Clinical trial results:
A Phase 2a, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of ANB019 in the Treatment of Acneiform Rash in Subjects with Neoplasm Receiving EGFRi or MEKi Therapy

Summary

EudraCT number	2020-003494-22
Trial protocol	PL CZ LV BG HU
Global end of trial date	13 December 2021

Results information

Result version number	v1 (current)
This version publication date	20 January 2023
First version publication date	20 January 2023

Trial information

Trial identification

Sponsor protocol code	ANB019-207

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04697069
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	AnaptysBio, Inc
Sponsor organisation address	10770 Wateridge Circle, Suite 210, San Diego, CA, United States, 92121
Public contact	Bruce Randazzo, AnaptysBio Inc., 001 (858) 362-6343, brandazzo@anaptysbio.com
Scientific contact	Bruce Randazzo, AnaptysBio Inc., 001 (858) 362-6343, brandazzo@anaptysbio.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	13 December 2021
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	13 December 2021
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To assess the efficacy of imsidolimab (ANB019) compared with placebo in the reduction of acneiform rash in participants receiving epidermal growth factor receptor inhibitor (EGFRi) or mitogen-activated protein (MAP)/extracellular signal-regulated kinase (ERK) kinase inhibitor (MEKi) therapy as measured by the facial inflammatory lesion count.

Protection of trial subjects:

This study was performed in compliance with ethical principles that have their origin in the Declaration of Helsinki and that are consistent with Good Clinical Practice (GCP) and the applicable laws and regulations.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	04 May 2021
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	Poland: 1
Country: Number of subjects enrolled	Czechia: 1
Country: Number of subjects enrolled	Georgia: 2
Worldwide total number of subjects	4
EEA total number of subjects	2

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	3

From 65 to 84 years	1
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants with neoplasms who were receiving epidermal growth factor inhibitors or mitogen-activated protein/extracellular signal regulated kinase inhibitor were enrolled into the study.

Pre-assignment

Screening details:

11 participants were screened for eligibility and 4 participants were randomized into the study.

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

Blinding implementation details:

The Sponsor, Investigator, and participants were blinded to treatment assignment of imsidolimab or placebo. An unblinded pharmacist was responsible for study treatment dispensing.

Arms

Are arms mutually exclusive?	Yes
Arm title	Imsidolimab

Arm description:

Participants received a starting dose of 400 milligrams (mg) of imsidolimab on Day 1 followed by 200 mg imsidolimab every 4 weeks (Days 29, 57 and 85) by subcutaneous injection.

Arm type	Experimental
Investigational medicinal product name	Imsidolimab
Investigational medicinal product code	ANB019
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Imsidolimab was administered by clinic staff trained in best practices for subcutaneous administration at starting dose of on Day 1 followed by 200 mg imsidolimab every 4 weeks (Days 29, 57 and 85).

Arm title	Placebo

Arm description:

Participants received imsidolimab matching placebo on Day 1 and thereafter, every 4 weeks (Days 29, 57 and 85) by subcutaneous injection.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Placebo matched to imsidolimab was administered by clinic staff trained in best practices for subcutaneous administration on Days 1, 29, 57 and 85.

Number of subjects in period 1	Imsidolimab	Placebo
Started	2	2
Completed	0	0
Not completed	2	2
Study termination	2	1
Withdrew consent	-	1

Baseline characteristics

Reporting groups	
Reporting group title	Imsidolimab
Reporting group description:	
Participants received a starting dose of 400 milligrams (mg) of imsidolimab on Day 1 followed by 200 mg imsidolimab every 4 weeks (Days 29, 57 and 85) by subcutaneous injection.	
Reporting group title	Placebo
Reporting group description:	
Participants received imsidolimab matching placebo on Day 1 and thereafter, every 4 weeks (Days 29, 57 and 85) by subcutaneous injection.	

Reporting group values	Imsidolimab	Placebo	Total
Number of subjects	2	2	4
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	50.0	65.0	
standard deviation	± 9.90	± 2.83	-
Gender categorical Units: Subjects			
Female	1	0	1
Male	1	2	3
Ethnicity Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	2	2	4
Unknown or Not Reported	0	0	0
Race Units: Subjects			
White	2	2	4

End points

End points reporting groups

Reporting group title	Imsidolimab
Reporting group description:	
Participants received a starting dose of 400 milligrams (mg) of imsidolimab on Day 1 followed by 200 mg imsidolimab every 4 weeks (Days 29, 57 and 85) by subcutaneous injection.	
Reporting group title	Placebo
Reporting group description:	
Participants received imsidolimab matching placebo on Day 1 and thereafter, every 4 weeks (Days 29, 57 and 85) by subcutaneous injection.	

Primary: Change From Baseline in Facial Inflammatory Lesion Count (Papules and Pustules) at Week 8

End point title	Change From Baseline in Facial Inflammatory Lesion Count (Papules and Pustules) at Week 8[1]
End point description:	
The number of facial inflammatory lesions (papules and pustules) on the face (excluding the neck and scalp area) was counted. Papule was a small, solid elevation 5 millimeters (mm) or less in diameter. Pastule was a small, circumscribed elevation of the skin that contains yellow-white exudate. Due to early study termination, no participant was evaluated in the imsidolimab group and 1 participant was evaluated in the placebo group. Since only 1 participant was evaluated, results were not reported for the protection of personal data and to avoid re-identification.	
End point type	Primary
End point timeframe:	
Baseline, Week 8	

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 statistical analysis was performed for the primary endpoint. Due to early study termination, no participant was evaluated in the imsidolimab group and 1 participant was evaluated in the placebo group. Since only 1 participant was evaluated, results were not reported for the protection of personal data and to avoid re-identification.

End point values	Imsidolimab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[2]	0[3]		
Units: lesion count				
arithmetic mean (standard deviation)	()	()		

Notes:

[2] - Due to early study termination, no participant was evaluated

[3] - Only 1 participant was evaluated. Results were not reported for the protection of personal data.

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change From Baseline in Facial Inflammatory Lesion Count (Papules and Pustules) at Week 8

End point title	Percent Change From Baseline in Facial Inflammatory Lesion Count (Papules and Pustules) at Week 8

End point description:

The number of facial inflammatory lesions (papules and pustules) on the face (excluding the neck and scalp area) was counted. Papule was a small, solid elevation 5 mm or less in diameter. Pastule was a small, circumscribed elevation of the skin that contains yellow-white exudate.

Due to early study termination, no participant was evaluated in the imsidolimab group and 1 participant was evaluated in the placebo group. Since only 1 participant was evaluated, results were not reported for the protection of personal data and to avoid re-identification.

End point type	Secondary

End point timeframe:

Baseline, Week 8

End point values	Imsidolimab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[4]	0[5]		
Units: percent change				
arithmetic mean (standard deviation)	()	()		

Notes:

[4] - Due to early study termination, no participant was evaluated.

[5] - Only 1 participant was evaluated. Results were not reported for the protection of personal data.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With an Improvement of at Least 1 Grade From Baseline in Acneiform Rash Common Terminology Criteria for Adverse Events (CTCAE) Grading Scale at Week 8

End point title	Percentage of Participants With an Improvement of at Least 1 Grade From Baseline in Acneiform Rash Common Terminology Criteria for Adverse Events (CTCAE) Grading Scale at Week 8

End point description:

The acneiform rash CTCAE grading scale of severity was 6-point scale ranging from 0-5.
Scale 0=no evidence of rash.
Scale 1=papules and/or pustules covering <10% body surface area (BSA),which may or may not be associated with symptoms of pruritus or tenderness.
Scale 2=papules and/or pustules covering 10-30% BSA, which may or may not be associated with symptoms of pruritus
or tenderness; associated with psychosocial impact;limiting instrumental activities of daily living (ADL); papules and/or
pustules covering >30% BSA with or without mild symptoms.
Scale 3=papules and/or pustules covering >30% BSA with moderate or severe symptoms; limiting self-care ADL;
associated with local superinfection with oral antibiotics.
Scale 4=life-threatening consequences; papules and/or pustules covering any %BSA, which may or may not be
associated with symptoms of pruritus or tenderness and are associated with extensive superinfection with intravenous
(IV) antibiotics indicated.
Scale 5=death

End point type	Secondary

End point timeframe:

Baseline, Week 8

End point values	Imsidolimab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[6]	0[7]		
Units: percentage of participants				
number (not applicable)				

Notes:

[6] - Due to early study termination, no participant was evaluated.

[7] - Only 1 participant was evaluated. Results were not reported for the protection of personal data.

Statistical analyses

No statistical analyses for this end point

Secondary: Time to First Response of 1 Grade Improvement From Baseline on the Acneiform Rash CTCAE Grading Scale

End point title	Time to First Response of 1 Grade Improvement From Baseline on the Acneiform Rash CTCAE Grading Scale

End point description:

Time to first response of 1 grade improvement from baseline on the acneiform rash CTCAE grading scale: Date of the first response of 1 grade improvement from baseline on the acneiform rash CTCAE grading scale – Date of the first dose of study treatment (or from randomization for any participant randomized but not treated) + 1.

Due to early study termination, no participant was evaluated in the imsidolimab group and 1 participant was evaluated in the placebo group. Since only 1 participant was evaluated, results were not reported for the protection of personal data and to avoid re-identification.

End point type	Secondary

End point timeframe:

Baseline up to 55 days

End point values	Imsidolimab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[8]	0[9]		
Units: days				
arithmetic mean (standard deviation)	()	()		

Notes:

[8] - Due to early study termination, no participant was evaluated.

[9] - Only 1 participant was evaluated. Results were not reported for the protection of personal data.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With an Improvement of at Least 1 Grade From Baseline in Acneiform Rash Modified Multinational Association for Supportive Care in Cancer (MASCC) EGFRi Skin Toxicity Tool (MESTT) Grading Scale (Total Score) at Week 8

End point title	Percentage of Participants With an Improvement of at Least 1

	Grade From Baseline in Acneiform Rash Modified Multinational Association for Supportive Care in Cancer (MASCC) EGFRi Skin Toxicity Tool (MESTT) Grading Scale (Total Score) at Week 8

End point description:

The MESTT grading scale of the acneiform rash severity was a 3-point scale ranging from 1 to 3:
Scale 1 = 1A: papules or pustules ≤5; OR 1 area of erythema or edema <1 centimeter (cm) in size. 1B: papules or
pustules ≤5; OR 1 area of erythema or edema <1 cm in size; AND pain or pruritus.
Scale 2 = 2A: papules or pustules 6-20; OR 2-5 areas of erythema or edema <1 cm in size. 2B: Papules or pustules
6-20; OR 2-5 areas of erythema or edema <1 cm in size; AND pain, pruritus, or effect on emotions or functioning.
Scale 3 = 3A: papules or pustules > 20; OR more than 5 areas of erythema or edema <1 cm in size. 3B: papules or
pustules > 20; OR more than 5 areas of erythema or edema <1 cm in size; AND pain, pruritus, or effect on emotions or
functioning.
Grading was performed individually for the face, scalp, chest, and back. The sum of all body region scores yielded the
total score (range: 4 to 12).

End point type	Secondary

End point timeframe:

Baseline, Week 8

End point values	Imsidolimab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[10]	0[11]		
Units: percentage of participants				
number (not applicable)				

Notes:

[10] - Due to early study termination, no participant was evaluated.

[11] - Only 1 participant was evaluated. Results were not reported for the protection of personal data.

Statistical analyses

No statistical analyses for this end point

Secondary: Time to First Response of 1 Grade Improvement From Baseline on the Acneiform Rash Modified MESTT Grading Scale (Total Score)

End point title	Time to First Response of 1 Grade Improvement From Baseline on the Acneiform Rash Modified MESTT Grading Scale (Total Score)

End point description:

Time to first response of 1 grade improvement from baseline on the acneiform rash modified MESTT grading scale (total score): Date of onset of the first response of 1 grade improvement from baseline on the acneiform rash modified MESTT grading scale (total score) – Date of the first dose of study treatment (or from randomization for any participant randomized but not treated) + 1.

Due to early study termination, no participant was evaluated in the imsidolimab group and 1 participant was evaluated in the placebo group. Since only 1 participant was evaluated, results were not reported for the protection of personal data and to avoid re-identification.

End point type	Secondary

End point timeframe:

Baseline to 55 days

End point values	Imsidolimab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[12]	0[13]		
Units: days				
arithmetic mean (standard deviation)	()	()		

Notes:

[12] - Due to early study termination, no participant was evaluated.

[13] - Only 1 participant was evaluated. Results were not reported for the protection of personal data.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With an Improvement of at Least 1 Grade From Baseline in Acneiform Rash Modified MESTT Grading Scale (Facial Assessment) at Week 8

End point title	Percentage of Participants With an Improvement of at Least 1 Grade From Baseline in Acneiform Rash Modified MESTT Grading Scale (Facial Assessment) at Week 8

End point description:

The MESTT grading scale of the acneiform rash severity was a 3-point scale ranging from 1 to 3:
Scale 1 = 1A: papules or pustules ≤5; OR 1 area of erythema or edema <1cm in size. 1B: papules or pustules ≤5; OR 1
area of erythema or edema <1 cm in size; AND pain or pruritus.
Scale 2 = 2A: papules or pustules 6-20; OR 2-5 areas of erythema or edema <1 cm in size. 2B: Papules or pustules
6-20; OR 2-5 areas of erythema or edema <1 cm in size; AND pain, pruritus, or effect on emotions or functioning.
Scale 3 = 3A: papules or pustules > 20; OR more than 5 areas of erythema or edema <1 cm in size. 3B: papules or
pustules > 20; OR more than 5 areas of erythema or edema <1 cm in size; AND pain, pruritus, or effect on emotions or
functioning.
Grading was performed individually for the face. The score ranged from 1 to 3.

End point type	Secondary

End point timeframe:

Baseline, Week 8

End point values	Imsidolimab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[14]	0[15]		
Units: percentage of participants				
number (not applicable)				

Notes:

[14] - Due to early study termination, no participant was evaluated.

[15] - Only 1 participant was evaluated. Results were not reported for the protection of personal data.

Statistical analyses

No statistical analyses for this end point

Secondary: Time to First Response of 1 Grade Improvement From Baseline on the Acneiform Rash Modified MESTT Grading Scale (Facial Assessment)

End point title	Time to First Response of 1 Grade Improvement From Baseline on the Acneiform Rash Modified MESTT Grading Scale (Facial Assessment)

End point description:

Time to first response of 1 grade improvement from baseline on the acneiform rash modified MESTT grading scale
(facial assessment): Date of onset of the first response of 1 grade improvement from baseline on the acneiform rash
modified MESTT grading scale (facial assessment) – Date of the first dose of study treatment (or from randomization for
any participant randomized but not treated) + 1.

Due to early study termination, no participant was evaluated in the imsidolimab group and 1 participant was evaluated in the placebo group. Since only 1 participant was evaluated, results were not reported for the protection of personal data and to avoid re-identification.

End point type	Secondary

End point timeframe:

Baseline to 55 days

End point values	Imsidolimab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[16]	0[17]		
Units: days				
arithmetic mean (standard deviation)	()	()		

Notes:

[16] - Due to early study termination, no participant was evaluated.

[17] - Only 1 participant was evaluated. Results were not reported for the protection of personal data.

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Pruritus Numeric Rating Scale (NRS) at Week 8

End point title	Change From Baseline in Pruritus Numeric Rating Scale (NRS) at Week 8

End point description:

The intensity of pruritus was evaluated by asking participants to assign a numerical score representing the worst
intensity over the last 24 hours of their symptoms on a scale from 0 to 10, with 0 indicating no itch and 10 indicating the
worst imaginable itch.

Due to early study termination, no participant was evaluated in the imsidolimab group and 1 participant was evaluated in the placebo group. Since only 1 participant was evaluated, results were not reported for the protection of personal data and to avoid re-identification.

End point type	Secondary

End point timeframe:

Baseline, Week 8

End point values	Imsidolimab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[18]	0[19]		
Units: units on a scale				
arithmetic mean (standard deviation)	()	()		

Notes:

[18] - Due to early study termination, no participant was evaluated.

[19] - Only 1 participant was evaluated. Results were not reported for the protection of personal data.

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change From Baseline in Pruritus NRS at Week 8

End point title	Percent Change From Baseline in Pruritus NRS at Week 8

End point description:

The intensity of pruritus was evaluated by asking participants to assign a numerical score representing the worst
intensity over the last 24 hours of their symptoms on a scale from 0 to 10, with 0 indicating no itch and 10 indicating the
worst imaginable itch.

Due to early study termination, no participant was evaluated in the imsidolimab group and 1 participant was evaluated in the placebo group. Since only 1 participant was evaluated, results were not reported for the protection of personal data and to avoid re-identification.

End point type	Secondary

End point timeframe:

Baseline, Week 8

End point values	Imsidolimab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[20]	0[21]		
Units: percent change				
arithmetic mean (standard deviation)	()	()		

Notes:

[20] - Due to early study termination, no participant was evaluated.

[21] - Only 1 participant was evaluated. Results were not reported for the protection of personal data.

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Pain NRS at Week 8

End point title	Change From Baseline in Pain NRS at Week 8

End point description:

The intensity of pain was evaluated by asking participants to assign a numerical score representing the worst intensity

over the last 24 hours of their symptoms on a scale from 0 to 10, with 0 indicating no pain and 10 indicating the worst
imaginable pain.

Due to early study termination, no participant was evaluated in the imsidolimab group and 1 participant was evaluated in the placebo group. Since only 1 participant was evaluated, results were not reported for the protection of personal data and to avoid re-identification.

End point type	Secondary

End point timeframe:

Baseline, Week 8

End point values	Imsidolimab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[22]	0[23]		
Units: units on a scale				
arithmetic mean (standard deviation)	()	()		

Notes:

[22] - Due to early study termination, no participant was evaluated.

[23] - Only 1 participant was evaluated. Results were not reported for the protection of personal data.

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change From Baseline in Pain NRS at Week 8

End point title	Percent Change From Baseline in Pain NRS at Week 8

End point description:

The intensity of pain was evaluated by asking participants to assign a numerical score representing the worst intensity
over the last 24 hours of their symptoms on a scale from 0 to 10, with 0 indicating no pain and 10 indicating the worst
imaginable pain.

Due to early study termination, no participant was evaluated in the imsidolimab group and 1 participant was evaluated in the placebo group. Since only 1 participant was evaluated, results were not reported for the protection of personal data and to avoid re-identification.

End point type	Secondary

End point timeframe:

Baseline, Week 8

End point values	Imsidolimab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[24]	0[25]		
Units: percent change				
arithmetic mean (standard deviation)	()	()		

Notes:

[24] - Due to early study termination, no participant was evaluated.

[25] - Only 1 participant was evaluated. Results were not reported for the protection of personal data.

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Functional Assessment of Cancer Therapy - Epidermal Growth Factor Receptor Inhibitor 18 (FACT-EGFRi-18) at Week 8

End point title	Change From Baseline in Functional Assessment of Cancer Therapy - Epidermal Growth Factor Receptor Inhibitor 18 (FACT-EGFRi-18) at Week 8

End point description:

The FACT-EGFRi-18 was an 18-item likert-scaled questionnaire, arranged in three dimensions: physical (seven items),
social/emotional (six items), and functional well-being (five items). The response scores ranged from 0 (not at all) to 4
(very much).
The total score was obtained by multiplying the sum of the subscale by the number of items in the scale (18), and then
dividing by the number of items actually answered.
The total score ranged from 0-72 with a higher score represented a high level of symptomatology (problems).

Due to early study termination, no participant was evaluated in the imsidolimab group and 1 participant was evaluated in the placebo group. Since only 1 participant was evaluated, results were not reported for the protection of personal data and to avoid re-identification.

End point type	Secondary

End point timeframe:

Baseline, Week 8

End point values	Imsidolimab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[26]	0[27]		
Units: units on a scale				
arithmetic mean (standard deviation)	()	()		

Notes:

[26] - Due to early study termination, no participant was evaluated.

[27] - Only 1 participant was evaluated. Results were not reported for the protection of personal data.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Treatment-Emergent Adverse Events

End point title	Number of Participants With Treatment-Emergent Adverse Events

End point description:

An adverse event (AE) was any untoward medical occurrence in a participant temporally associated with the use of a study treatment, whether or not considered related to study treatment. An AE could therefore be any unfavorable and unintended sign (including abnormal laboratory finding), symptom, or disease temporally associated with use of study treatment that did not necessarily have a causal relationship with this treatment. An AE was considered "serious" if there was any of the following outcomes: death, life-threatening, Inpatient hospitalization or prolongation of existing hospitalization, persistent or significant incapacity or substantial disruption of ability to conduct normal life functions, congenital anomaly/birth defect, other important medical events. An AE was considered treatment-emergent if the date of onset was during or after first dose of study treatment, or if the AE present at baseline worsened in either intensity or frequency after first dose of study treatment.

End point type	Secondary

End point timeframe:
From first dose to 55 days

End point values	Imsidolimab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	2		
Units: participants				
Any TEAEs	0	2		
Serious TEAEs	0	0		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
From first dose to 55 days	
Adverse event reporting additional description:	
Safety analysis set included all randomized participants who received at least 1 dose of imsidolimab or placebo.	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	24.1

Reporting groups	
Reporting group title	Imsidolimab
Reporting group description:	
Participants received a starting dose of 400 mg of imsidolimab on Day 1 followed by 200 mg imsidolimab every 4 weeks (Days 29, 57 and 85) by subcutaneous injection.	
Reporting group title	Placebo
Reporting group description:	
Participants received imsidolimab matching placebo on Day 1 and thereafter, every 4 weeks (Days 29, 57 and 85) by subcutaneous injection.	

Serious adverse events	Imsidolimab	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Imsidolimab	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 2 (0.00%)	2 / 2 (100.00%)	
Investigations			
Electrocardiogram T wave inversion			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	
occurrences (all)	0	1	
Gastrointestinal disorders			
Diarrhoea			

subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	1 / 2 (50.00%) 1	
Metabolism and nutrition disorders Hypokalaemia subjects affected / exposed occurrences (all)	 0 / 2 (0.00%) 0	 1 / 2 (50.00%) 1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
11 February 2021	This amendment was prepared to address the following issues: 1) Permit small editorial changes for correctness. 2) Clarify modifications to MESTT, use of CTCAE scoring and corresponding statistical analysis. 3) Permit (optional) home health visits during the COVID-19 pandemic, describe home nursing visit procedures, and acknowledge that COVID-19 measures only apply if they are in accordance with current, locally-applicable recommendations/regulations. 4) Permit the use of remaining serum from samples collected for PK/immunogenicity endpoints to be retained for assay method development, troubleshooting, or validation. 5) Clarify timing for administration of live attenuated vaccines after the participant completes the 12-week standard safety follow-up period of the study or after 12 weeks following the last administration of the study drug for participant who discontinued from the study early. 6) Clarify timing requirements for use of hormonal contraceptives prior to and during study participation and to identify which oral hormonal contraceptives are permissible. 7) Permit enrolment of participants treated with any commercially-available EGFRi or MEKi therapy. 8) Include a 30-minute observation period of study participants after application of each dose of imsidolimab to identify any potential allergic/anaphylactic reaction. 9) Clarify timing of anti-drug antibody sample collection.
05 August 2021	This amendment was prepared to address the following issues: 1) Permit small editorial changes for clarity and correctness. 2) Update the name of the Sponsor medical expert and signatory, and address of the Sponsor. 3) Allow inclusion of participants with benign neoplasm (not cancer). 4) Revised eligibility criteria for body weight to ≥40kg. 5) Updated tuberculosis screening as inclusion criteria. 6) Clarified definition of childbearing potential in contraceptive use exclusion criteria. 7) Allow screening of participants prior to rash onset. 8) Reduce the number of study visits by removing Week 1 and Week 6 visits. 9) Modify the list of study endpoints by removing percent change from baseline from some endpoints and revised exploratory endpoints based on planned data collection. 10) Clarify the recommended order of assessments to be followed during the study visits. 11) Add an evaluation of the Fitzpatrick Skin Type Classification. 12) Reduce the number of electrocardiograms (ECGs) to be performed during the study. 13) Reduce the number of tape strip samples to be collected and clarify the location for sample collection. 14) Reduce the number of blood samples to be collected for pharmacokinetic (PK) evaluations. 15) Removal of noncompartmental analysis (NCA) due to limited PK sampling. 16) Update washout periods for prohibited treatments. 17) Add clarification related to vaccines allowed during the study. 18) Clarify if a participant were to discontinue early from the study, an early termination visit will be required. 19) Remove the possibility of participants' replacement. 20) Clarify assessment of facial lesions. 21) Remove facsimile as an option to report serious adverse events (SAEs). 22) Update the text to indicate local laboratory tests will be allowed at Screening for tuberculosis and viral serology testing

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported