



Clinical trial results:

A Phase 3b/4, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate The Efficacy and Safety of Deucravacitinib in Participants with Moderate-To-Severe Scalp Psoriasis (Psoriatyk Scalp)

Summary

EudraCT number	2022-000797-26
Trial protocol	FR DE
Global end of trial date	17 October 2024

Results information

Result version number	v1 (current)
This version publication date	23 October 2025
First version publication date	23 October 2025

Trial information

Trial identification

Sponsor protocol code	IM011-220
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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 November 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	17 October 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Compare efficacy and safety of deucravacitinib versus placebo in participants with moderate-to-severe scalp psoriasis

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 participants were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	06 October 2022
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	France: 7
Country: Number of subjects enrolled	Germany: 42
Country: Number of subjects enrolled	Poland: 37
Country: Number of subjects enrolled	United Kingdom: 11
Country: Number of subjects enrolled	United States: 57
Worldwide total number of subjects	154
EEA total number of subjects	86

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)	137

From 65 to 84 years	17
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

154 randomized and treated

Period 1

Period 1 title	Placebo Controlled: Week 0 - 16
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
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Arm title	Deucravacitinib
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Arm description:

Deucravacitinib 6 mg daily (QD)

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 daily

Arm title	Placebo
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Arm description:

Placebo matching Deucravacitinib daily (QD)

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:

daily

Number of subjects in period 1	Deucravacitinib	Placebo
Started	103	51
Completed	94	45
Not completed	9	6
Consent withdrawn by subject	3	2
Adverse event, non-fatal	4	2

Other reasons	-	2
Lost to follow-up	1	-
Lack of efficacy	1	-

Period 2

Period 2 title	Active Treatment: Week 16 - Week 52
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Deucravacitinib

Arm description:

Deucravacitinib 6 mg daily (QD)

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 daily

Arm title	Placebo
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Arm description:

Placebo matching Deucravacitinib daily (QD)

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:

daily

Number of subjects in period 2	Deucravacitinib	Placebo
Started	94	45
Completed	80	39
Not completed	14	6
Adverse event, serious fatal	1	-

Consent withdrawn by subject	4	2
Adverse event, non-fatal	4	-
Non-compliance with protocol	-	1
Lost to follow-up	1	2
Lack of efficacy	4	1

Baseline characteristics

Reporting groups

Reporting group title	Deucravacitinib
Reporting group description: Deucravacitinib 6 mg daily (QD)	
Reporting group title	Placebo
Reporting group description: Placebo matching Deucravacitinib daily (QD)	

Reporting group values	Deucravacitinib	Placebo	Total
Number of subjects	103	51	154
Age categorical Units:			

Age Continuous Units: years arithmetic mean standard deviation	42.8 ± 15.70	43.2 ± 13.08	-
Sex: Female, Male Units: Participants			
Female	45	20	65
Male	58	31	89
Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	3	2	5
Black or African American	5	2	7
Native Hawaiian or other pacific islander	0	0	0
White	93	47	140
Other	2	0	2
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	6	8	14
Not Hispanic or Latino	95	43	138
Unknown or Not Reported	2	0	2

End points

End points reporting groups

Reporting group title	Deucravacitinib
Reporting group description: Deucravacitinib 6 mg daily (QD)	
Reporting group title	Placebo
Reporting group description: Placebo matching Deucravacitinib daily (QD)	
Reporting group title	Deucravacitinib
Reporting group description: Deucravacitinib 6 mg daily (QD)	
Reporting group title	Placebo
Reporting group description: Placebo matching Deucravacitinib daily (QD)	

Primary: Percentage of Participants with a Scalp-specific Physician Global Assessment Score of 0 or 1 (ss-PGA 0/1) at Week 16

End point title	Percentage of Participants with a Scalp-specific Physician Global Assessment Score of 0 or 1 (ss-PGA 0/1) at Week 16
End point description: ss-PGA 0/1 response as a percentage of participants with an ss-PGA score of 0 (clear) or 1 (almost clear) with at least a 2-point reduction from baseline at Week 16. Scalp lesions are evaluated in terms of clinical signs of redness, thickness, and scaliness and scored on the following 5-point ss-PGA scale: 0 = absence of disease, 1 = very mild disease, 2 = mild disease, 3 = moderate disease, 4 = severe disease.	
End point type	Primary
End point timeframe: Baseline and Week 16	

End point values	Deucravacitinib	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	103	51		
Units: Percentage of responders				
number (confidence interval 95%)				
Full Analysis Set	48.5 (38.6 to 58.6)	13.7 (5.7 to 26.3)		
Patient sub-population (s-PGA \geq 3)	50.0 (39.6 to 60.4)	12.8 (4.8 to 25.7)		

Statistical analyses

Statistical analysis title	Odds Ratio (OR)
Statistical analysis description: Patient sub-population (s-PGA \geq 3)	
Comparison groups	Deucravacitinib v Placebo

Number of subjects included in analysis	154
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	7
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.7
upper limit	18.4

Statistical analysis title	Odds Ratio (OR)
Statistical analysis description:	
Full Analysis Set	
Comparison groups	Deucravacitinib v Placebo
Number of subjects included in analysis	154
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	6.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.5
upper limit	15.3

Secondary: Percentage of Participants with a Psoriasis Scalp Severity Index 90 (PSSI 90) at Week 16

End point title	Percentage of Participants with a Psoriasis Scalp Severity Index 90 (PSSI 90) at Week 16
End point description:	
<p>PSSI 90 response as a percentage of participants who achieve at least 90% improvement from baseline in the PSSI score at Week 16. PSSI assesses severity of scalp disease in participants with scalp involvement with a 5-point Likert-type scale on the clinical parameters of erythema, induration, and desquamation. The scores are summed and multiplied by an integer (0 to 6) that represents the area of affected scalp. The PSSI score ranges from 0 to 72 with higher scores indicating more severe symptoms. NA= -99999</p>	
End point type	Secondary
End point timeframe:	
Baseline and Week 16	

End point values	Deucravacitinib	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	103	51		
Units: Percentage of responders				
number (confidence interval 95%)				
Full Analysis Set	38.8 (29.4 to 48.9)	2.0 (-99999 to 10.4)		
Patient sub-population (s-PGA \geq 3)	40.6 (30.7 to 51.1)	2.1 (-99999 to 11.3)		

Statistical analyses

Statistical analysis title	Odds Ratio (OR)
Statistical analysis description:	
Patient sub-population (s-PGA \geq 3)	
Comparison groups	Deucravacitinib v Placebo
Number of subjects included in analysis	154
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	37.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.4
upper limit	317.6

Statistical analysis title	Odds Ratio (OR)
Statistical analysis description:	
Full Analysis Set	
Comparison groups	Deucravacitinib v Placebo
Number of subjects included in analysis	154
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	40.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.6
upper limit	352

Secondary: Change from Baseline in Scalp-specific Itch Numerical Rating Scale (NRS) Score at Week 16

End point title	Change from Baseline in Scalp-specific Itch Numerical Rating Scale (NRS) Score at Week 16
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End point description:

Change from baseline in scalp-specific itch numerical rating scale (NRS) score at week 16. The scalp-specific itch NRS is an 11-point horizontal scale anchored at 0 and 10 with 0 representing "no scalp itch" and 10 representing "worst scalp itch imaginable.". Overall severity of a participant's itching from scalp psoriasis is indicated by selecting the number that best describes the worst level of scalp itching within the past 24 hours.

End point type	Secondary
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End point timeframe:

Baseline and Week 16

End point values	Deucravacitinib	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	103	51		
Units: Score on a scale				
arithmetic mean (standard deviation)				
Full Analysis Set	-3.2 (± 2.95)	-0.7 (± 2.27)		
Patient sub-population (s-PGA ≥ 3)	-3.3 (± 2.87)	-0.9 (± 2.29)		

Statistical analyses

Statistical analysis title	Adjusted mean difference
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Statistical analysis description:

Patient sub-population (s-PGA ≥ 3)

Comparison groups	Deucravacitinib v Placebo
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Number of subjects included in analysis	154
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Analysis specification	Pre-specified
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Analysis type

P-value	< 0.0001
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Method	analysis of covariance model
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Parameter estimate	Adjusted mean difference
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Point estimate	-2.4
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Confidence interval

level	95 %
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sides	2-sided
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lower limit	-3.3
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upper limit	-1.5
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Variability estimate	Standard error of the mean
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Dispersion value	0.44
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Statistical analysis title	Adjusted mean difference
Statistical analysis description:	
Full Analysis Set	
Comparison groups	Deucravacitinib v Placebo
Number of subjects included in analysis	154
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	analysis of covariance model
Parameter estimate	Adjusted mean difference
Point estimate	-2.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.3
upper limit	-1.6
Variability estimate	Standard error of the mean
Dispersion value	0.42

Secondary: Percentage of Participants with a Static Physician Global Assessment Score of 0 or 1 (s-PGA 0/1) at Week 16

End point title	Percentage of Participants with a Static Physician Global Assessment Score of 0 or 1 (s-PGA 0/1) at Week 16
End point description:	
s-PGA 0/1 response as a percentage of participants with an s-PGA score of 0 (clear) or 1 (almost clear) with at least a 2-point reduction from baseline at Week 16. The s-PGA is a 5-point scale of an average assessment of all psoriatic lesions based on erythema, scale, and induration. The s-PGA measure determines psoriasis severity at a single point in time (without taking into account the baseline disease condition) as clear (0), almost clear (1), mild (2), moderate (3), or severe (4).	
End point type	Secondary
End point timeframe:	
Baseline and Week 16	

End point values	Deucravacitinib	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	96	47		
Units: Percentage of responders				
number (confidence interval 95%)	51.0 (40.6 to 61.4)	4.3 (0.5 to 14.5)		

Statistical analyses

Statistical analysis title	Odds Ratio (OR)
Comparison groups	Deucravacitinib v Placebo
Number of subjects included in analysis	143
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	23.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.4
upper limit	105.6

Secondary: Number of Participants Experiencing Treatment Emergent Adverse Events (TEAEs)

End point title	Number of Participants Experiencing Treatment Emergent Adverse Events (TEAEs)
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 that does not necessarily have a causal relation with this treatment.	
End point type	Secondary
End point timeframe: From week 0 through week 16	

End point values	Deucravacitinib	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	103	51		
Units: Participants	73	26		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants Experiencing Laboratory Test Results of Worst Toxicity Grade

End point title	Number of Participants Experiencing Laboratory Test Results of Worst Toxicity Grade
End point description: Laboratory test results summary of Worst toxicity grade in SI units for hematology and chemistry using the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 5.0. Grade 1= mild and asymptomatic; Grade 2= moderate requiring minimal, local or noninvasive intervention; Grade 3= severe or medically significant but not immediately life-threatening; Grade 4= events are usually severe enough to require hospitalization.	

End point type	Secondary
End point timeframe:	
Week 0 through Week 16	

End point values	Deucravacitinib	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	103	51		
Units: Participants				
Basophils (10 ⁹ /L) Grade 1-4	0	0		
Eosinophils (10 ⁹ /L) Grade 1	4	2		
Eosinophils (10 ⁹ /L) Grade 2-4	0	0		
Hemoglobin (g/L) Grade 1	5	4		
Hemoglobin (g/L) Grade 2	1	0		
Hemoglobin (g/L) Grade 3	0	0		
Leukocytes (10 ⁹ /L) Grade 1	8	1		
Leukocytes (10 ⁹ /L) Grade 2	0	1		
Leukocytes (10 ⁹ /L) Grade 3-4	0	0		
Lymphocytes Blood Test (10 ⁹ /L) Grade 1	1	1		
Lymphocytes Blood Test (10 ⁹ /L) Grade 2	1	0		
Lymphocytes Blood Test (10 ⁹ /L) Grade 3-4	0	0		
Lymphocytes Plasma Test (10 ⁹ /L) Grade 1	1	1		
Lymphocytes Plasma Test (10 ⁹ /L) Grade 2	1	0		
Lymphocytes Plasma Test (10 ⁹ /L) Grade 3-4	0	0		
Neutrophils (x10 ⁹ /L) Grade 1	5	2		
Neutrophils (x10 ⁹ /L) Grade 2-4	0	0		
Platelets (10 ⁹ /L) Grade 1-4	0	0		
Alanine Aminotransferase (U/L) Grade 1	8	8		
Alanine Aminotransferase (U/L) Grade 2	0	1		
Alanine Aminotransferase (U/L) Grade 3-4	0	0		
Albumin (g/L) Grade 1-4	0	0		
Alkaline Phosphatase (U/L) Grade 1	1	2		
Alkaline Phosphatase (U/L) Grade 2-4	0	0		
Aspartate Aminotransferase (U/L) Grade 1	5	5		
Aspartate Aminotransferase (U/L) Grade 2-4	0	0		
Bilirubin (umol/L) Grade 1	5	3		
Bilirubin (umol/L) Grade 2	1	0		
Bilirubin (umol/L) Grade 3-4	0	0		
Calcium (mmol/L) Grade 1	1	0		
Calcium (mmol/L) Grade 2-4	0	0		
Chloride (mmol/L) Grade 1-4	0	0		
Cholesterol (mmol/L) Grade 1	5	0		

Cholesterol (mmol/L) Grade 2-4	0	0		
Creatine Kinase (U/L) Grade 1-4	0	99999		
Creatinine (umol/L) Grade 1	3	0		
Creatinine (umol/L) Grade 2	1	0		
Creatinine (umol/L) Grade 3-4	0	0		
Direct Bilirubin (umol/L) Grade 1-4	0	0		
Glucose (mmol/L) Grade 1	2	0		
Glucose (mmol/L) Grade 2-4	0	0		
Lactate Dehydrogenase (U/L) Grade 1-4	0	99999		
Magnesium (mmol/L) Grade 1-4	0	99999		
Phosphate (mmol/L) Grade 1-4	0	0		
Potassium (mmol/L) Grade 1	6	2		
Potassium (mmol/L) Grade 2	8	1		
Potassium (mmol/L) Grade 3	0	1		
Potassium (mmol/L) Grade 4	0	0		
Sodium (mmol/L) Grade 1	0	2		
Sodium (mmol/L) Grade 2	1	0		
Sodium (mmol/L) Grade 3-4	0	0		
Triglycerides (mmol/L) Grade 1	27	7		
Triglycerides (mmol/L) Grade 2	2	3		
Triglycerides (mmol/L) Grade 3	1	0		
Triglycerides (mmol/L) Grade 4	0	1		
Urate (umol/L) Grade 1-4	0	99999		
Urea Nitrogen (mmol/L) Grade 1-4	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants Experiencing Serious Treatment Emergent Adverse Events (TEAEs)

End point title	Number of Participants Experiencing Serious Treatment Emergent Adverse Events (TEAEs)
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End point description:

A 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.

End point type	Secondary
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End point timeframe:

From week 0 through week 16

End point values	Deucravacitinib	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	103	51		
Units: Participants	1	1		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants Experiencing Laboratory Abnormalities in Potential Drug-Induced Liver Injury Tests

End point title	Number of Participants Experiencing Laboratory Abnormalities in Potential Drug-Induced Liver Injury Tests
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End point description:

Number of participants with laboratory abnormalities in potential drug-induced liver injury tests.

ALT=alanine aminotransferase

AST=aspartate aminotransferase

ULN=upper limit of normal

End point type	Secondary
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End point timeframe:

Week 0 through Week 16

End point values	Deucravacitinib	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	103	51		
Units: Participants				
ALT or AST > 3 X ULN	0	1		
ALT or AST > 5 X ULN	0	0		
Total Bilirubin > 2 X ULN	0	0		
ALT/AST>3XULN, total bilirubin>2XULN on same day	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Abnormalities in Vital Signs

End point title	Number of Participants with Abnormalities in Vital Signs
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End point description:

Number of participants with abnormalities in vital signs including heart rate (HR), systolic blood pressure (SBP), and diastolic blood pressure (DBP).

End point type	Secondary
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End point timeframe:

Week 0 through Week 16

End point values	Deucravacitinib	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	103	51		
Units: Participants				
HR (BEATS/MIN): >100 AND CHANGE FROM BASELINE>30	0	0		
HR (BEATS/MIN) <55 AND CHANGE FROM BASELINE<-15	1	3		
HR (BEATS/MIN): NOT REPORTED	0	0		
SBP (MMHG) >140 AND CHANGE FROM BASELINE >20	3	4		
SBP (MMHG) <90 AND CHANGE FROM BASELINE <-20	0	0		
SBP (MMHG): NOT REPORTED	0	0		
DBP (MMHG) >90 AND CHANGE FROM BASELINE >10	8	3		
DBP (MMHG): <55 AND CHANGE FROM BASELINE <-10	0	2		
DBP (MMHG): NOT REPORTED	0	0		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Participants were assessed for deaths (all-cause) from their first dose to their study completion (Up to 24 months). SAEs and Other AEs were assessed from first dose up to 30 days post last dose (Up to 13 months).

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
Dictionary version	27.1

Reporting groups

Reporting group title	Placebo Controlled - Deucravacitinib
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Reporting group description:

Deucravacitinib 6 mg daily (QD)

Reporting group title	Active Treatment – Placebo - Deucravacitinib
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Reporting group description:

Deucravacitinib 6 mg daily (QD)

Reporting group title	Active Treatment - Deucravacitinib - Deucravacitinib
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Reporting group description:

Deucravacitinib 6 mg daily (QD)

Reporting group title	Placebo Controlled - Placebo
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Reporting group description:

Placebo matching Deucravacitinib daily (QD)

Serious adverse events	Placebo Controlled - Deucravacitinib	Active Treatment – Placebo - Deucravacitinib	Active Treatment - Deucravacitinib - Deucravacitinib
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 103 (0.97%)	0 / 45 (0.00%)	4 / 94 (4.26%)
number of deaths (all causes)	0	0	1
number of deaths resulting from adverse events	0	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Colorectal adenocarcinoma			
subjects affected / exposed	0 / 103 (0.00%)	0 / 45 (0.00%)	1 / 94 (1.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Meniscus injury			
subjects affected / exposed	1 / 103 (0.97%)	0 / 45 (0.00%)	0 / 94 (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

Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 103 (0.00%)	0 / 45 (0.00%)	0 / 94 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 103 (0.00%)	0 / 45 (0.00%)	1 / 94 (1.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Respiratory, thoracic and mediastinal disorders			
Pulmonary embolism			
subjects affected / exposed	0 / 103 (0.00%)	0 / 45 (0.00%)	1 / 94 (1.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Ligament disorder			
subjects affected / exposed	0 / 103 (0.00%)	0 / 45 (0.00%)	1 / 94 (1.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Placebo Controlled - Placebo		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 51 (1.96%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Colorectal adenocarcinoma			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Meniscus injury			

subjects affected / exposed	0 / 51 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	1 / 51 (1.96%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Myocardial infarction			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Pulmonary embolism			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Ligament disorder			
subjects affected / exposed	0 / 51 (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	Placebo Controlled - Deucravacitinib	Active Treatment – Placebo - Deucravacitinib	Active Treatment - Deucravacitinib - Deucravacitinib
Total subjects affected by non-serious adverse events			
subjects affected / exposed	47 / 103 (45.63%)	16 / 45 (35.56%)	42 / 94 (44.68%)
Nervous system disorders			
Headache			
subjects affected / exposed	8 / 103 (7.77%)	1 / 45 (2.22%)	2 / 94 (2.13%)
occurrences (all)	9	1	2
Skin and subcutaneous tissue disorders			

Psoriasis			
subjects affected / exposed	2 / 103 (1.94%)	0 / 45 (0.00%)	4 / 94 (4.26%)
occurrences (all)	2	0	4
Acne			
subjects affected / exposed	10 / 103 (9.71%)	1 / 45 (2.22%)	1 / 94 (1.06%)
occurrences (all)	12	1	1
Infections and infestations			
Acne pustular			
subjects affected / exposed	6 / 103 (5.83%)	0 / 45 (0.00%)	3 / 94 (3.19%)
occurrences (all)	6	0	3
COVID-19			
subjects affected / exposed	6 / 103 (5.83%)	4 / 45 (8.89%)	12 / 94 (12.77%)
occurrences (all)	6	4	12
Nasopharyngitis			
subjects affected / exposed	16 / 103 (15.53%)	8 / 45 (17.78%)	22 / 94 (23.40%)
occurrences (all)	20	12	25
Upper respiratory tract infection			
subjects affected / exposed	12 / 103 (11.65%)	3 / 45 (6.67%)	11 / 94 (11.70%)
occurrences (all)	13	3	13

Non-serious adverse events	Placebo Controlled - Placebo		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	14 / 51 (27.45%)		
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 51 (3.92%)		
occurrences (all)	3		
Skin and subcutaneous tissue disorders			
Psoriasis			
subjects affected / exposed	3 / 51 (5.88%)		
occurrences (all)	3		
Acne			
subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Acne pustular			

subjects affected / exposed	0 / 51 (0.00%)		
occurrences (all)	0		
COVID-19			
subjects affected / exposed	4 / 51 (7.84%)		
occurrences (all)	4		
Nasopharyngitis			
subjects affected / exposed	7 / 51 (13.73%)		
occurrences (all)	7		
Upper respiratory tract infection			
subjects affected / exposed	2 / 51 (3.92%)		
occurrences (all)	2		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
19 May 2022	Endpoints Classification Update
05 December 2022	Schedule of Activity Update
23 May 2023	exclusion criteria update

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported