controlled 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

Number of subjects in period 1	Deucravacitinib 6 mg QD	Deucravacitinib 6 mg BID	Placebo
Started	32	31	31
Completed	32	26	31
Not completed	0	5	0
Consent withdrawn by subject	-	1	-
Adverse event, non-fatal	-	2	-
Participant request to discontinue study treatment	-	2	-

Period 2

Period 2 title	Active Treatment (Week 25 to Week 52)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes

Arm title	Deucravacitinib 6 mg QD

Arm description:

Participants with alopecia areata received deucravacitinib 6 mg tablet orally once daily (QD) from Day 1 to Week 24 in Placebo-controlled Period.

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

Dosage and administration details:

6mg QD

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Placebo

Investigational medicinal product name	Deucravacitinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

6mg BID

Arm title	Deucravacitinib 6 mg BID

Arm description:

Participants with alopecia areata received deucravacitinib 6 mg tablet orally twice daily (BID) from Day 1 to Week 24 in Placebo-controlled Period.

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

Dosage and administration details:

Placebo

Arm title	Placebo followed by Deucravacitinib 6 mg QD

Arm description:

Participants initially randomized to receive placebo in Placebo-controlled Period were re-randomized to this arm at the Week 24 visit. Participants in this arm received 6 mg deucravacitinib tablet orally QD till Week 52 in Active Treatment Period.

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

Dosage and administration details:

Placebo

Investigational medicinal product name	Deucravacitinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

6mg QD

Arm title	Placebo followed by Deucravacitinib 6 mg BID

Arm description:

Participants initially randomized to receive placebo in Placebo-controlled Period were re-randomized to this arm at the Week 24 visit. Participants in this arm received 6 mg deucravacitinib tablet orally BID till Week 52 in Active Treatment Period.

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

Dosage and administration details:

6mg BID

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Placebo

Number of subjects in period 2	Deucravacitinib 6 mg QD	Deucravacitinib 6 mg BID	Placebo followed by Deucravacitinib 6 mg QD
Started	32	26	16
Completed	8	5	5
Not completed	24	21	11
Consent withdrawn by subject	2	2	3
Adverse event, non-fatal	1	1	1
Study terminated by sponsor	19	12	6
Lost to follow-up	-	2	-
Participant request to discontinue study treatment	1	3	-
Lack of efficacy	1	1	1

Number of subjects in period 2	Placebo followed by Deucravacitinib 6 mg BID
Started	15
Completed	3
Not completed	12

Consent withdrawn by subject	1
Adverse event, non-fatal	-
Study terminated by sponsor	9
Lost to follow-up	1
Participant request to discontinue study treatment	1
Lack of efficacy	-

Baseline characteristics

Reporting groups	
Reporting group title	Deucravacitinib 6 mg QD
Reporting group description:	
Participants with alopecia areata received deucravacitinib 6 mg tablet orally once daily (QD) from Day 1 to Week 24 in Placebo-controlled Period.	
Reporting group title	Deucravacitinib 6 mg BID
Reporting group description:	
Participants with alopecia areata received deucravacitinib 6 mg tablet orally twice daily (BID) from Day 1 to Week 24 in Placebo-controlled Period.	
Reporting group title	Placebo
Reporting group description:	
Participants with alopecia areata received placebo tablet orally twice daily (BID) from Day 1 to Week 24 in Placebo-controlled Period.	

Reporting group values	Deucravacitinib 6 mg QD	Deucravacitinib 6 mg BID	Placebo
Number of subjects	32	31	31
Age categorical Units: Subjects			
Adults (18-64 years)	32	30	31
From 65-84 years	0	1	0
Age Continuous Units: years			
arithmetic mean	36.1	43.4	38.9
standard deviation	± 13.37	± 13.81	± 14.40
Sex: Female, Male Units: Participants			
Female	22	22	20
Male	10	9	11
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	8	6	10
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	1	4	2
White	22	20	19
More than one race	0	0	0
Unknown or Not Reported	1	1	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	1	3	0
Not Hispanic or Latino	31	28	31
Unknown or Not Reported	0	0	0

Reporting group values	Total		
Number of subjects	94		

Age categorical Units: Subjects			
Adults (18-64 years)	93		
From 65-84 years	1		
Age Continuous Units: years arithmetic mean standard deviation	 -		
Sex: Female, Male Units: Participants			
Female	64		
Male	30		
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0		
Asian	24		
Native Hawaiian or Other Pacific Islander	0		
Black or African American	7		
White	61		
More than one race	0		
Unknown or Not Reported	2		
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	4		
Not Hispanic or Latino	90		
Unknown or Not Reported	0		

End points

End points reporting groups

Reporting group title	Deucravacitinib 6 mg QD
Reporting group description:	
Participants with alopecia areata received deucravacitinib 6 mg tablet orally once daily (QD) from Day 1 to Week 24 in Placebo-controlled Period.	
Reporting group title	Deucravacitinib 6 mg BID
Reporting group description:	
Participants with alopecia areata received deucravacitinib 6 mg tablet orally twice daily (BID) from Day 1 to Week 24 in Placebo-controlled Period.	
Reporting group title	Placebo
Reporting group description:	
Participants with alopecia areata received placebo tablet orally twice daily (BID) from Day 1 to Week 24 in Placebo-controlled Period.	
Reporting group title	Deucravacitinib 6 mg QD
Reporting group description:	
Participants with alopecia areata received deucravacitinib 6 mg tablet orally once daily (QD) from Day 1 to Week 24 in Placebo-controlled Period.	
Reporting group title	Deucravacitinib 6 mg BID
Reporting group description:	
Participants with alopecia areata received deucravacitinib 6 mg tablet orally twice daily (BID) from Day 1 to Week 24 in Placebo-controlled Period.	
Reporting group title	Placebo followed by Deucravacitinib 6 mg QD
Reporting group description:	
Participants initially randomized to receive placebo in Placebo-controlled Period were re-randomized to this arm at the Week 24 visit. Participants in this arm received 6 mg deucravacitinib tablet orally QD till Week 52 in Active Treatment Period.	
Reporting group title	Placebo followed by Deucravacitinib 6 mg BID
Reporting group description:	
Participants initially randomized to receive placebo in Placebo-controlled Period were re-randomized to this arm at the Week 24 visit. Participants in this arm received 6 mg deucravacitinib tablet orally BID till Week 52 in Active Treatment Period.	
Subject analysis set title	Placebo-Controlled: Deucravacitinib 6 mg QD
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
Participants with alopecia areata received deucravacitinib 6 mg tablet orally once daily (QD) from Day 1 to Week 24 in Placebo-controlled Period.	
Subject analysis set title	Placebo-Controlled: Deucravacitinib 6 mg BID
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
Participants with alopecia areata received deucravacitinib 6 mg tablet orally twice daily (BID) from Day 1 to Week 24 in Placebo-controlled Period.	
Subject analysis set title	Placebo-Controlled: Deucravacitinib 6 mg QD
Subject analysis set type	Safety analysis
Subject analysis set description:	
Participants with alopecia areata received deucravacitinib 6 mg tablet orally once daily (QD) from Day 1 to Week 24 in Placebo-controlled Period	
Subject analysis set title	Active Treatment Period: Deucravacitinib 6 mg QD
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
Participants initially randomized to deucravacitinib 6 mg QD in placebo-controlled period continued on their assigned dosage in Active Treatment Period till Week 52.	
Subject analysis set title	Active Treatment Period: Deucravacitinib 6 mg BID
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Participants initially randomized to deucravacitinib 6 mg BID in Placebo-controlled Period continued on their assigned dosage in Active Treatment Period till Week 52.

Subject analysis set title	PBO followed by Deucravacitinib 6 mg BID
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Participants initially randomized to receive placebo in Placebo-controlled period were re-randomized to this arm at the Week 24 visit. Participants in this arm received 6 mg deucravacitinib tablet orally BID till Week 52 in Active Treatment Period.

Subject analysis set title	Active Treatment Period: Deucravacitinib 6 mg QD
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Participants initially randomized to deucravacitinib 6 mg QD in Placebo-controlled Period continued on their assigned dosage in Active Treatment Period till Week 52.

Subject analysis set title	PBO followed by Deucravacitinib 6 mg BID
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Participants initially randomized to receive placebo in Placebo-controlled Period were re-randomized to this arm at the Week 24 visit. Participants in this arm received 6 mg deucravacitinib tablet orally BID till Week 52 in Active Treatment Period.

Subject analysis set title	Placebo-Controlled: Deucravacitinib 6 mg BID
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants with alopecia areata received deucravacitinib 6 mg tablet orally twice daily (BID) from Day 1 to Week 24 in Placebo-controlled Period.

Subject analysis set title	Active Treatment Period: Deucravacitinib 6 mg QD
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants initially randomized to deucravacitinib 6 mg QD in Placebo-controlled Period continued on their assigned dosage in Active Treatment Period till Week 52.

Subject analysis set title	Active Treatment Period: Deucravacitinib 6 mg BID
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants initially randomized to deucravacitinib 6 mg BID in Placebo-controlled Period continued on their assigned dosage in Active Treatment Period till Week 52.

Subject analysis set title	PBO followed by Deucravacitinib 6 mg BID
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants initially randomized to receive placebo in Placebo-controlled Period were re-randomized to this arm at the Week 24 visit. Participants in this arm received 6 mg deucravacitinib tablet orally BID till Week 52 in Active Treatment Period.

Subject analysis set title	Placebo-Controlled: Deucravacitinib 6 mg BID
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants with alopecia areata received deucravacitinib 6 mg tablet orally twice daily (BID) from Day 1 to Week 24 in Placebo-controlled Period.

Subject analysis set title	PBO followed by Deucravacitinib 6 mg BID
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants initially randomized to receive placebo in Placebo-controlled Period were re-randomized to this arm at the Week 24 visit. Participants in this arm received 6 mg deucravacitinib tablet orally BID till Week 52 in Active Treatment Period.

Subject analysis set title	ATP: PBO followed by Deucravacitinib 6 mg QD
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Participants initially randomized to receive placebo in Placebo-controlled Period were re-randomized to

this arm at the Week 24 visit. Participants in this arm received 6 mg deucravacitinib tablet orally QD till Week 52 in Active Treatment Period.

Subject analysis set title	ATP: PBO followed by Deucravacitinib 6 mg QD
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants initially randomized to receive placebo in Placebo-controlled Period were re-randomized to this arm at the Week 24 visit. Participants in this arm received 6 mg deucravacitinib tablet orally QD till Week 52 in Active Treatment Period.

Primary: Change from Baseline in Severity of Alopecia Tool Score at Week 24 in Placebo-Controlled Treatment Period

End point title	Change from Baseline in Severity of Alopecia Tool Score at Week 24 in Placebo-Controlled Treatment Period[1]

End point description:

The Severity of Alopecia Tool (SALT) score is a quantitative rating scale for measuring the severity of alopecia areata based on the amount of terminal hair loss in each of the 4 quadrants of the scalp: back region, top region, left and right regions of the scalp. To calculate a SALT score, the degree of scalp hair loss, as a percentage of each scalp region affected, is determined. Each region is multiplied by it's respective weighting factor (percentage surface area of the scalp in that area; back region [24%], top region [40%], left region [18%] and, right region [18%]), in order to achieve a subtotal for each region. The SALT score is the sum of the scalp hair loss in each area (sum of the subtotals). The score ranges from 0 to 100, the higher score reflects high severity of alopecia areata.

End point type	Primary

End point timeframe:

Baseline (Day 1) and Week 24

Notes:

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

End point values	Deucravacitinib 6 mg QD	Deucravacitinib 6 mg BID	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	32	31	31	
Units: Score on a Scale				
arithmetic mean (standard deviation)	-5.809 (± 13.3892)	1.027 (± 14.7258)	-7.302 (± 17.8732)	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants with Treatment Emergent Adverse Events in Placebo-Controlled Period

End point title	Number of Participants with Treatment Emergent Adverse Events in Placebo-Controlled Period[2]

End point description:

An Adverse Event (AE) is defined as any new untoward medical occurrence or worsening of a pre-existing medical condition in a clinical investigation participant administered study treatment and that does not necessarily have a causal relationship with this treatment. Serious Adverse Event (SAE) is defined as any untoward medical occurrence that, at any dose results in death, is life-threatening, requires inpatient hospitalization or causes prolongation of existing hospitalization. Adverse event of interest included herpes zoster, malignancy, opportunistic infection or tuberculosis infection.

Interest-Malignancy-Nodular lymphocyte predominant Hodgkin Lymphoma = IMN-HL

End point type	Primary

End point timeframe:

From first dose (Day 1) and up to 30 days after last dose for all participants (up to approximately 28 weeks)

Notes:

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

End point values	Deucravacitinib 6 mg QD	Deucravacitinib 6 mg BID	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	32	31	31	
Units: Participants				
Treatment Emergent Adverse Events	25	28	20	
Serious Treatment Emergent Adverse Events	1	1	0	
TEAE Leading to Discontinuation of Study	1	3	0	
TEAE of Interest-Herpes Zoster	1	0	0	
TEAE of Interest-Malignancy-Bowen's Disease)	0	1	0	
TEAE of IMN-HL	0	1	0	
TEAE of Interest - Opportunistic Infections	0	0	0	
TEAE of Interest - Tuberculosis Infection	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants with Treatment Emergent Adverse Events in Active Treatment Period

End point title	Number of Participants with Treatment Emergent Adverse Events in Active Treatment Period[3]

End point description:

An Adverse Event (AE) is defined as any new untoward medical occurrence or worsening of a pre-existing medical condition in a clinical investigation participant administered study treatment and that does not necessarily have a causal relationship with this treatment. Serious Adverse Event (SAE) is defined as any untoward medical occurrence that, at any dose results in death, is life-threatening, requires inpatient hospitalization or causes prolongation of existing hospitalization. Adverse event of interest included Herpes zoster, malignancy, opportunities infection or tuberculosis infection.

Interest-Malignancy-Nodular lymphocyte predominant Hodgkin Lymphoma = IMN-HL

End point type	Primary

End point timeframe:

From first dose (Day 1) of Week 25 and up to 30 days after last dose for all participants (up to approximately 28 weeks)

Notes:

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

End point values	Active Treatment Period: Deucravacitinib 6 mg QD	Active Treatment Period: Deucravacitinib 6 mg BID	PBO followed by Deucravacitinib 6 mg BID	ATP: PBO followed by Deucravacitinib 6 mg QD
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	32	26	15	16
Units: Participants				
Treatment Emergent Adverse Events	21	17	14	13
Serious Treatment Emergent Adverse Events	0	1	0	0
TEAE Leading to Discontinuation of Study	1	0	0	1
TEAE of Interest-Herpes Zoster	0	0	0	0
TEAE of Interest-Malignancy-Bowen's Disease	0	0	0	0
TEAE of IMN-HL	0	0	0	0
TEAE of Interest - Opportunistic Infections	0	0	0	0
TEAE of Interest - Tuberculosis Infection	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants with Worst Toxicity Grade Change from Baseline to Grade 3/Grade 4 in Laboratory Test Results as per Common Terminology Criteria for Adverse Events (CTCAE) v5.0 in Placebo-Controlled Period

End point title	Number of Participants with Worst Toxicity Grade Change from Baseline to Grade 3/Grade 4 in Laboratory Test Results as per Common Terminology Criteria for Adverse Events (CTCAE) v5.0 in Placebo-Controlled Period[4]

End point description:

Blood samples were collected for assessment of laboratory test results. All abnormalities were graded as per CTCAE v5.0 on a scale from 1 to 4, with Grade 1 being mild and asymptomatic; Grade 2 is moderate requiring minimal, local or noninvasive intervention; Grade 3 is severe or medically significant but not immediately life-threatening; Grade 4 events are usually severe enough to require hospitalization.

End point type	Primary

End point timeframe:

From first dose (Day 1) through Week 24

Notes:

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

End point values	Deucravacitinib 6 mg QD	Deucravacitinib 6 mg BID	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	32	31	31	
Units: participants				
HEMOGLOBIN, LOW	0	0	0	
PLATELET COUNT, LOW	0	0	0	
LEUKOCYTES, LOW	0	0	0	
ALANINE AMINOTRANSFERASE (ALT), HIGH	0	0	0	

ALKALINE PHOSPHATASE (ALP), HIGH	0	0	0	
ASPARTATE AMINOTRANSFERASE (AST), HIGH	0	0	0	
BILIRUBIN, TOTAL, HIGH	0	0	0	
CREATININE, ENZYMATIC, HIGH	0	0	0	
ALBUMIN, LOW	0	0	0	
CALCIUM, LOW	0	0	0	
CALCIUM, HIGH	0	0	0	
CHOLESTEROL, TOTAL (TC), HIGH	0	0	0	
CREATINE KINASE (CK), HIGH	0	1	2	
GLUCOSE, LOW	0	0	0	
POTASSIUM, LOW	0	0	0	
POTASSIUM, HIGH	1	0	0	
SODIUM, LOW	0	0	0	
SODIUM, HIGH	0	0	0	
TRIGLYCERIDES, HIGH	0	0	0	
GLUCOSE FASTING, LOW	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants with Worst Toxicity Grade Change from Baseline to Grade 3/Grade 4 in Laboratory Test Results as per Common Terminology Criteria for Adverse Events (CTCAE) v5.0 in in Active Treatment Period

End point title	Number of Participants with Worst Toxicity Grade Change from Baseline to Grade 3/Grade 4 in Laboratory Test Results as per Common Terminology Criteria for Adverse Events (CTCAE) v5.0 in in Active Treatment Period[5]

End point description:

Blood samples were collected for assessment of laboratory test results. All abnormalities are graded as per CTCAE v5.0 on a scale from 1 to 4, with Grade 1 being mild and asymptomatic; Grade 2 is moderate requiring minimal, local or noninvasive intervention; Grade 3 is severe or medically significant but not immediately life-threatening; Grade 4 events are usually severe enough to require hospitalization.

End point type	Primary

End point timeframe:

From Week 25 to Week 52

Notes:

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

End point values	Active Treatment Period: Deucravacitinib 6 mg QD	Active Treatment Period: Deucravacitinib 6 mg BID	PBO followed by Deucravacitinib 6 mg BID	ATP: PBO followed by Deucravacitinib 6 mg QD
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	32	26	15	16
Units: participants				
HEMOGLOBIN, LOW	0	0	0	0
PLATELET COUNT, LOW	0	0	0	0
LEUKOCYTES, LOW	0	0	0	0

ALANINE AMINOTRANSFERASE (ALT), HIGH	0	0	0	0
ALKALINE PHOSPHATASE (ALP), HIGH	0	0	0	0
ASPARTATE AMINOTRANSFERASE (AST), HIGH	0	0	0	0
BILIRUBIN, TOTAL, HIGH	0	0	0	0
CREATININE, ENZYMATIC, HIGH	0	0	0	0
ALBUMIN, LOW	0	0	0	0
CALCIUM, LOW	0	0	0	0
CALCIUM, HIGH	0	0	0	0
CHOLESTEROL, TOTAL (TC), HIGH	0	0	0	0
CREATINE KINASE (CK), HIGH	0	0	0	0
GLUCOSE, LOW	0	0	0	0
POTASSIUM, LOW	0	0	0	0
POTASSIUM, HIGH	0	0	0	0
SODIUM, LOW	0	0	0	0
SODIUM, HIGH	0	0	0	0
TRIGLYCERIDES, HIGH	0	0	0	0
GLUCOSE FASTING, LOW	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants with Marked Electrocardiogram Abnormalities in Placebo-Controlled period

End point title	Number of Participants with Marked Electrocardiogram Abnormalities in Placebo-Controlled period[6][7]

End point description:

A 12-lead ECG was performed after the participant remained supine for at least 5 minutes prior to the ECG. The ECG results read by the principal study investigator or a qualified and delegated designee as per local requirements

End point type	Primary

End point timeframe:

First dose (Day 1) to Week 24

Notes:

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

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: placebo group from period 1 is represented in the 2 placebo to treatment groups.

End point values	Placebo	Placebo-Controlled: Deucravacitinib 6 mg QD	Placebo-Controlled: Deucravacitinib 6 mg BID	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	31	32	29	
Units: Participants				
QTCF 450 -< 480 MILLISECONDS (MSEC)	1	0	2	
QTCF 480 -< 500 MSEC	0	0	0	

QTCF >= 500 MSEC	0	0	0	
QTCF 30 < CHANGE FROM BASELINE <= 60 MSEC	0	0	1	
QTCF CHANGE FROM BASELINE > 60 MSEC	0	0	0	
PR INTERVAL >= 200 MSEC	1	2	0	
QRS INTERVAL >= 120 MSEC	1	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants with Marked Electrocardiogram Abnormalities in Active Treatment Period

End point title	Number of Participants with Marked Electrocardiogram Abnormalities in Active Treatment Period[8]

End point description:

A 12-lead ECG should be performed after the participant has remained supine for at least 5 minutes prior to the ECG. The ECG results will be read by the principal study investigator or a qualified and delegated designee as per local requirements

End point type	Primary

End point timeframe:

Week 25 to Week 52

Notes:

[8] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: no further statistical analysis done for this endpoint

End point values	Active Treatment Period: Deucravacitinib 6 mg QD	Active Treatment Period: Deucravacitinib 6 mg BID	PBO followed by Deucravacitinib 6 mg BID	ATP: PBO followed by Deucravacitinib 6 mg QD
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	28	19	14	14
Units: Participants				
QTCF 450 -< 480 MILLISECONDS (MSEC)	0	0	0	0
QTCF 480 -< 500 MSEC	0	0	0	0
QTCF >= 500 MSEC	0	0	0	0
QTCF 30 < CHANGE FROM BASELINE <= 60 MSEC	1	1	1	1
QTCF CHANGE FROM BASELINE > 60 MSEC	0	0	0	0
PR INTERVAL >= 200 MSEC	1	0	1	1
QRS INTERVAL >= 120 MSEC	1	0	0	1

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants with Abnormalities in Marked Vital Signs in Placebo-Controlled period

End point title	Number of Participants with Abnormalities in Marked Vital Signs in Placebo-Controlled period[9][10]

End point description:

Vital signs such as systolic blood pressures (SBP), diastolic blood pressure (DBP) and heart rate were assessed. The evaluation of the marked abnormality criteria is based on participants highest change from baseline in the period. Blood pressure and heart rate were to be measured after the participant has been resting quietly for at least 5 minutes.

Change from Baseline = CFB

End point type	Primary

End point timeframe:

First dose (Day 1) to Week 24

Notes:

[9] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: no further statistical analysis done for this endpoint

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: placebo group from period 1 is represented in the 2 placebo to treatment groups.

End point values	Placebo	Placebo-Controlled: Deucravacitinib 6 mg QD	Placebo-Controlled: Deucravacitinib 6 mg BID	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	31	32	30	
Units: Participants				
HEART RATE > 100 BPM AND CFB > 30 BPM	0	0	1	
HEART RATE < 55 BPM AND CFB < -15 BPM	0	1	0	
SBP >140 MM HG AND CFB > 20 MM HG	1	1	4	
SBP <90 MM HG AND CFB < -20 MM HG	1	0	0	
DBP >90 MM HG AND CFB > 10 MM HG	1	3	0	
DBP <55 MM HG AND CFB < -10 MM HG	1	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants with Abnormalities in Marked Vital Signs in Active Treatment Period

End point title	Number of Participants with Abnormalities in Marked Vital Signs in Active Treatment Period[11]

End point description:

Vital signs such as systolic blood pressures (SBP), diastolic blood pressure (DBP) and heart rate were assessed. The evaluation of the marked abnormality criteria is based on participants highest change from baseline in the period. Blood pressure and heart rate were to be measured after the participant had been resting quietly for at least 5 minutes.

Change from Baseline = CFB

End point type	Primary

End point timeframe:

Week 25 to Week 52

Notes:

[11] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: no further statistical analysis done for this endpoint

End point values	Active Treatment Period: Deucravacitinib 6 mg QD	Active Treatment Period: Deucravacitinib 6 mg BID	PBO followed by Deucravacitinib 6 mg BID	ATP: PBO followed by Deucravacitinib 6 mg QD
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	32	26	15	16
Units: Participants				
HEART RATE > 100 BPM AND CFB > 30 BPM	0	0	1	0
HEART RATE < 55 BPM AND CFB < -15 BPM	1	1	0	0
SBP >140 MM HG AND CFB > 20 MM HG	1	1	1	0
SBP <90 MM HG AND CFB < -20 MM HG	0	0	0	0
DBP >90 MM HG AND CFB > 10 MM HG	0	1	3	0
DBP <55 MM HG AND CFB < -10 MM HG	1	0	0	1

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants with Abnormalities in Targeted Physical Examination Parameters in Placebo-Controlled Period

End point title	Number of Participants with Abnormalities in Targeted Physical Examination Parameters in Placebo-Controlled Period[12][13]

End point description:

Participants were assessed for abnormalities in targeted physical parameters.

End point type	Primary

End point timeframe:

First dose (Day 1) to Week 24

Notes:

[12] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: no further statistical analysis done for this endpoint

[13] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: placebo group from period 1 is represented in the 2 placebo to treatment groups.

End point values	Placebo	Placebo-Controlled: Deucravacitinib 6 mg QD	Placebo-Controlled: Deucravacitinib 6 mg BID	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	31	32	31	
Units: Participants				
Abdomen	1	0	0	

Extremities	1	0	1	
General Appearance	0	1	1	
Genitourinary	0	1	0	
Head, Eyes, Ears, Nose, Throat	2	3	6	
Lymph Nodes	0	0	0	
Mouth	0	3	0	
Musculoskeletal	0	1	1	
Neck	0	0	0	
Neurological	1	2	0	
Psychiatric	1	1	0	
Respiratory	1	0	1	
Skin	6	9	14	
Other	0	1	1	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants with Abnormalities in Targeted Physical Examination Parameters in Active Treatment Parameters

End point title	Number of Participants with Abnormalities in Targeted Physical Examination Parameters in Active Treatment Parameters[14]

End point description:

Participants were assessed for abnormalities in targeted physical parameters.

End point type	Primary

End point timeframe:

Week 25 to Week 52

Notes:

[14] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: no further statistical analysis done for this endpoint

End point values	Active Treatment Period: Deucravacitinib 6 mg QD	Active Treatment Period: Deucravacitinib 6 mg BID	PBO followed by Deucravacitinib 6 mg BID	ATP: PBO followed by Deucravacitinib 6 mg QD
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	32	26	15	16
Units: Participants				
Abdomen	0	3	0	0
Extremities	0	1	0	0
General Appearance	0	0	0	0
Genitourinary	1	1	0	0
Head, Eyes, Ears, Nose, Throat	0	5	2	2
Lymph Nodes	0	1	0	0
Mouth	2	1	2	1
Musculoskeletal	1	2	0	1
Neck	0	1	0	0
Neurological	0	0	0	0
Other	2	2	4	0

Psychiatric	0	0	1	0
Respiratory	1	3	2	0
Skin	8	6	8	5

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving a ≥ 50% Reduction in Severity of Alopecia Tool (SALT) score (SALT50 response) from Baseline at Week 24

End point title	Percentage of Participants Achieving a ≥ 50% Reduction in Severity of Alopecia Tool (SALT) score (SALT50 response) from Baseline at Week 24[15]

End point description:

The Severity of Alopecia Tool (SALT) score is a quantitative rating scale for measuring the severity of alopecia areata based on the amount of terminal hair loss in each of the 4 quadrants of the scalp; back region, top region, left and right regions of the scalp. To calculate a SALT score, the degree of scalp hair loss, as a percentage of each scalp region affected, is determined. Each region is multiplied by its respective weighting factor (percentage surface area of the scalp in that area; Back region [24%], Left Region [18%], Right Region [18%], Top Region [40%]), in order to achieve a subtotal for each region. The SALT score is the sum of the scalp hair loss in each area (sum of the subtotals). The score ranges from 0 to 100, the higher score reflects high severity of alopecia areata. SALT50 response indicates at least a 50% improvement from baseline in the SALT score at a particular time point, indicating 50% hair regrowth.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Week 24

Notes:

[15] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: placebo group from period 1 is represented in the 2 placebo to treatment groups.

End point values	Placebo	Placebo-Controlled: Deucravacitinib 6 mg QD	Placebo-Controlled: Deucravacitinib 6 mg BID	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	31	32	31	
Units: Percentage of participants				
number (not applicable)	6.5	3.1	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving a Severity of Alopecia Tool (SALT) score ≤20 at Week 24

End point title	Percentage of Participants Achieving a Severity of Alopecia Tool (SALT) score ≤20 at Week 24[16]

End point description:

The Severity of Alopecia Tool (SALT) score is a quantitative rating scale for measuring the severity of

alopecia areata based on the amount of terminal hair loss in each of the 4 quadrants of the scalp; back region, top region, left and right regions of the scalp. To calculate a SALT score, the degree of scalp hair loss, as a percentage of each scalp region affected, is determined. Each region is multiplied by its respective weighting factor (percentage surface area of the scalp in that area; Back region [24%], Left Region [18%], Right Region [18%], Top Region [40%]), in order to achieve a subtotal for each region. The SALT score is the sum of the scalp hair loss in each area (sum of the subtotals). The score ranges from 0 to 100, the higher score reflects high severity of alopecia areata. percentage of participants achieving an absolute SALT score ≤ 20, indicates ≤ 20% scalp hair loss.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Week 24

Notes:

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

End point values	Placebo	Placebo-Controlled: Deucravacitinib 6 mg QD	Placebo-Controlled: Deucravacitinib 6 mg BID	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	31	32	31	
Units: Percentage of participants				
number (not applicable)	0	3.1	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving an Alopecia Areata Investigator Global Assessment (AA-IGA) Score of 0 or 1 at Week 24 with at least a 2-Point Change from Baseline

End point title	Percentage of Participants Achieving an Alopecia Areata Investigator Global Assessment (AA-IGA) Score of 0 or 1 at Week 24 with at least a 2-Point Change from Baseline[17]

End point description:

The AA-IGA utilizes a 5-points scale, in which the investigator assesses scalp hair loss based on the SALT assessment. The AA-IGA measures alopecia areata severity at a single point in time(without taking into account the baseline disease condition).The participant’s scalp hair loss, as it look at the time of evaluation is scored as none (0) (0% scalp hair loss), limited (1) (1%-20% scalp hair loss), moderate (2) (21%-49% scalp hair loss), severe (3) (50%-94% scalp hair loss), or very severe (4)(95%-100 % scalp hair loss).

End point type	Secondary

End point timeframe:

Baseline (Day 1) and week 24

Notes:

[17] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: placebo group from period 1 is represented in the 2 placebo to treatment groups.

End point values	Placebo	Placebo-Controlled: Deucravacitinib 6 mg QD	Placebo-Controlled: Deucravacitinib 6 mg BID	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	31	32	31	
Units: Percentage of participants				
number (not applicable)	0	3.1	0	

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

All-cause mortality: Week 0 to 52. Serious AEs were collected from ICF signing to 30 days post last dose (up to 32 weeks and 28 weeks) in both periods. Non-serious AEs were collected from Day 1 to 30 days post last dose (up to 28 weeks for both periods).

Adverse event reporting additional description:

Safety population included all participants who were in the randomized population and received at least 1 dose of study intervention.

ATP = Active Treatment Period
PBO = Placebo

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	27.0

Reporting groups

Reporting group title	PBO-Controlled: Deucravacitinib 6mg QD

Reporting group description:

Participants with alopecia areata received deucravacitinib 6 mg tablet orally once daily (QD) from Day 1 to Week 24 in Placebo-controlled Period.

Reporting group title	PBO-Controlled: Deucravacitinib 6mgBID

Reporting group description:

Participants with alopecia areata received deucravacitinib 6 mg tablet orally twice daily (BID) from Day 1 to Week 24 in Placebo-controlled Period.

Reporting group title	Placebo

Reporting group description:

Participants with alopecia areata received placebo tablet orally twice daily (BID) from Day 1 to Week 24 in Placebo-controlled Period.

Reporting group title	ATP: PBO followed by Deucravacitinib 6 mg BID

Reporting group description:

Participants initially randomized to receive placebo in Placebo-controlled Period were re-randomized to this arm at the Week 24 visit. Participants in this arm received 6 mg deucravacitinib tablet orally BID till Week 52 in Active Treatment Period.

Reporting group title	ATP: Deucravacitinib 6 mg BID

Reporting group description:

Participants initially randomized to deucravacitinib 6 mg BID in Placebo-controlled Period continued on their assigned dosage in Active Treatment Period till Week 52.

Reporting group title	ATP: PBO followed by Deucravacitinib 6 mg QD

Reporting group description:

Participants initially randomized to receive placebo in Placebo-controlled Period were re-randomized to this arm at the Week 24 visit. Participants in this arm received 6 mg deucravacitinib QD tablet orally till Week 52 in Active Treatment Period.

Reporting group title	ATP: Deucravacitinib 6 mg QD

Reporting group description:

Participants initially randomized to deucravacitinib 6 mg QD in Placebo-controlled Period continued on their assigned dosage in Active Treatment Period till Week 52.

Serious adverse events	PBO-Controlled: Deucravacitinib 6mg QD	PBO-Controlled: Deucravacitinib 6mgBID	Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 32 (3.13%)	0 / 31 (0.00%)	0 / 31 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Ligament sprain			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 32 (3.13%)	0 / 31 (0.00%)	0 / 31 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	ATP: PBO followed by Deucravacitinib 6 mg BID	ATP: Deucravacitinib 6 mg BID	ATP: PBO followed by Deucravacitinib 6 mg QD
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 15 (0.00%)	1 / 26 (3.85%)	0 / 16 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Ligament sprain			
subjects affected / exposed	0 / 15 (0.00%)	1 / 26 (3.85%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 26 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	ATP: Deucravacitinib 6 mg QD		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 32 (0.00%)		

number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Injury, poisoning and procedural complications			
Ligament sprain			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	PBO-Controlled: Deucravacitinib 6mg QD	PBO-Controlled: Deucravacitinib 6mgBID	Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	24 / 32 (75.00%)	26 / 31 (83.87%)	16 / 31 (51.61%)
Investigations			
Weight increased			
subjects affected / exposed	1 / 32 (3.13%)	2 / 31 (6.45%)	0 / 31 (0.00%)
occurrences (all)	1	2	0
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 32 (3.13%)	2 / 31 (6.45%)	1 / 31 (3.23%)
occurrences (all)	1	2	1
Nervous system disorders			
Headache			
subjects affected / exposed	3 / 32 (9.38%)	3 / 31 (9.68%)	3 / 31 (9.68%)
occurrences (all)	3	3	4
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 32 (0.00%)	2 / 31 (6.45%)	0 / 31 (0.00%)
occurrences (all)	0	2	0
Mass			

subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 32 (0.00%)	1 / 31 (3.23%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Ear and labyrinth disorders			
Hypoacusis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Mouth ulceration			
subjects affected / exposed	2 / 32 (6.25%)	2 / 31 (6.45%)	0 / 31 (0.00%)
occurrences (all)	3	2	0
Diarrhoea			
subjects affected / exposed	1 / 32 (3.13%)	4 / 31 (12.90%)	0 / 31 (0.00%)
occurrences (all)	1	4	0
Aphthous ulcer			
subjects affected / exposed	3 / 32 (9.38%)	4 / 31 (12.90%)	1 / 31 (3.23%)
occurrences (all)	4	7	1
Amalgam tattoo			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	1 / 32 (3.13%)	1 / 31 (3.23%)	0 / 31 (0.00%)
occurrences (all)	1	1	0
Food poisoning			
subjects affected / exposed	0 / 32 (0.00%)	1 / 31 (3.23%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Acne			

subjects affected / exposed	5 / 32 (15.63%)	4 / 31 (12.90%)	3 / 31 (9.68%)
occurrences (all)	5	4	3
Pruritus			
subjects affected / exposed	2 / 32 (6.25%)	0 / 31 (0.00%)	1 / 31 (3.23%)
occurrences (all)	2	0	1
Eczema			
subjects affected / exposed	1 / 32 (3.13%)	1 / 31 (3.23%)	0 / 31 (0.00%)
occurrences (all)	1	1	0
Dermatitis contact			
subjects affected / exposed	1 / 32 (3.13%)	0 / 31 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Urticaria			
subjects affected / exposed	1 / 32 (3.13%)	0 / 31 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Rosacea			
subjects affected / exposed	0 / 32 (0.00%)	2 / 31 (6.45%)	2 / 31 (6.45%)
occurrences (all)	0	2	2
Renal and urinary disorders			
Leukocyturia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Acute kidney injury			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	1 / 32 (3.13%)	2 / 31 (6.45%)	0 / 31 (0.00%)
occurrences (all)	1	2	0
Muscle spasms			
subjects affected / exposed	0 / 32 (0.00%)	2 / 31 (6.45%)	0 / 31 (0.00%)
occurrences (all)	0	2	0
Infections and infestations			
Nail infection			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Laryngitis			

subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	1 / 32 (3.13%)	0 / 31 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Gastroenteritis			
subjects affected / exposed	2 / 32 (6.25%)	0 / 31 (0.00%)	0 / 31 (0.00%)
occurrences (all)	2	0	0
Fungal infection			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	5 / 32 (15.63%)	6 / 31 (19.35%)	1 / 31 (3.23%)
occurrences (all)	5	6	1
Cystitis			
subjects affected / exposed	2 / 32 (6.25%)	0 / 31 (0.00%)	2 / 31 (6.45%)
occurrences (all)	2	0	2
Conjunctivitis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	5 / 32 (15.63%)	8 / 31 (25.81%)	0 / 31 (0.00%)
occurrences (all)	5	13	0
COVID-19			
subjects affected / exposed	3 / 32 (9.38%)	1 / 31 (3.23%)	0 / 31 (0.00%)
occurrences (all)	3	2	0
Oral herpes			
subjects affected / exposed	1 / 32 (3.13%)	2 / 31 (6.45%)	2 / 31 (6.45%)
occurrences (all)	1	2	3
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal candidiasis			

subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	1 / 32 (3.13%)	3 / 31 (9.68%)	0 / 31 (0.00%)
occurrences (all)	1	7	0
Upper respiratory tract infection			
subjects affected / exposed	2 / 32 (6.25%)	4 / 31 (12.90%)	4 / 31 (12.90%)
occurrences (all)	2	5	4
Tonsillitis			
subjects affected / exposed	2 / 32 (6.25%)	0 / 31 (0.00%)	0 / 31 (0.00%)
occurrences (all)	2	0	0
Sinusitis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	1 / 32 (3.13%)	1 / 31 (3.23%)	0 / 31 (0.00%)
occurrences (all)	1	1	0
Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed	1 / 32 (3.13%)	2 / 31 (6.45%)	0 / 31 (0.00%)
occurrences (all)	1	2	0

Non-serious adverse events	ATP: PBO followed by Deucravacitinib 6 mg BID	ATP: Deucravacitinib 6 mg BID	ATP: PBO followed by Deucravacitinib 6 mg QD
Total subjects affected by non-serious adverse events			
subjects affected / exposed	14 / 15 (93.33%)	14 / 26 (53.85%)	13 / 16 (81.25%)
Investigations			
Weight increased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 26 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 15 (6.67%)	0 / 26 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 15 (0.00%)	0 / 26 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0

General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 15 (0.00%)	1 / 26 (3.85%)	1 / 16 (6.25%)
occurrences (all)	0	1	1
Mass			
subjects affected / exposed	1 / 15 (6.67%)	0 / 26 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	1 / 15 (6.67%)	0 / 26 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Ear and labyrinth disorders			
Hypoacusis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 26 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Mouth ulceration			
subjects affected / exposed	0 / 15 (0.00%)	0 / 26 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 15 (0.00%)	0 / 26 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Aphthous ulcer			
subjects affected / exposed	2 / 15 (13.33%)	2 / 26 (7.69%)	1 / 16 (6.25%)
occurrences (all)	2	2	1
Amalgam tattoo			
subjects affected / exposed	0 / 15 (0.00%)	0 / 26 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Abdominal pain			
subjects affected / exposed	1 / 15 (6.67%)	1 / 26 (3.85%)	0 / 16 (0.00%)
occurrences (all)	1	1	0
Food poisoning			
subjects affected / exposed	2 / 15 (13.33%)	0 / 26 (0.00%)	0 / 16 (0.00%)
occurrences (all)	2	0	0
Respiratory, thoracic and mediastinal disorders			

Cough			
subjects affected / exposed	1 / 15 (6.67%)	2 / 26 (7.69%)	0 / 16 (0.00%)
occurrences (all)	1	2	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	4 / 15 (26.67%)	0 / 26 (0.00%)	3 / 16 (18.75%)
occurrences (all)	4	0	3
Pruritus			
subjects affected / exposed	1 / 15 (6.67%)	0 / 26 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Eczema			
subjects affected / exposed	1 / 15 (6.67%)	0 / 26 (0.00%)	2 / 16 (12.50%)
occurrences (all)	1	0	2
Dermatitis contact			
subjects affected / exposed	1 / 15 (6.67%)	0 / 26 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Urticaria			
subjects affected / exposed	1 / 15 (6.67%)	0 / 26 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Rosacea			
subjects affected / exposed	0 / 15 (0.00%)	0 / 26 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Leukocyturia			
subjects affected / exposed	1 / 15 (6.67%)	0 / 26 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Acute kidney injury			
subjects affected / exposed	0 / 15 (0.00%)	0 / 26 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 26 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 15 (0.00%)	0 / 26 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0

Infections and infestations			
Nail infection			
subjects affected / exposed	1 / 15 (6.67%)	0 / 26 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Laryngitis			
subjects affected / exposed	0 / 15 (0.00%)	1 / 26 (3.85%)	1 / 16 (6.25%)
occurrences (all)	0	1	1
Influenza			
subjects affected / exposed	0 / 15 (0.00%)	1 / 26 (3.85%)	1 / 16 (6.25%)
occurrences (all)	0	1	1
Gastroenteritis			
subjects affected / exposed	1 / 15 (6.67%)	2 / 26 (7.69%)	0 / 16 (0.00%)
occurrences (all)	1	2	0
Fungal infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 26 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Folliculitis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 26 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Cystitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 26 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 26 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Cellulitis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 26 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 15 (6.67%)	6 / 26 (23.08%)	2 / 16 (12.50%)
occurrences (all)	1	10	2
COVID-19			
subjects affected / exposed	2 / 15 (13.33%)	1 / 26 (3.85%)	0 / 16 (0.00%)
occurrences (all)	2	1	0
Oral herpes			

subjects affected / exposed	1 / 15 (6.67%)	1 / 26 (3.85%)	1 / 16 (6.25%)
occurrences (all)	1	1	2
Vulvovaginal mycotic infection			
subjects affected / exposed	1 / 15 (6.67%)	0 / 26 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Vulvovaginal candidiasis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 26 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Urinary tract infection			
subjects affected / exposed	0 / 15 (0.00%)	1 / 26 (3.85%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Upper respiratory tract infection			
subjects affected / exposed	4 / 15 (26.67%)	5 / 26 (19.23%)	4 / 16 (25.00%)
occurrences (all)	7	5	5
Tonsillitis			
subjects affected / exposed	1 / 15 (6.67%)	1 / 26 (3.85%)	1 / 16 (6.25%)
occurrences (all)	1	1	1
Sinusitis			
subjects affected / exposed	0 / 15 (0.00%)	2 / 26 (7.69%)	0 / 16 (0.00%)
occurrences (all)	0	2	0
Pharyngitis			
subjects affected / exposed	1 / 15 (6.67%)	1 / 26 (3.85%)	0 / 16 (0.00%)
occurrences (all)	1	1	0
Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 26 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	ATP: Deucravacitinib 6 mg QD		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	15 / 32 (46.88%)		
Investigations			
Weight increased			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Blood creatine phosphokinase increased			

subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Headache			
subjects affected / exposed	3 / 32 (9.38%)		
occurrences (all)	3		
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Mass			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Ear and labyrinth disorders			
Hypoacusis			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Mouth ulceration			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences (all)	1		
Diarrhoea			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Aphthous ulcer			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Amalgam tattoo			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Abdominal pain			

subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Food poisoning			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences (all)	1		
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Pruritus			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Eczema			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Dermatitis contact			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences (all)	1		
Urticaria			
subjects affected / exposed	2 / 32 (6.25%)		
occurrences (all)	2		
Rosacea			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Renal and urinary disorders			
Leukocyturia			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Acute kidney injury			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			

Back pain			
subjects affected / exposed	2 / 32 (6.25%)		
occurrences (all)	2		
Muscle spasms			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Nail infection			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Laryngitis			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Influenza			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Gastroenteritis			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences (all)	1		
Fungal infection			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Folliculitis			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Cystitis			
subjects affected / exposed	2 / 32 (6.25%)		
occurrences (all)	2		
Conjunctivitis			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Cellulitis			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Nasopharyngitis			

subjects affected / exposed	2 / 32 (6.25%)		
occurrences (all)	4		
COVID-19			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences (all)	1		
Oral herpes			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Urinary tract infection			
subjects affected / exposed	2 / 32 (6.25%)		
occurrences (all)	2		
Upper respiratory tract infection			
subjects affected / exposed	4 / 32 (12.50%)		
occurrences (all)	4		
Tonsillitis			
subjects affected / exposed	2 / 32 (6.25%)		
occurrences (all)	2		
Sinusitis			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Pharyngitis			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		
Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed	0 / 32 (0.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
29 August 2023	The primary purpose of this amendment is to incorporate changes based on comments received from United States Food and Drug Administration (US FDA) as well as to add clarifications based on feedback from study investigators. Language from the Japan-specific Amendment 01, related to the interpretation of hepatitis B virus test results to assess eligibility and to clarify expectations for assessments and sample collections, has been incorporated into this global amendment. Other edits were incorporated throughout the protocol to correct minor errors, add clarity, and improve consistency. Key changes are summarized below. This protocol amendment applies to all participants.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported