



Clinical trial results:

Phase 1/2A, randomized, placebo-controlled, single-ascending dose (Part A, participant- and investigator-blind) and repeated-dose (Part B, participant-, investigator-, and sponsor-blind) study to investigate the safety, pharmacokinetics, and efficacy of UCB9741 in healthy study participants (Part A) and in study participants with moderate-to-severe atopic dermatitis (Part B)

Summary

EudraCT number	2020-003639-41
Trial protocol	GB NL BG DE ES BE
Global end of trial date	06 June 2024

Results information

Result version number	v2 (current)
This version publication date	23 October 2025
First version publication date	21 June 2025
Version creation reason	<ul style="list-style-type: none">• Correction of full data set Correction of data in all efficacy outcome measures.

Trial information

Trial identification

Sponsor protocol code	UP0089
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04643457
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	UCB Biopharma SRL
Sponsor organisation address	Allée de la Recherche 60, Brussels, Belgium, 1070
Public contact	Clin Trial Reg & Results Disclosure, UCB BIOSCIENCES GmbH, clinicaltrials@ucb.com
Scientific contact	Clin Trial Reg & Results Disclosure, UCB BIOSCIENCES GmbH, clinicaltrials@ucb.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	18 July 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	23 April 2024
Global end of trial reached?	Yes
Global end of trial date	06 June 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

- Investigation of safety and tolerability of single-ascending doses of UCB9741 administered by intravenous (iv) infusion or subcutaneous (sc) injection to healthy study participants
- Investigation of safety and tolerability of UCB9741 following repeat-dosing at a single dose level in study participants with atopic dermatitis (AtD)
- Investigation of a primary clinical outcome in study participants with AtD after administration of UCB9741 by iv infusion

Protection of trial subjects:

During the conduct of the study all participants were closely monitored.

Background therapy:

Part A

The following concomitant medications were permitted during Part A of the study:

- Analgesics, such as paracetamol (acetaminophen), with or without caffeine, with a maximal dose of 4 gram per day (g/day) and 10g/14 days
- Contraceptives (oral, implant, or intrauterine devices)

Part B

The following concomitant medications were permitted during Part B of the study:

- Mild topical corticosteroids (TCS), under the direction of the investigator, were permitted for rescue use to treat flares occurring during the study period once a randomized participant reached 2 weeks after first investigational medicinal product (IMP) administration. Such use of mild TCS was discontinued if the investigator and study participant agreed that it was no longer clinically required. Nevertheless, the study participant continued to receive IMP and complete the study as planned. Participants were not randomized if any TCS was used during the 2 weeks prior to randomization.
- Non-pharmacologically-active topical interventions (unguents or creams). Skin emollients/moisturizers, when applied, was used at a stable dose and frequency for 7 days prior to the Baseline Visit.
- Analgesics, such as paracetamol (acetaminophen), with or without caffeine, with a maximal dose of 4g/day and 10g/14 days
- Intranasal corticosteroids for seasonal rhinitis or inhaled bronchodilators and/or inhaled low dose corticosteroids in participants with mild asthma
- Contraceptives (oral, implants, or intrauterine devices)

If a coronavirus disease 2019 (COVID-19) or influenza vaccine dose was administered during study participation, full details were recorded in the concomitant medication electronic Case Report form (eCRF) page. The specific name of the vaccine and the exact date of administration was recorded.

Evidence for comparator:

Not applicable

Actual start date of recruitment	27 November 2020
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	United Kingdom: 73
Country: Number of subjects enrolled	Bulgaria: 20
Country: Number of subjects enrolled	Germany: 6
Country: Number of subjects enrolled	Netherlands: 7
Worldwide total number of subjects	106
EEA total number of subjects	33

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)	106
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study started to enroll participants in November 2020 and concluded in June 2024.

Pre-assignment

Screening details:

The Participant Flow refers to the All Study Participants Set. A total of 107 participants were randomized and enrolled in this study. Out of them, 106 participants have received any treatment. One participant from Part B: UCB9741 Dose 6 discontinued before taking any treatment.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Part A: Placebo

Arm description:

Healthy participants received placebo (matching to UCB9741) as a single intravenous (iv) or subcutaneous (sc) administration within each cohort of Part A on Day 1. Participant assigned were dosed in a sentinel dosing strategy i.e. one participant was dosed with placebo iv or sc and assessed for safety at least 24 hours in advance and then rest of the cohort follows. Pooled data of placebo (matching to UCB9741) is reported.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use, Subcutaneous use

Dosage and administration details:

Healthy participants received placebo (matching to UCB9741) within each cohort of Part A on Day 1.

Arm title	Part A: UCB9741 Dose 1
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Arm description:

Healthy participants received UCB9741 Dose 1 as a single administration on Day 1. Participant assigned were dosed in a sentinel dosing strategy i.e. one participant was dosed with UCB9741 Dose 1 and assessed for safety at least 24 hours in advance and then rest of the cohort follows.

Arm type	Experimental
Investigational medicinal product name	UCB9741
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Not mentioned

Dosage and administration details:

Healthy participants received UCB9741 Dose 1 on Day 1.

Arm title	Part A: UCB9741 Dose 2
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Arm description:

Healthy participants received UCB9741 Dose 2 as a single administration on Day 1. Participant assigned were dosed in a sentinel dosing strategy i.e. one participant was dosed with UCB9741 Dose 2 and assessed for safety at least 24 hours in advance and then rest of the cohort follows.

Arm type	Experimental
Investigational medicinal product name	UCB9741
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Not mentioned

Dosage and administration details:

Healthy participants received UCB9741 Dose 2 on Day 1.

Arm title	Part A: UCB9741 Dose 3
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Arm description:

Healthy participants received UCB9741 Dose 3 as a single administration on Day 1. Participant assigned were dosed in a sentinel dosing strategy i.e. one participant was dosed with UCB9741 Dose 3 and assessed for safety at least 24 hours in advance and then rest of the cohort follows.

Arm type	Experimental
Investigational medicinal product name	UCB9741
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Not mentioned

Dosage and administration details:

Healthy participants received UCB9741 Dose 3 on Day 1.

Arm title	Part A: UCB9741 Dose 4
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Arm description:

Healthy participants received UCB9741 Dose 4 as a single administration on Day 1. Participant assigned were dosed in a sentinel dosing strategy i.e. one participant was dosed with UCB9741 Dose 4 and assessed for safety at least 24 hours in advance and then rest of the cohort follows.

Arm type	Experimental
Investigational medicinal product name	UCB9741
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Not mentioned

Dosage and administration details:

Healthy participants received UCB9741 Dose 4 on Day 1.

Arm title	Part A: UCB9741 Dose 5
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Arm description:

Healthy participants received UCB9741 Dose 5 as a single administration on Day 1. Participant assigned were dosed in a sentinel dosing strategy i.e. one participant was dosed with UCB9741 Dose 5 and assessed for safety at least 24 hours in advance and then rest of the cohort follows.

Arm type	Experimental
Investigational medicinal product name	UCB9741
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Not mentioned

Dosage and administration details:

Healthy participants received UCB9741 Dose 5 on Day 1.

Arm title	Part A: UCB9741 Dose 6
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Arm description:

Healthy participants received UCB9741 Dose 6 as a single administration on Day 1. Participant assigned were dosed in a sentinel dosing strategy i.e. one participant was dosed with UCB9741 Dose 6 and assessed for safety at least 24 hours in advance and then rest of the cohort follows.

Arm type	Experimental
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Investigational medicinal product name	UCB9741
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Not mentioned

Dosage and administration details:

Healthy participants received UCB9741 Dose 6 on Day 1.

Arm title	Part A: UCB9741 Dose 7
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Arm description:

Healthy participants received UCB9741 Dose 7 as a single administration on Day 1. Participant assigned were dosed in a sentinel dosing strategy i.e. one participant was dosed with UCB9741 Dose 7 and assessed for safety at least 24 hours in advance and then rest of the cohort follows.

Arm type	Experimental
Investigational medicinal product name	UCB9741
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Not mentioned

Dosage and administration details:

Healthy participants received UCB9741 Dose 7 on Day 1.

Arm title	Part B: Placebo
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Arm description:

Participants with moderate-to-severe atopic dermatitis received placebo (matched to UCB9741). Participant assigned were dosed in a sentinel dosing strategy i.e. after the eighth participant received their first dose, dosing of any subsequent participants was held until the eighth participant received their third dose of study medication and assessed for safety at least 48 hours in advance and then dosing in rest of the participants followed.

Arm type	Placebo
Investigational medicinal product name	UCB9741
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Not mentioned

Dosage and administration details:

Participants with moderate-to-severe atopic dermatitis received placebo (matched to UCB9741) at repeated interval.

Arm title	Part B: UCB9741 Dose 6
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Arm description:

Participants with moderate-to-severe atopic dermatitis received UCB9741 Dose 6. Participant assigned were dosed in a sentinel dosing strategy i.e. after the eighth participant received their first dose, dosing of any subsequent participants was held until the eighth participant received their third dose of study medication and assessed for safety at least 48 hours in advance and then dosing in rest of the participants followed.

Arm type	Experimental
Investigational medicinal product name	UCB9741
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Not mentioned

Dosage and administration details:

Participants with moderate-to-severe atopic dermatitis received UCB9741 Dose 6 at repeated interval.

Number of subjects in period 1	Part A: Placebo	Part A: UCB9741 Dose 1	Part A: UCB9741 Dose 2
Started	16	6	6
Part A: Placebo iv	11 ^[1]	0 ^[2]	0 ^[3]
Part A: Placebo sc	5 ^[4]	0 ^[5]	0 ^[6]
Completed	16	6	6
Not completed	0	0	0
Adverse event, non-fatal	-	-	-
Consent Withdrawn	-	-	-

Number of subjects in period 1	Part A: UCB9741 Dose 3	Part A: UCB9741 Dose 4	Part A: UCB9741 Dose 5
Started	6	6	7
Part A: Placebo iv	0 ^[7]	0 ^[8]	0 ^[9]
Part A: Placebo sc	0 ^[10]	0 ^[11]	0 ^[12]
Completed	6	6	7
Not completed	0	0	0
Adverse event, non-fatal	-	-	-
Consent Withdrawn	-	-	-

Number of subjects in period 1	Part A: UCB9741 Dose 6	Part A: UCB9741 Dose 7	Part B: Placebo
Started	6	6	14
Part A: Placebo iv	0 ^[13]	0 ^[14]	0 ^[15]
Part A: Placebo sc	0 ^[16]	0 ^[17]	0 ^[18]
Completed	6	6	13
Not completed	0	0	1
Adverse event, non-fatal	-	-	1
Consent Withdrawn	-	-	-

Number of subjects in period 1	Part B: UCB9741 Dose 6
Started	33
Part A: Placebo iv	0 ^[19]
Part A: Placebo sc	0 ^[20]
Completed	30
Not completed	3
Adverse event, non-fatal	2
Consent Withdrawn	1

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: 11 participants received Placebo iv and 5 participants received Placebo sc.

[2] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that

[18] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: 11 participants received Placebo iv and 5 participants received Placebo sc.

[19] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: 11 participants received Placebo iv and 5 participants received Placebo sc.

[20] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: 11 participants received Placebo iv and 5 participants received Placebo sc.

Baseline characteristics

Reporting groups

Reporting group title	Part A: Placebo
Reporting group description: Healthy participants received placebo (matching to UCB9741) as a single intravenous (iv) or subcutaneous (sc) administration within each cohort of Part A on Day 1. Participant assigned were dosed in a sentinel dosing strategy i.e. one participant was dosed with placebo iv or sc and assessed for safety at least 24 hours in advance and then rest of the cohort follows. Pooled data of placebo (matching to UCB9741) is reported.	
Reporting group title	Part A: UCB9741 Dose 1
Reporting group description: Healthy participants received UCB9741 Dose 1 as a single administration on Day 1. Participant assigned were dosed in a sentinel dosing strategy i.e. one participant was dosed with UCB9741 Dose 1 and assessed for safety at least 24 hours in advance and then rest of the cohort follows.	
Reporting group title	Part A: UCB9741 Dose 2
Reporting group description: Healthy participants received UCB9741 Dose 2 as a single administration on Day 1. Participant assigned were dosed in a sentinel dosing strategy i.e. one participant was dosed with UCB9741 Dose 2 and assessed for safety at least 24 hours in advance and then rest of the cohort follows.	
Reporting group title	Part A: UCB9741 Dose 3
Reporting group description: Healthy participants received UCB9741 Dose 3 as a single administration on Day 1. Participant assigned were dosed in a sentinel dosing strategy i.e. one participant was dosed with UCB9741 Dose 3 and assessed for safety at least 24 hours in advance and then rest of the cohort follows.	
Reporting group title	Part A: UCB9741 Dose 4
Reporting group description: Healthy participants received UCB9741 Dose 4 as a single administration on Day 1. Participant assigned were dosed in a sentinel dosing strategy i.e. one participant was dosed with UCB9741 Dose 4 and assessed for safety at least 24 hours in advance and then rest of the cohort follows.	
Reporting group title	Part A: UCB9741 Dose 5
Reporting group description: Healthy participants received UCB9741 Dose 5 as a single administration on Day 1. Participant assigned were dosed in a sentinel dosing strategy i.e. one participant was dosed with UCB9741 Dose 5 and assessed for safety at least 24 hours in advance and then rest of the cohort follows.	
Reporting group title	Part A: UCB9741 Dose 6
Reporting group description: Healthy participants received UCB9741 Dose 6 as a single administration on Day 1. Participant assigned were dosed in a sentinel dosing strategy i.e. one participant was dosed with UCB9741 Dose 6 and assessed for safety at least 24 hours in advance and then rest of the cohort follows.	
Reporting group title	Part A: UCB9741 Dose 7
Reporting group description: Healthy participants received UCB9741 Dose 7 as a single administration on Day 1. Participant assigned were dosed in a sentinel dosing strategy i.e. one participant was dosed with UCB9741 Dose 7 and assessed for safety at least 24 hours in advance and then rest of the cohort follows.	
Reporting group title	Part B: Placebo
Reporting group description: Participants with moderate-to-severe atopic dermatitis received placebo (matched to UCB9741). Participant assigned were dosed in a sentinel dosing strategy i.e. after the eighth participant received their first dose, dosing of any subsequent participants was held until the eighth participant received their third dose of study medication and assessed for safety at least 48 hours in advance and then dosing in rest of the participants followed.	
Reporting group title	Part B: UCB9741 Dose 6
Reporting group description: Participants with moderate-to-severe atopic dermatitis received UCB9741 Dose 6. Participant assigned were dosed in a sentinel dosing strategy i.e. after the eighth participant received their first dose, dosing of any subsequent participants was held until the eighth participant received their third dose of study medication and assessed for safety at least 48 hours in advance and then dosing in rest of the	

Reporting group values	Part A: Placebo	Part A: UCB9741 Dose 1	Part A: UCB9741 Dose 2
Number of subjects	16	6	6
Age Categorical Units: participants			
18 - <65 years	16	6	6
65 - <85 years	0	0	0
>=85 years	0	0	0
Age Continuous Units: years			
arithmetic mean	32.7	23.2	34.0
standard deviation	± 11.0	± 5.2	± 9.8
Sex: Female, Male Units: participants			
Female	7	4	2
Male	9	2	4

Reporting group values	Part A: UCB9741 Dose 3	Part A: UCB9741 Dose 4	Part A: UCB9741 Dose 5
Number of subjects	6	6	7
Age Categorical Units: participants			
18 - <65 years	6	6	7
65 - <85 years	0	0	0
>=85 years	0	0	0
Age Continuous Units: years			
arithmetic mean	29.0	26.2	27.4
standard deviation	± 8.2	± 8.5	± 10.5
Sex: Female, Male Units: participants			
Female	3	2	2
Male	3	4	5

Reporting group values	Part A: UCB9741 Dose 6	Part A: UCB9741 Dose 7	Part B: Placebo
Number of subjects	6	6	14
Age Categorical Units: participants			
18 - <65 years	6	6	14
65 - <85 years	0	0	0
>=85 years	0	0	0
Age Continuous Units: years			
arithmetic mean	35.5	39.8	39.2
standard deviation	± 14.1	± 13.7	± 15.4

Sex: Female, Male			
Units: participants			
Female	3	3	6
Male	3	3	8

Reporting group values	Part B: UCB9741 Dose 6	Total	
Number of subjects	33	106	
Age Categorical			
Units: participants			
18 - <65 years	33	106	
65 - <85 years	0	0	
>=85 years	0	0	
Age Continuous			
Units: years			
arithmetic mean	36.1		
standard deviation	± 10.7	-	
Sex: Female, Male			
Units: participants			
Female	12	44	
Male	21	62	

End points

End points reporting groups

Reporting group title	Part A: Placebo
Reporting group description: Healthy participants received placebo (matching to UCB9741) as a single intravenous (iv) or subcutaneous (sc) administration within each cohort of Part A on Day 1. Participant assigned were dosed in a sentinel dosing strategy i.e. one participant was dosed with placebo iv or sc and assessed for safety at least 24 hours in advance and then rest of the cohort follows. Pooled data of placebo (matching to UCB9741) is reported.	
Reporting group title	Part A: UCB9741 Dose 1
Reporting group description: Healthy participants received UCB9741 Dose 1 as a single administration on Day 1. Participant assigned were dosed in a sentinel dosing strategy i.e. one participant was dosed with UCB9741 Dose 1 and assessed for safety at least 24 hours in advance and then rest of the cohort follows.	
Reporting group title	Part A: UCB9741 Dose 2
Reporting group description: Healthy participants received UCB9741 Dose 2 as a single administration on Day 1. Participant assigned were dosed in a sentinel dosing strategy i.e. one participant was dosed with UCB9741 Dose 2 and assessed for safety at least 24 hours in advance and then rest of the cohort follows.	
Reporting group title	Part A: UCB9741 Dose 3
Reporting group description: Healthy participants received UCB9741 Dose 3 as a single administration on Day 1. Participant assigned were dosed in a sentinel dosing strategy i.e. one participant was dosed with UCB9741 Dose 3 and assessed for safety at least 24 hours in advance and then rest of the cohort follows.	
Reporting group title	Part A: UCB9741 Dose 4
Reporting group description: Healthy participants received UCB9741 Dose 4 as a single administration on Day 1. Participant assigned were dosed in a sentinel dosing strategy i.e. one participant was dosed with UCB9741 Dose 4 and assessed for safety at least 24 hours in advance and then rest of the cohort follows.	
Reporting group title	Part A: UCB9741 Dose 5
Reporting group description: Healthy participants received UCB9741 Dose 5 as a single administration on Day 1. Participant assigned were dosed in a sentinel dosing strategy i.e. one participant was dosed with UCB9741 Dose 5 and assessed for safety at least 24 hours in advance and then rest of the cohort follows.	
Reporting group title	Part A: UCB9741 Dose 6
Reporting group description: Healthy participants received UCB9741 Dose 6 as a single administration on Day 1. Participant assigned were dosed in a sentinel dosing strategy i.e. one participant was dosed with UCB9741 Dose 6 and assessed for safety at least 24 hours in advance and then rest of the cohort follows.	
Reporting group title	Part A: UCB9741 Dose 7
Reporting group description: Healthy participants received UCB9741 Dose 7 as a single administration on Day 1. Participant assigned were dosed in a sentinel dosing strategy i.e. one participant was dosed with UCB9741 Dose 7 and assessed for safety at least 24 hours in advance and then rest of the cohort follows.	
Reporting group title	Part B: Placebo
Reporting group description: Participants with moderate-to-severe atopic dermatitis received placebo (matched to UCB9741). Participant assigned were dosed in a sentinel dosing strategy i.e. after the eighth participant received their first dose, dosing of any subsequent participants was held until the eighth participant received their third dose of study medication and assessed for safety at least 48 hours in advance and then dosing in rest of the participants followed.	
Reporting group title	Part B: UCB9741 Dose 6
Reporting group description: Participants with moderate-to-severe atopic dermatitis received UCB9741 Dose 6. Participant assigned were dosed in a sentinel dosing strategy i.e. after the eighth participant received their first dose, dosing of any subsequent participants was held until the eighth participant received their third dose of study medication and assessed for safety at least 48 hours in advance and then dosing in rest of the	

participants followed.

Subject analysis set title	Part A: Placebo iv
Subject analysis set type	Safety analysis

Subject analysis set description:

Healthy participants received placebo (matching to UCB9741) as a single intravenous (iv) administration within each cohort of Part A on Day 1. Participant assigned were dosed in a sentinel dosing strategy i.e. one participant was dosed with placebo iv and assessed for safety at least 24 hours in advance and then rest of the cohort follows. Pooled data of placebo (matching to UCB9741) is reported.

Subject analysis set title	Part A: Placebo sc
Subject analysis set type	Safety analysis

Subject analysis set description:

Healthy participants received placebo (matching to UCB9741) as a single subcutaneous (sc) administration within each cohort of Part A on Day 1. Participant assigned were dosed in a sentinel dosing strategy i.e. one participant was dosed with placebo sc and assessed for safety at least 24 hours in advance and then rest of the cohort follows. Pooled data of placebo (matching to UCB9741) is reported.

Primary: Percentage of participants with treatment-emergent adverse events (TEAEs) during Part A

End point title	Percentage of participants with treatment-emergent adverse events (TEAEs) during Part A ^{[1][2]}
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End point description:

An AE was any untoward medical occurrence in a patient or clinical study participant temporally associated with the use of IMP, whether or not considered related to the IMP. A TEAE was defined as any AE with a start date/time on or after the first dose of treatment or any unresolved event already present before administration of treatment that worsens in intensity following exposure to the treatment. SS included all study participants who received at least 1 dose of IMP. Study participants were included according to the actual treatment they received.

End point type	Primary
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End point timeframe:

From Baseline up to the End of Study Visit (Week 12) during Part A

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 formal statistical hypothesis testing was planned for this study. Results were summarized as descriptive statistics only.

[2] - 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: Percent change from Baseline in the Eczema Area and Severity Index (EASI) score at Week 12 of Part B

End point values	Part A: UCB9741 Dose 1	Part A: UCB9741 Dose 2	Part A: UCB9741 Dose 3	Part A: UCB9741 Dose 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	6	6	6
Units: percentage of participants				
number (not applicable)	66.7	50.0	66.7	66.7

End point values	Part A: UCB9741 Dose 5	Part A: UCB9741 Dose 6	Part A: UCB9741 Dose 7	Part A: Placebo iv
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	7	6	6	11
Units: percentage of participants				

number (not applicable)	85.7	83.3	66.7	54.5
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End point values	Part A: Placebo SC			
Subject group type	Subject analysis set			
Number of subjects analysed	5			
Units: percentage of participants				
number (not applicable)	80.0			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants with treatment-emergent serious adverse events (TESAEs) during Part A

End point title	Percentage of Participants with treatment-emergent serious adverse events (TESAEs) during Part A ^[3] ^[4]
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End point description:

A TEAE was defined as any AE with a start date/time on or after the first dose of treatment or any unresolved event already present before administration of treatment that worsens in intensity following exposure to the treatment. A Serious Adverse Event (SAE) was any untoward medical occurrence that at any dose:

Results in death

Is life-threatening

Requires inpatient hospitalisation or prolongation of existing hospitalisation

Results in persistent or significant disability/incapacity, or

Is a congenital anomaly/birth defect Other important medical events which based on medical or scientific judgement may jeopardize the patients, or may require medical or surgical intervention to prevent any of the above

SS included all study participants who received at least 1 dose of IMP. Study participants were included according to the actual treatment they received.

End point type	Primary
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End point timeframe:

From Baseline up to the End of Study Visit (Week 12) during Part A

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 formal statistical hypothesis testing was planned for this study. Results were summarized as descriptive statistics only.

[4] - 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: Percent change from Baseline in the Eczema Area and Severity Index (EASI) score at Week 12 of Part B

End point values	Part A: UCB9741 Dose 1	Part A: UCB9741 Dose 2	Part A: UCB9741 Dose 3	Part A: UCB9741 Dose 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	6	6	6
Units: percentage of participants				
number (not applicable)	0	0	0	0

End point values	Part A: UCB9741 Dose 5	Part A: UCB9741 Dose 6	Part A: UCB9741 Dose 7	Part A: Placebo iv
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	7	6	6	11
Units: percentage of participants				
number (not applicable)	14.3	0	0	0

End point values	Part A: Placebo SC			
Subject group type	Subject analysis set			
Number of subjects analysed	5			
Units: percentage of participants				
number (not applicable)	0			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants with TEAEs during Part B

End point title	Percentage of Participants with TEAEs during Part B ^[5] ^[6]
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End point description:

An AE was any untoward medical occurrence in a patient or clinical study participant temporally associated with the use of IMP, whether or not considered related to the IMP. A TEAE was defined as any AE with a start date/time on or after the first dose of treatment or any unresolved event already present before administration of treatment that worsens in intensity following exposure to the treatment. Safety set included all study participants who received at least 1 dose of IMP. Study participants were included according to the actual treatment they received.

End point type	Primary
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End point timeframe:

From Baseline up to the End of Study Visit (Week 18) during Part B

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 formal statistical hypothesis testing was planned for this study. Results were summarized as descriptive statistics only.

[6] - 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: UCB9741 data for Part A is reported in the separate endpoint. Therefore, no data was reported for Part-A arms in this endpoint.

End point values	Part B: Placebo	Part B: UCB9741 Dose 6		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	14	33		
Units: percentage of participants				
number (not applicable)	50.0	72.7		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants with TESAEs during Part B

End point title	Percentage of Participants with TESAEs during Part B ^{[7][8]}
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End point description:

A TEAE was defined as any AE with a start date/time on or after the first dose of treatment or any unresolved event already present before administration of treatment that worsens in intensity following exposure to the treatment. A Serious Adverse Event (SAE) was any untoward medical occurrence that at any dose:

Results in death

Is life-threatening

Requires inpatient hospitalisation or prolongation of existing hospitalisation

Results in persistent or significant disability/incapacity, or

Is a congenital anomaly/birth defect

Other important medical events which based on medical or scientific judgement may jeopardize the patients, or may require medical or surgical intervention to prevent any of the above.

Safety set included all study participants who received at least 1 dose of IMP. Study participants were included according to the actual treatment they received.

End point type	Primary
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End point timeframe:

From Baseline up to the End of Study Visit (Week 18) during Part B

Notes:

[7] - 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 formal statistical hypothesis testing was planned for this study. Results were summarized as descriptive statistics only.

[8] - 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: UCB9741 data for Part A is reported in the separate endpoint. Therefore, no data was reported for Part-A arms in this endpoint.

End point values	Part B: Placebo	Part B: UCB9741 Dose 6		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	14	33		
Units: percentage of participants				
number (not applicable)	0	3.0		

Statistical analyses

Primary: Percentage of Participants with $\geq 75\%$ improvement vs Baseline in Eczema Area and Severity Index (EASI75) score during Part B

End point title	Percentage of Participants with $\geq 75\%$ improvement vs Baseline in Eczema Area and Severity Index (EASI75) score during Part B ^[9] ^[10]
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End point description:

The Eczema Area and Severity Index (EASI) is a validated scoring system that grades physical signs of atopic dermatitis/eczema. A participant's EASI is scored through evaluation of 4 body regions: Head and neck; Trunk; Upper extremities; Lower extremities. The severity of disease is evaluated by assessing each of 4 clinical signs for each area: Erythema; Edema/papulation; Excoriation; Lichenification. The severity of each clinical sign is scored as: 0=None, 1=Mild, 2=Moderate, 3=Severe. The total EASI score ranges from 0 (minimum) to 72 (maximum) points, with the higher scores reflecting the worse severity of atopic dermatitis. A study participant was classified as an EASI75 responder if the EASI score at Week 12 had improved by $\geq 75\%$ from Baseline. For calculation the stringent Non-responder imputation (NRI) has been used. Full analysis set (FAS) included all study participants who were randomized, received IMP, and had at least 1 valid post-Baseline primary assessment observation.

End point type	Primary
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End point timeframe:

Baseline, Week 12

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 formal statistical hypothesis testing was planned for this study. Results were summarized as descriptive statistics only.

[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: UCB9741 data for Part A is reported in the separate endpoint. Therefore, no data was reported for Part-A arms in this endpoint.

End point values	Part B: Placebo	Part B: UCB9741 Dose 6		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	14	33		
Units: percentage of participants				
number (not applicable)	7.1	60.6		

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax from Baseline through the End of Study (EoS) Visit of Part A

End point title	Cmax from Baseline through the End of Study (EoS) Visit of Part A ^[11]
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End point description:

Cmax was the maximum observed serum concentration of UCB9741. Pharmacokinetic information has not been published due to commercial confidentiality. Once this restriction no longer applies, the information will be made available on this registry.

End point type	Secondary
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End point timeframe:

Day (D) 1 predose, end of administration and up to D85 (EoS visit) postdose

Notes:

[11] - 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: Percent change from Baseline in the Eczema Area and Severity Index (EASI) score at Week 12 of Part B

End point values	Part A: UCB9741 Dose 1	Part A: UCB9741 Dose 2	Part A: UCB9741 Dose 3	Part A: UCB9741 Dose 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[12]	0 ^[13]	0 ^[14]	0 ^[15]
Units: micrograms/milliliter (µg/mL)				
geometric mean (geometric coefficient of variation)	()	()	()	()

Notes:

[12] - Pharmacokinetic data withheld for confidentiality; will be shared once restriction ends.

[13] - Pharmacokinetic data withheld for confidentiality; will be shared once restriction ends.

[14] - Pharmacokinetic data withheld for confidentiality; will be shared once restriction ends.

[15] - Pharmacokinetic data withheld for confidentiality; will be shared once restriction ends.

End point values	Part A: UCB9741 Dose 5	Part A: UCB9741 Dose 6	Part A: UCB9741 Dose 7	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0 ^[16]	0 ^[17]	0 ^[18]	
Units: micrograms/milliliter (µg/mL)				
geometric mean (geometric coefficient of variation)	()	()	()	

Notes:

[16] - Pharmacokinetic data withheld for confidentiality; will be shared once restriction ends.

[17] - Pharmacokinetic data withheld for confidentiality; will be shared once restriction ends.

[18] - Pharmacokinetic data withheld for confidentiality; will be shared once restriction ends.

Statistical analyses

No statistical analyses for this end point

Secondary: tmax from Baseline through the End of Study (EoS) Visit of Part A

End point title	tmax from Baseline through the End of Study (EoS) Visit of Part A ^[19]
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End point description:

tmax was the time of occurrence of Cmax. Pharmacokinetic information has not been published due to commercial confidentiality. Once this restriction no longer applies, the information will be made available on this registry.

End point type	Secondary
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End point timeframe:

Day (D) 1 predose, end of administration and up to D85 (EoS visit) postdose

Notes:

[19] - 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: Percent change from Baseline in the Eczema Area and Severity Index (EASI) score at Week 12 of Part B

End point values	Part A: UCB9741 Dose 1	Part A: UCB9741 Dose 2	Part A: UCB9741 Dose 3	Part A: UCB9741 Dose 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[20]	0 ^[21]	0 ^[22]	0 ^[23]
Units: hour				
median (full range (min-max))	(to)	(to)	(to)	(to)

Notes:

[20] - Pharmacokinetic data withheld for confidentiality; will be shared once restriction ends.

[21] - Pharmacokinetic data withheld for confidentiality; will be shared once restriction ends.

[22] - Pharmacokinetic data withheld for confidentiality; will be shared once restriction ends.

[23] - Pharmacokinetic data withheld for confidentiality; will be shared once restriction ends.

End point values	Part A: UCB9741 Dose 5	Part A: UCB9741 Dose 6	Part A: UCB9741 Dose 7	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0 ^[24]	0 ^[25]	0 ^[26]	
Units: hour				
median (full range (min-max))	(to)	(to)	(to)	

Notes:

[24] - Pharmacokinetic data withheld for confidentiality; will be shared once restriction ends.

[25] - Pharmacokinetic data withheld for confidentiality; will be shared once restriction ends.

[26] - Pharmacokinetic data withheld for confidentiality; will be shared once restriction ends.

Statistical analyses

No statistical analyses for this end point

Secondary: AUC(0-t) from Baseline through the End of Study (EoS) Visit of Part A

End point title	AUC(0-t) from Baseline through the End of Study (EoS) Visit of Part A ^[27]
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End point description:

AUC(0-t) was the area under the serum concentration-time curve from time zero to the time of last detectable concentration. Pharmacokinetic information has not been published due to commercial confidentiality. Once this restriction no longer applies, the information will be made available on this registry.

End point type	Secondary
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End point timeframe:

Day (D) 1 predose, end of administration and up to D85 (EoS visit) postdose

Notes:

[27] - 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: Percent change from Baseline in the Eczema Area and Severity Index (EASI) score at Week 12 of Part B

End point values	Part A: UCB9741 Dose 1	Part A: UCB9741 Dose 2	Part A: UCB9741 Dose 3	Part A: UCB9741 Dose 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[28]	0 ^[29]	0 ^[30]	0 ^[31]
Units: day*µg/mL				
geometric mean (geometric coefficient of variation)	()	()	()	()

Notes:

[28] - Pharmacokinetic data withheld for confidentiality; will be shared once restriction ends.

[29] - Pharmacokinetic data withheld for confidentiality; will be shared once restriction ends.

[30] - Pharmacokinetic data withheld for confidentiality; will be shared once restriction ends.

[31] - Pharmacokinetic data withheld for confidentiality; will be shared once restriction ends.

End point values	Part A: UCB9741 Dose 5	Part A: UCB9741 Dose 6	Part A: UCB9741 Dose 7	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0 ^[32]	0 ^[33]	0 ^[34]	
Units: day*µg/mL				
geometric mean (geometric coefficient of variation)	()	()	()	

Notes:

[32] - Pharmacokinetic data withheld for confidentiality; will be shared once restriction ends.

[33] - Pharmacokinetic data withheld for confidentiality; will be shared once restriction ends.

[34] - Pharmacokinetic data withheld for confidentiality; will be shared once restriction ends.

Statistical analyses

No statistical analyses for this end point

Secondary: AUC from Baseline through the End of Study (EoS) Visit of Part A

End point title	AUC from Baseline through the End of Study (EoS) Visit of Part A ^[35]
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End point description:

AUC was the area under the serum concentration-time curve from time zero to infinity, calculated as $AUC = AUC(0-t) + C_{last}/k_{el}$, where C_{last} was the last observed quantifiable serum concentration and k_{el} is the apparent terminal elimination rate constant. Pharmacokinetic information has not been published due to commercial confidentiality. Once this restriction no longer applies, the information will be made available on this registry.

End point type	Secondary
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End point timeframe:

Day (D) 1 predose, end of administration and up to D85 (EoS visit) postdose

Notes:

[35] - 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: Percent change from Baseline in the Eczema Area and Severity Index (EASI) score at Week 12 of Part B

End point values	Part A: UCB9741 Dose 1	Part A: UCB9741 Dose 2	Part A: UCB9741 Dose 3	Part A: UCB9741 Dose 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[36]	0 ^[37]	0 ^[38]	0 ^[39]
Units: day*µg/mL				
geometric mean (geometric coefficient of variation)	()	()	()	()

Notes:

[36] - Pharmacokinetic data withheld for confidentiality; will be shared once restriction ends.

[37] - Pharmacokinetic data withheld for confidentiality; will be shared once restriction ends.

[38] - Pharmacokinetic data withheld for confidentiality; will be shared once restriction ends.

[39] - Pharmacokinetic data withheld for confidentiality; will be shared once restriction ends.

End point values	Part A: UCB9741 Dose 5	Part A: UCB9741 Dose 6	Part A: UCB9741 Dose 7	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0 ^[40]	0 ^[41]	0 ^[42]	
Units: day*µg/mL				
geometric mean (geometric coefficient of variation)	()	()	()	

Notes:

[40] - Pharmacokinetic data withheld for confidentiality; will be shared once restriction ends.

[41] - Pharmacokinetic data withheld for confidentiality; will be shared once restriction ends.

[42] - Pharmacokinetic data withheld for confidentiality; will be shared once restriction ends.

Statistical analyses

No statistical analyses for this end point

Secondary: Bioavailability (F%) of SC administration from Baseline through the End of Study (EoS) Visit of Part A

End point title	Bioavailability (F%) of SC administration from Baseline through the End of Study (EoS) Visit of Part A ^[43]
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End point description:

F%= Bioavailability of subcutaneous route. F absolute(%)=(geometric mean AUC sc/geometric mean AUC iv)*(Dose iv/Dose sc)*100.

Pharmacokinetic information has not been published due to commercial confidentiality. Once this restriction no longer applies, the information will be made available on this registry.

End point type	Secondary
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End point timeframe:

Day (D) 1 predose, end of administration and up to D85 (EoS visit) postdose

Notes:

[43] - 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: Percent change from Baseline in the Eczema Area and Severity Index (EASI) score at Week 12 of Part B

End point values	Part A: UCB9741 Dose 5	Part A: UCB9741 Dose 6		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0 ^[44]	0 ^[45]		
Units: percent bioavailability				
geometric mean (confidence interval 95%)	(to)	(to)		

Notes:

[44] - Pharmacokinetic data withheld for confidentiality; will be shared once restriction ends.

[45] - Pharmacokinetic data withheld for confidentiality; will be shared once restriction ends.

Statistical analyses

No statistical analyses for this end point

Secondary: Percent change from Baseline in the Eczema Area and Severity Index (EASI) score at Week 12 of Part B

End point title	Percent change from Baseline in the Eczema Area and Severity Index (EASI) score at Week 12 of Part B ^[46]
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End point description:

The EASI is a validated scoring system that grades the physical signs of atopic dermatitis/eczema. A participant's EASI is scored through evaluation of 4 body regions: Head and neck; Trunk; Upper extremities; Lower extremities. The severity of disease is evaluated by assessing each of 4 clinical signs for each area: Erythema; Edema/papulation; Excoriation; Lichenification. The severity of each clinical sign is scored as: 0=None, 1=Mild, 2=Moderate, 3=Severe. The total EASI score ranges from 0 (minimum) to 72 (maximum) points, with the higher scores reflecting the worse severity of atopic dermatitis. Lower values for percent change from Baseline in EASI scores (ie, more negative values) indicated improvement. FAS included all study participants who were randomized, received IMP, and had at least 1 valid post-Baseline primary assessment observation.

End point type	Secondary
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End point timeframe:

Baseline, Week 12

Notes:

[46] - 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: UCB9741 data for Part A is reported in the separate endpoint. Therefore, no data was reported for Part-A arms in this endpoint.

End point values	Part B: Placebo	Part B: UCB9741 Dose 6		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	14	33		
Units: percent change				
least squares mean (standard error)	-24.69 (± 10.461)	-80.68 (± 6.395)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with ≥50% improvement vs Baseline in EASI score (EASI50) at Week 12 during Part B

End point title	Percentage of Participants with ≥50% improvement vs Baseline in EASI score (EASI50) at Week 12 during Part B ^[47]
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End point description:

The Eczema Area and Severity Index (EASI) is a validated scoring system that grades the physical signs of atopic dermatitis/eczema. A participant's EASI is scored through evaluation of 4 body regions: Head and neck; Trunk; Upper extremities; Lower extremities. The severity of disease is evaluated by assessing each of 4 clinical signs for each area: Erythema; Edema/papulation; Excoriation; Lichenification. The severity of each clinical sign is scored as: 0=None, 1=Mild, 2=Moderate, 3=Severe. The total EASI score ranges from 0 (minimum) to 72 (maximum) points, with the higher scores reflecting the worse severity of atopic dermatitis. An EASI50 response was defined as a 50% or more improvement from Baseline. For calculation NRI has been used. For calculation the stringent NRI has been used. FAS included all study participants who were randomized, received IMP, and had at least 1 valid post-Baseline primary assessment observation.

End point type	Secondary
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End point timeframe:

Baseline, Week 12

Notes:

[47] - 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: UCB9741 data for Part A is reported in the separate endpoint. Therefore, no data was reported for Part-A arms in this endpoint.

End point values	Part B: Placebo	Part B: UCB9741 Dose 6		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	14	33		
Units: percentage of participants				
number (not applicable)	14.3	75.8		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with $\geq 90\%$ improvement vs Baseline in EASI score (EASI90) at Week 12 during Part B

End point title	Percentage of Participants with $\geq 90\%$ improvement vs Baseline in EASI score (EASI90) at Week 12 during Part B ^[48]
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End point description:

The Eczema Area and Severity Index (EASI) is a validated scoring system that grades the physical signs of atopic dermatitis/eczema. A participant's EASI is scored through evaluation of 4 body regions: Head and neck; Trunk; Upper extremities; Lower extremities. The severity of disease is evaluated by assessing each of 4 clinical signs for each area: Erythema; Edema/papulation; Excoriation; Lichenification. The severity of each clinical sign is scored as: 0=None, 1=Mild, 2=Moderate, 3=Severe. The total EASI score ranges from 0 (minimum) to 72 (maximum) points, with the higher scores reflecting the worse severity of atopic dermatitis. An EASI90 response was defined as a 90% or more improvement from Baseline. For calculation the stringent NRI has been used. FAS included all study participants who were randomized, received IMP, and had at least 1 valid post-Baseline primary assessment observation.

End point type	Secondary
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End point timeframe:

Baseline, Week 12

Notes:

[48] - 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: UCB9741 data for Part A is reported in the separate endpoint. Therefore, no data was reported for Part-A arms in this endpoint.

End point values	Part B: Placebo	Part B: UCB9741 Dose 6		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	14	33		
Units: percentage of participants				
number (not applicable)	0	45.5		

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax after the final dose of Part B

End point title	Cmax after the final dose of Part B ^[49]
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End point description:

C_{max} was the maximum observed serum concentration of UCB9741. Pharmacokinetic information has not been published due to commercial confidentiality. Once this restriction no longer applies, the information will be made available on this registry.

End point type	Secondary
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End point timeframe:

Day 1 predose, end of administration and up to D127

Notes:

[49] - 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: UCB9741 data for Part A is reported in the separate endpoint. Therefore, no data was reported for Part-A arms in this endpoint.

End point values	Part B: UCB9741 Dose 6			
Subject group type	Reporting group			
Number of subjects analysed	0 ^[50]			
Units: µg/mL				
geometric mean (geometric coefficient of variation)	()			

Notes:

[50] - Pharmacokinetic data withheld for confidentiality; will be shared once restriction ends.

Statistical analyses

No statistical analyses for this end point

Secondary: t_{max} after the final dose of Part B

End point title	t _{max} after the final dose of Part B ^[51]
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End point description:

t_{max} was the time of occurrence of C_{max}. Pharmacokinetic information has not been published due to commercial confidentiality. Once this restriction no longer applies, the information will be made available on this registry.

End point type	Secondary
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End point timeframe:

Day 1 predose, end of administration and up to D127

Notes:

[51] - 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: UCB9741 data for Part A is reported in the separate endpoint. Therefore, no data was reported for Part-A arms in this endpoint.

End point values	Part B: UCB9741 Dose 6			
Subject group type	Reporting group			
Number of subjects analysed	0 ^[52]			
Units: hour				
median (full range (min-max))	(to)			

Notes:

[52] - Pharmacokinetic data withheld for confidentiality; will be shared once restriction ends.

Statistical analyses

No statistical analyses for this end point

Secondary: AUCtau after the final dose of Part B

End point title	AUCtau after the final dose of Part B ^[53]
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End point description:

AUCtau was the area under the curve for the dosing interval after the final dose. Pharmacokinetic information has not been published due to commercial confidentiality. Once this restriction no longer applies, the information will be made available on this registry.

End point type	Secondary
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End point timeframe:

Day 1 predose, end of administration and up to D127

Notes:

[53] - 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: UCB9741 data for Part A is reported in the separate endpoint. Therefore, no data was reported for Part-A arms in this endpoint.

End point values	Part B: UCB9741 Dose 6			
Subject group type	Reporting group			
Number of subjects analysed	0 ^[54]			
Units: day*µg/mL				
geometric mean (geometric coefficient of variation)	()			

Notes:

[54] - Pharmacokinetic data withheld for confidentiality; will be shared once restriction ends.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Part A: From Baseline up to the End of Study Visit (Week 12); Part B: From Baseline up to the End of Study Visit (Week 18)

Adverse event reporting additional description:

A TEAE was defined as any AE with a start date/time on or after the first dose of treatment or any unresolved event already present before administration of treatment that worsened in intensity following exposure to the treatment. SS included all study participants who received at least one dose of study treatment.

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	27.0
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Reporting groups

Reporting group title	Part A: Placebo iv
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Reporting group description:

Healthy participants received placebo (matching to UCB9741) as a single intravenous (iv) administration within each cohort of Part A on Day 1. One participant within each cohort assigned to placebo was dosed with a sentinel dosing strategy i.e. participant was dosed at least 24 hours in advance of the rest of the cohort and assessed for safety. Pooled data of placebo (matching to UCB9741) is reported.

Reporting group title	Part A: Placebo sc
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Reporting group description:

Healthy participants received placebo (matching to UCB9741) as a single subcutaneous (sc) administration within each cohort of Part A on Day 1. One participant within each cohort assigned to placebo was dosed with a sentinel dosing strategy i.e. participant was dosed at least 24 hours in advance of the rest of the cohort and assessed for safety. Pooled data of placebo (matching to UCB9741) is reported.

Reporting group title	Part A: UCB9741 Dose 1
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Reporting group description:

Healthy participants received UCB9741 Dose 1 as a single administration on Day 1. One participant assigned to UCB9741 Dose 1 was dosed with a sentinel dosing strategy i.e. participant was dosed at least 24 hours in advance of the rest of the cohort and assessed for safety.

Reporting group title	Part A: UCB9741 Dose 2
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Reporting group description:

Healthy participants received UCB9741 Dose 2 as a single administration on Day 1. One participant assigned to UCB9741 Dose 2 was dosed with a sentinel dosing strategy i.e. participant was dosed at least 24 hours in advance of the rest of the cohort and assessed for safety.

Reporting group title	Part A: UCB9741 Dose 3
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Reporting group description:

Healthy participants received UCB9741 Dose 3 as a single administration on Day 1. One participant assigned to UCB9741 Dose 3 was dosed with a sentinel dosing strategy i.e. participant was dosed at least 24 hours in advance of the rest of the cohort and assessed for safety.

Reporting group title	Part A: UCB9741 Dose 4
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Reporting group description:

Healthy participants received UCB9741 Dose 4 as a single administration on Day 1. One participant assigned to UCB9741 Dose 4 was dosed with a sentinel dosing strategy i.e. participant was dosed at least 24 hours in advance of the rest of the cohort and assessed for safety.

Reporting group title	Part A: UCB9741 Dose 6
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Reporting group description:

Healthy participants received UCB9741 Dose 6 as a single administration on Day 1. One participant assigned to UCB9741 Dose 6 was dosed with a sentinel dosing strategy i.e. participant was dosed at least 24 hours in advance of the rest of the cohort and assessed for safety.

Reporting group title	Part A: UCB9741 Dose 5
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Reporting group description:

Healthy participants received UCB9741 Dose 5 as a single administration on Day 1. One participant assigned to UCB9741 Dose 5 was dosed with a sentinel dosing strategy i.e. participant was dosed at least 24 hours in advance of the rest of the cohort and assessed for safety.

Reporting group title	Part B: Placebo
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Reporting group description:

Participants with moderate-to-severe atopic dermatitis received placebo (matched to UCB9741). Participant assigned were dosed in a sentinel dosing strategy i.e. after the eighth participant received their first dose, dosing of any subsequent participants was held until the eighth participant received their third dose of study medication and assessed for safety at least 48 hours in advance and then dosing in rest of the participants followed.

Reporting group title	Part A: UCB9741 Dose 7
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Reporting group description:

Healthy participants received UCB9741 Dose 7 as a single administration on Day 1. One participant assigned to UCB9741 Dose 7 was dosed with a sentinel dosing strategy i.e. participant was dosed at least 24 hours in advance of the rest of the cohort and assessed for safety.

Reporting group title	Part B: UCB9741 Dose 6
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Reporting group description:

Participants with moderate-to-severe atopic dermatitis received UCB9741 Dose 6. Participant assigned were dosed in a sentinel dosing strategy i.e. after the eighth participant received their first dose, dosing of any subsequent participants was held until the eighth participant received their third dose of study medication and assessed for safety at least 48 hours in advance and then dosing in rest of the participants followed.

Serious adverse events	Part A: Placebo iv	Part A: Placebo sc	Part A: UCB9741 Dose 1
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 11 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Gastrointestinal disorders			
Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 11 (0.00%)	0 / 5 (0.00%)	0 / 6 (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
Psychiatric disorders			
Suicide attempt			
subjects affected / exposed	0 / 11 (0.00%)	0 / 5 (0.00%)	0 / 6 (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	Part A: UCB9741 Dose 2	Part A: UCB9741 Dose 3	Part A: UCB9741 Dose 4
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from	0	0	0

adverse events			
Gastrointestinal disorders			
Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (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
Psychiatric disorders			
Suicide attempt			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (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	Part A: UCB9741 Dose 6	Part A: UCB9741 Dose 5	Part B: Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 14 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Gastrointestinal disorders			
Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 14 (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
Psychiatric disorders			
Suicide attempt			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 14 (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

Serious adverse events	Part A: UCB9741 Dose 7	Part B: UCB9741 Dose 6	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 6 (0.00%)	1 / 33 (3.03%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Gastrointestinal disorders			
Diarrhoea haemorrhagic			

subjects affected / exposed	0 / 6 (0.00%)	1 / 33 (3.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Suicide attempt			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Part A: Placebo iv	Part A: Placebo sc	Part A: UCB9741 Dose 1
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 11 (54.55%)	4 / 5 (80.00%)	4 / 6 (66.67%)
General disorders and administration site conditions			
Vessel puncture site bruise			
subjects affected / exposed	0 / 11 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Medical device site erythema			
subjects affected / exposed	1 / 11 (9.09%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Medical device site dermatitis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 5 (20.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Fatigue			
subjects affected / exposed	0 / 11 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Pyrexia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Catheter site bruise			
subjects affected / exposed	1 / 11 (9.09%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Catheter site swelling			

subjects affected / exposed	1 / 11 (9.09%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Infusion site pain			
subjects affected / exposed	1 / 11 (9.09%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Infusion site dermatitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Injection site erythema			
subjects affected / exposed	0 / 11 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Administration site discomfort			
subjects affected / exposed	0 / 11 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Allergy to animal			
subjects affected / exposed	0 / 11 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Vulvovaginal pruritus			
subjects affected / exposed	0 / 11 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Throat irritation			
subjects affected / exposed	1 / 11 (9.09%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 11 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			

Insomnia subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Investigations Liver function test abnormal subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 5 (0.00%) 0	1 / 6 (16.67%) 1
Injury, poisoning and procedural complications Ligament sprain subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Nervous system disorders Paraesthesia subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	1 / 5 (20.00%) 1	0 / 6 (0.00%) 0
Anosmia subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Tension headache subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 5 (0.00%) 0	1 / 6 (16.67%) 1
Headache subjects affected / exposed occurrences (all)	2 / 11 (18.18%) 4	2 / 5 (40.00%) 2	0 / 6 (0.00%) 0
Hypogeusia subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Dizziness subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Gastrointestinal disorders Toothache subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Nausea			

subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Diarrhoea subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Vomiting subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Skin and subcutaneous tissue disorders			
Dry skin subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Dermatitis contact subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Eczema subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Dermatitis subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Erythema subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	1 / 5 (20.00%) 1	0 / 6 (0.00%) 0
Rash subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Pruritus subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Rash maculo-papular subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0
Dermatitis atopic subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0

Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 11 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 11 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Oral candidiasis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 11 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 11 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
COVID-19			
subjects affected / exposed	0 / 11 (0.00%)	1 / 5 (20.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Tinea barbae			
subjects affected / exposed	0 / 11 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 11 (9.09%)	1 / 5 (20.00%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Rhinitis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 5 (20.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0

Pharyngitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 11 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 11 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part A: UCB9741 Dose 2	Part A: UCB9741 Dose 3	Part A: UCB9741 Dose 4
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 6 (50.00%)	4 / 6 (66.67%)	4 / 6 (66.67%)
General disorders and administration site conditions			
Vessel puncture site bruise			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Medical device site erythema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Medical device site dermatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Fatigue			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Catheter site bruise			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Catheter site swelling			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Infusion site pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Infusion site dermatitis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Injection site erythema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Administration site discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Allergy to animal			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Vulvovaginal pruritus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Throat irritation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Cough			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			

Insomnia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	1 / 6 (16.67%) 2	0 / 6 (0.00%) 0
Investigations Liver function test abnormal subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Injury, poisoning and procedural complications Ligament sprain subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Nervous system disorders Paraesthesia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Anosmia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	1 / 6 (16.67%) 1	0 / 6 (0.00%) 0
Tension headache subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Headache subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1	2 / 6 (33.33%) 2	1 / 6 (16.67%) 1
Hypogeusia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	1 / 6 (16.67%) 1	0 / 6 (0.00%) 0
Dizziness subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Gastrointestinal disorders Toothache subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0
Nausea			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dry skin			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Eczema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Rash			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Pruritus			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dermatitis atopic			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Infections and infestations			
Oral candidiasis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Tinea barbae			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Rhinitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Pharyngitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part A: UCB9741 Dose 6	Part A: UCB9741 Dose 5	Part B: Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 6 (83.33%)	6 / 7 (85.71%)	7 / 14 (50.00%)
General disorders and administration site conditions			
Vessel puncture site bruise			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Medical device site erythema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Medical device site dermatitis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Fatigue			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	1 / 14 (7.14%)
occurrences (all)	0	1	1
Pyrexia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	1 / 14 (7.14%)
occurrences (all)	0	1	1
Catheter site bruise			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Catheter site swelling			

subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Infusion site pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Infusion site dermatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Injection site erythema			
subjects affected / exposed	2 / 6 (33.33%)	2 / 7 (28.57%)	0 / 14 (0.00%)
occurrences (all)	2	2	0
Injection site pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Administration site discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Immune system disorders			
Allergy to animal			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Reproductive system and breast disorders			
Vulvovaginal pruritus			
subjects affected / exposed	1 / 6 (16.67%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	2	0	0
Respiratory, thoracic and mediastinal disorders			
Throat irritation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	2 / 6 (33.33%)	1 / 7 (14.29%)	0 / 14 (0.00%)
occurrences (all)	2	1	0
Cough			
subjects affected / exposed	1 / 6 (16.67%)	0 / 7 (0.00%)	1 / 14 (7.14%)
occurrences (all)	1	0	1
Psychiatric disorders			

Insomnia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 7 (0.00%) 0	0 / 14 (0.00%) 0
Investigations Liver function test abnormal subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	1 / 7 (14.29%) 1	0 / 14 (0.00%) 0
Injury, poisoning and procedural complications Ligament sprain subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 7 (0.00%) 0	0 / 14 (0.00%) 0
Nervous system disorders Paraesthesia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 7 (0.00%) 0	0 / 14 (0.00%) 0
Anosmia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 7 (0.00%) 0	0 / 14 (0.00%) 0
Tension headache subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 7 (0.00%) 0	0 / 14 (0.00%) 0
Headache subjects affected / exposed occurrences (all)	2 / 6 (33.33%) 2	2 / 7 (28.57%) 2	1 / 14 (7.14%) 1
Hypogeusia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 7 (0.00%) 0	0 / 14 (0.00%) 0
Dizziness subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 7 (0.00%) 0	0 / 14 (0.00%) 0
Gastrointestinal disorders Toothache subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 7 (0.00%) 0	0 / 14 (0.00%) 0
Nausea			

subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Diarrhoea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	2
Vomiting			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Dry skin			
subjects affected / exposed	1 / 6 (16.67%)	1 / 7 (14.29%)	0 / 14 (0.00%)
occurrences (all)	1	1	0
Dermatitis contact			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	1 / 6 (16.67%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	2	0	0
Dermatitis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Erythema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Dermatitis atopic			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	3 / 14 (21.43%)
occurrences (all)	0	0	5

Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Myalgia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Pain in extremity			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Oral candidiasis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Oral herpes			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Tinea barbae			
subjects affected / exposed	1 / 6 (16.67%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Rhinitis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	3 / 14 (21.43%)
occurrences (all)	0	1	4

Pharyngitis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	1 / 14 (7.14%)
occurrences (all)	0	1	1
Urinary tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1

Non-serious adverse events	Part A: UCB9741 Dose 7	Part B: UCB9741 Dose 6	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 6 (66.67%)	24 / 33 (72.73%)	
General disorders and administration site conditions			
Vessel puncture site bruise			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	
occurrences (all)	0	0	
Medical device site erythema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	
occurrences (all)	0	0	
Medical device site dermatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	
occurrences (all)	0	0	
Fatigue			
subjects affected / exposed	0 / 6 (0.00%)	1 / 33 (3.03%)	
occurrences (all)	0	1	
Pyrexia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 33 (3.03%)	
occurrences (all)	0	1	
Catheter site bruise			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	
occurrences (all)	0	0	
Catheter site swelling			

subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	
occurrences (all)	0	0	
Infusion site pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 33 (3.03%)	
occurrences (all)	0	1	
Infusion site dermatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	
occurrences (all)	0	0	
Injection site erythema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	
occurrences (all)	0	0	
Injection site pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	
occurrences (all)	0	0	
Administration site discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	
occurrences (all)	0	0	
Immune system disorders			
Allergy to animal			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	
occurrences (all)	0	0	
Reproductive system and breast disorders			
Vulvovaginal pruritus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
Throat irritation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	
occurrences (all)	0	0	
Oropharyngeal pain			
subjects affected / exposed	0 / 6 (0.00%)	4 / 33 (12.12%)	
occurrences (all)	0	4	
Cough			
subjects affected / exposed	0 / 6 (0.00%)	3 / 33 (9.09%)	
occurrences (all)	0	3	
Psychiatric disorders			

Insomnia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 33 (0.00%) 0	
Investigations Liver function test abnormal subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 33 (0.00%) 0	
Injury, poisoning and procedural complications Ligament sprain subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 33 (0.00%) 0	
Nervous system disorders Paraesthesia subjects affected / exposed occurrences (all) Anosmia subjects affected / exposed occurrences (all) Tension headache subjects affected / exposed occurrences (all) Headache subjects affected / exposed occurrences (all) Hypogeusia subjects affected / exposed occurrences (all) Dizziness subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0 0 / 6 (0.00%) 0 0 / 6 (0.00%) 0 2 / 6 (33.33%) 2 0 / 6 (0.00%) 0 0 / 6 (0.00%) 0	0 / 33 (0.00%) 0 0 / 33 (0.00%) 0 0 / 33 (0.00%) 0 4 / 33 (12.12%) 5 0 / 33 (0.00%) 0 4 / 33 (12.12%) 4	
Gastrointestinal disorders Toothache subjects affected / exposed occurrences (all) Nausea	1 / 6 (16.67%) 1	0 / 33 (0.00%) 0	

subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	
occurrences (all)	0	0	
Diarrhoea			
subjects affected / exposed	0 / 6 (0.00%)	3 / 33 (9.09%)	
occurrences (all)	0	3	
Vomiting			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			
Dry skin			
subjects affected / exposed	0 / 6 (0.00%)	1 / 33 (3.03%)	
occurrences (all)	0	1	
Dermatitis contact			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	
occurrences (all)	0	0	
Eczema			
subjects affected / exposed	0 / 6 (0.00%)	1 / 33 (3.03%)	
occurrences (all)	0	1	
Dermatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	
occurrences (all)	0	0	
Erythema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	
occurrences (all)	0	0	
Rash			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	
occurrences (all)	0	0	
Pruritus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	
occurrences (all)	0	0	
Rash maculo-papular			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	
occurrences (all)	0	0	
Dermatitis atopic			
subjects affected / exposed	0 / 6 (0.00%)	1 / 33 (3.03%)	
occurrences (all)	0	1	

Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	
occurrences (all)	0	0	
Myalgia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 33 (3.03%)	
occurrences (all)	0	1	
Pain in extremity			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
Oral candidiasis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	
occurrences (all)	0	0	
Oral herpes			
subjects affected / exposed	1 / 6 (16.67%)	1 / 33 (3.03%)	
occurrences (all)	1	1	
Tooth infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	
occurrences (all)	0	0	
COVID-19			
subjects affected / exposed	2 / 6 (33.33%)	3 / 33 (9.09%)	
occurrences (all)	2	3	
Tinea barbae			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	
occurrences (all)	0	0	
Nasopharyngitis			
subjects affected / exposed	0 / 6 (0.00%)	4 / 33 (12.12%)	
occurrences (all)	0	5	
Rhinitis			
subjects affected / exposed	0 / 6 (0.00%)	4 / 33 (12.12%)	
occurrences (all)	0	4	

Pharyngitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	
occurrences (all)	0	0	
Upper respiratory tract infection			
subjects affected / exposed	0 / 6 (0.00%)	2 / 33 (6.06%)	
occurrences (all)	0	2	
Urinary tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	
occurrences (all)	0	0	
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 33 (0.00%)	
occurrences (all)	0	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
01 March 2021	Protocol Amendment 2 (dated 01 Mar 2021) was implemented to clarify the relevant pharmacokinetic (PK) and safety data to be provided to the Safety Monitoring Committee (SMC) to allow decisions to be made on dose escalation (Part A) and transition to Part B. Aligned the PK sampling times relative to the start of the infusion/injection and included electrocardiogram (ECGs) on Day 71 (final IMP administration).
13 August 2021	Protocol Amendment 3 (dated 13 Aug 2021) was implemented to reduce the number of overnight stays and allowed the use of mild TCS prescribed by the investigator during Part B of the study once blinded treatment had commenced but not prior to randomization.
12 November 2021	Protocol Amendment 4 (dated 12 Nov 2021) was implemented to revise the eligibility criteria to ensure that the study population enrolled was representative of patients with moderate-to-severe AtD and allowed COVID-19 and inactivated flu vaccines for Part B of the study.
20 October 2022	Protocol Amendment 5 (dated 20 Oct 2022) was implemented to remove the requirement for in-clinic overnight stays after SMC review. Additionally, some eligibility criteria were revised following requests from local regulatory authorities.
02 May 2023	Protocol Amendment 7 (dated 01 May 2023) was implemented to reduce sample size in alignment with the removal of a decision criterion for the primary analysis, as it was for sponsor decision making only. Sample size was based only on the difference in the primary efficacy variable between galvokimig and placebo.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported