Clinical trial results:
A Phase 2, Randomized, Placebo-controlled, Double-blind, Multiple Dose Study to Evaluate the Efficacy and Safety of ANB019 in Subjects with Palmoplantar Pustulosis

Summary

EudraCT number	2017-004022-15
Trial protocol	DE
Global end of trial date	23 April 2021

Results information

Result version number	v1 (current)
This version publication date	21 May 2022
First version publication date	21 May 2022

Trial information

Trial identification

Sponsor protocol code	ANB019-003

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03633396
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	AnaptysBio Clinical Trials Info, AnaptysBio Inc, 001 8583626387, clinicaltrialinfo@anaptysbio.com
Scientific contact	AnaptysBio Clinical Trials Info, AnaptysBio Inc, 001 8583626387, clinicaltrialinfo@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	23 April 2021
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	23 April 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

- To determine the effect of imsidolimab (ANB019) compared with placebo in participants with palmoplantar pustulosis (PPP) as measured by the Palmoplantar Pustulosis Psoriasis Area Severity Index 50 (PPPASI50).
- To assess the safety and tolerability of imsidolimab in subjects with PPP.

Protection of trial subjects:

This study was conducted in compliance with the protocol, the International Council for Harmonisation (ICH) Guidance for Industry E6(R2) Good Clinical Practice (GCP): Consolidated Guidance, the Declaration of Helsinki, institutional review board (IRB)/independent ethics committee (IEC) requirements, and all applicable national and local regulatory requirements.
The investigator or his/her representative explained the nature of the study to the participant or his/her legally authorized representative and answered all questions regarding the study. Written informed consent was obtained before the participant was enrolled in the study.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	23 April 2019
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: 22
Country: Number of subjects enrolled	Germany: 14
Country: Number of subjects enrolled	Canada: 7
Country: Number of subjects enrolled	United States: 16
Worldwide total number of subjects	59
EEA total number of subjects	36

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	0

months)	
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	54
From 65 to 84 years	5
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants were enrolled in this trial at 36 sites located within North America and Europe.

Pre-assignment

Screening details:

Participants were randomized equally to one of two treatment groups. Randomization was stratified based on the participant's history of plaque psoriasis, to ensure that the number of participants enrolled with plaque psoriasis did not exceed 50%.

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Participants received placebo administered by subcutaneous injection on Day 1 followed by monthly doses on Days 29, 57, and 85.

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:

Administered by subcutaneous injection once a month.

Arm title	Imsidolimab

Arm description:

Participants received 200 mg imsidolimab by subcutaneous injection on Day 1 followed by monthly doses of 100 mg imsidolimab by subcutaneous injection on Days 29, 57, and 85.

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:

Administered by subcutaneous injection once a month.

Number of subjects in period 1	Placebo	Imsidolimab
Started	29	30
Completed	23	24
Not completed	6	6
Consent withdrawn by subject	4	4
Adverse event, non-fatal	1	1
Coronavirus disease 2019 (COVID-19) restrictions	-	1
Lack of efficacy	1	-

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Participants received placebo administered by subcutaneous injection on Day 1 followed by monthly doses on Days 29, 57, and 85.	
Reporting group title	Imsidolimab
Reporting group description:	
Participants received 200 mg imsidolimab by subcutaneous injection on Day 1 followed by monthly doses of 100 mg imsidolimab by subcutaneous injection on Days 29, 57, and 85.	

Reporting group values	Placebo	Imsidolimab	Total
Number of subjects	29	30	59
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	47.7	52.3	
standard deviation	± 10.59	± 12.10	-
Gender categorical Units: Subjects			
Female	24	22	46
Male	5	8	13
Ethnicity Units: Subjects			
Hispanic or Latino	3	0	3
Not Hispanic or Latino	26	30	56
Race Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	1	1	2
Black or African American	3	1	4
White	25	28	53
History of Plaque Psoriasis Units: Subjects			
Yes	7	7	14
No	22	23	45
Palmoplantar Pustulosis Psoriasis Area Severity Index Score			
The Palmoplantar Pustulosis Area and Severity Index (PPPASI) is used to assess the severity of palmoplantar pustulosis lesions. The glabrous skin of both palms and soles are assessed for erythema, pustules and desquamation (scaling) on a scale from 0 (none) to 4 (very severe). The area affected of each palm and sole is scored from 0 (0%) to 6 (90-100%). The PPPASI total score ranges from 0 to 72. A higher score indicates more severe disease.			
Units: score on a scale			
arithmetic mean	19.47	16.18	
standard deviation	± 11.633	± 8.045	-

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description:	
Participants received placebo administered by subcutaneous injection on Day 1 followed by monthly doses on Days 29, 57, and 85.	
Reporting group title	Imsidolimab
Reporting group description:	
Participants received 200 mg imsidolimab by subcutaneous injection on Day 1 followed by monthly doses of 100 mg imsidolimab by subcutaneous injection on Days 29, 57, and 85.	

Primary: Change From Baseline in Palmoplantar Pustulosis Psoriasis Area Severity Index (PPPASI)

End point title	Change From Baseline in Palmoplantar Pustulosis Psoriasis Area Severity Index (PPPASI)
End point description:	
The Palmoplantar Pustulosis Area and Severity Index (PPPASI) is used to assess the severity of palmoplantar pustulosis lesions and their response to therapy. The glabrous skin of both palms and both soles are assessed for erythema, pustules, and desquamation (scaling), each on a scale from 0 (none) to 4 (very severe). The area affected of each palm and sole is scored from 0 (0%) to 6 (90-100%). Scores for the 3 characteristics of PPP are summed and adjusted for the area affected, and the scores for each palm and sole are added to calculate the total score. The PPPASI total score ranges from 0 to 72. A higher score indicates more severe disease, and a negative change from Baseline indicates improvement.	
End point type	Primary
End point timeframe:	
Baseline to Week 16	

End point values	Placebo	Imsidolimab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24[1]	24[2]		
Units: score on a scale				
least squares mean (standard error)	-6.0 (± 1.48)	-6.1 (± 1.46)		

Notes:

[1] - Intent-to-treat analysis set with available data

[2] - Intent-to-treat analysis set with available data

Statistical analyses

Statistical analysis title	Analysis of Change in PPPASI Score
Statistical analysis description:	
The change from Baseline in PPPASI at Week 16 was analyzed using a a general linear mixed model for repeated measures (MMRM). The model included fixed effects for treatment, history of plaque psoriasis (Yes/No), visit, treatment by visit interaction, and Baseline PPPASI score as covariate.	
Comparison groups	Placebo v Imsidolimab

Number of subjects included in analysis	48
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.944 [3]
Method	Mixed-model Repeated Measures (MMRM)
Parameter estimate	Least Squares (LS) Mean Difference
Point estimate	-0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.05
upper limit	3.77
Variability estimate	Standard error of the mean
Dispersion value	1.98

Notes:

[3] - MMRM including fixed effects of treatment, history of plaque psoriasis, visit, treatment by visit interaction, and Baseline PPPASI score as covariate.

Primary: Number of Participants With Treatment-emergent Adverse Events (TEAEs)

End point title	Number of Participants With Treatment-emergent Adverse Events (TEAEs)[4]

End point description:

Clinical safety was evaluated by reporting incidence of adverse events up to Week 24. TEAEs are defined as new events that occured during or after first dose of study drug or any event that worsens after first dose of study drug.
A serious AE (SAE) is defined as any untoward medical occurrence that resulted in death, was life-threatening, resulted in persistent disability/incapacity, was a congenital anomaly/birth defect, or an important medical event that may jeopardize the participant or require medical or surgical intervention to prevent one of the outcomes listed above.
Severity was assessed by the Investigator as mild (easily tolerated, causing minimal discomfort and not interfering with everyday activities), moderate (causes sufficient discomfort and interferes with normal everyday activities) or severe (prevents normal everyday activities).
The Investigator assessed the relationship between study treatment and each AE based on clinical judgement.

End point type	Primary

End point timeframe:

From first dose of any study drug to Week 24

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: There were no statistical comparisons between the treatment groups for safety data.

End point values	Placebo	Imsidolimab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	29[5]	30[6]		
Units: participants				
Any treatment-emergent adverse event (TEAE)	20	21		
TEAE related to study drug	3	6		
Severe TEAE	1	0		
Serious TEAE	1	0		
TEAE of special interest	1	0		
TEAE leading to discontinuation of study treatment	2	1		
TEAE leading to study discontinuation	1	1		
TEAE leading to death	0	0		

TEAE related to injection site reaction	0	0		
Disease related TEAE	6	2		

Notes:

[5] - Safety analysis set

[6] - Safety analysis set

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Achieved 50% Reduction (Improvement) From Baseline in Palmoplantar Pustulosis Psoriasis Area Severity Index Score (PPPASI 50)

End point title	Percentage of Participants Who Achieved 50% Reduction (Improvement) From Baseline in Palmoplantar Pustulosis Psoriasis Area Severity Index Score (PPPASI 50)

End point description:

The Palmoplantar Pustulosis Area and Severity Index (PPPASI) is used to assess the severity of palmoplantar pustulosis lesions and their response to therapy. The glabrous skin of both palms and both soles are assessed for erythema, pustules, and desquamation (scaling), each on a scale from 0 (none) to 4 (very severe). The area affected of each palm and sole is scored from 0 (0%) to 6 (90-100%). Scores for the 3 characteristics of PPP are summed and adjusted for the area affected, and the scores for each palm and sole are added to calculate the total score. The PPPASI total score ranges from 0 to 72. A higher score indicates more severe disease.

End point type	Secondary

End point timeframe:

Baseline to Week 16

End point values	Placebo	Imsidolimab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24[7]	24[8]		
Units: percentage of participants				
number (confidence interval 95%)	50.0 (29.12 to 70.88)	45.8 (25.55 to 67.18)		

Notes:

[7] - Intent-to-treat analysis set with available data

[8] - Intent-to-treat analysis set with available data

Statistical analyses

Statistical analysis title	Analysis of PPPASI 50 Response

Statistical analysis description:

Response was analyzed using a logistic regression model including treatment as fixed effect, and history of plaque psoriasis (Yes/No) and Baseline PPPASI score as covariates. Missing PPPASI scores were imputed using multiple imputation while deriving PPPASI50 responses for executing the logistic regression model to obtain the odds ratio and the CI.

Comparison groups	Imsidolimab v Placebo

Number of subjects included in analysis	48
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Odds ratio (OR)
Point estimate	0.879
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.288
upper limit	2.686

Secondary: Percentage of Participants Who Achieved a Clear or Almost Clear PPPIGA Score at Week 16

End point title	Percentage of Participants Who Achieved a Clear or Almost Clear PPPIGA Score at Week 16

End point description:

The Investigator rated the severity of participants' disease on the following 5-point scale:
- 0: Clear - No signs of palmoplantar pustulosis; no scaling or crusts or pustules remain;
- 1: Almost clear - Slight scaling and/or erythema and/or slight crusts; very few (yellow) and/or old (brown) pustules;
- 2: Mild - Scaling and/or erythema and/or crusts; visible new (yellow) and/or old (brown) pustules of limited number and extent;
- 3: Moderate - Prominent scaling and/or erythema and/or crusting; prominent new (yellow) and/or old (brown) pustules covering most of the area involved;
- 4: Severe - Severe scaling and/or erythema and/or crusting; numerous new (yellow) and/or old (brown) pustules with / without major confluence, covering the entire area of at least 2 palmoplantar sites.

End point type	Secondary

End point timeframe:

Week 16

End point values	Placebo	Imsidolimab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24[9]	24[10]		
Units: percentage of participants				
number (confidence interval 95%)	12.5 (2.66 to 32.36)	20.8 (7.13 to 42.15)		

Notes:

[9] - Intent-to-treat analysis set with available data

[10] - Intent-to-treat analysis set with available data

Statistical analyses

Statistical analysis title	Analysis of PPPIGA Response

Statistical analysis description:

Response was analyzed with a logistic regression model including treatment as fixed effect, and history of psoriasis (Yes/No) and Baseline PPPIGA score as covariates.

Comparison groups	Imsidolimab v Placebo

Number of subjects included in analysis	48
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Odds ratio (OR)
Point estimate	2.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	13.9

Adverse events

Adverse events information	
Timeframe for reporting adverse events: From first dose of any study drug to Week 24.	
Assessment type	Systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	23.1
Reporting groups	
Reporting group title	Placebo
Reporting group description: Participants received placebo administered by subcutaneous injection on Day 1 followed by monthly doses on Days 29, 57, and 85.	
Reporting group title	Imsidolimab
Reporting group description: Participants received 200 mg imsidolimab by subcutaneous injection on Day 1 followed by monthly doses of 100 mg imsidolimab by subcutaneous injection on Days 29, 57, and 85.	

Serious adverse events	Placebo	Imsidolimab	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 29 (3.45%)	0 / 30 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Pregnancy, puerperium and perinatal conditions			
Abortion early			
subjects affected / exposed	1 / 29 (3.45%)	0 / 30 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Placebo	Imsidolimab	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	20 / 29 (68.97%)	21 / 30 (70.00%)	
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 29 (3.45%)	1 / 30 (3.33%)	
occurrences (all)	1	1	
General disorders and administration			

site conditions			
Pyrexia			
subjects affected / exposed	0 / 29 (0.00%)	2 / 30 (6.67%)	
occurrences (all)	0	2	
Fatigue			
subjects affected / exposed	1 / 29 (3.45%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Peripheral swelling			
subjects affected / exposed	1 / 29 (3.45%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 29 (0.00%)	2 / 30 (6.67%)	
occurrences (all)	0	3	
Reproductive system and breast disorders			
Vulvovaginal pruritus			
subjects affected / exposed	1 / 29 (3.45%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 29 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Oropharyngeal pain			
subjects affected / exposed	0 / 29 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 29 (0.00%)	2 / 30 (6.67%)	
occurrences (all)	0	2	
Panic attack			
subjects affected / exposed	0 / 29 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 29 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Aspartate aminotransferase			

increased			
subjects affected / exposed	0 / 29 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 29 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 29 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Blood pressure increased			
subjects affected / exposed	0 / 29 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 29 (3.45%)	1 / 30 (3.33%)	
occurrences (all)	1	1	
Blood triglycerides increased			
subjects affected / exposed	1 / 29 (3.45%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Injury, poisoning and procedural complications			
Ligament sprain			
subjects affected / exposed	1 / 29 (3.45%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 29 (6.90%)	2 / 30 (6.67%)	
occurrences (all)	8	2	
Nerve compression			
subjects affected / exposed	0 / 29 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Anosmia			
subjects affected / exposed	1 / 29 (3.45%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Intercostal neuralgia			
subjects affected / exposed	1 / 29 (3.45%)	0 / 30 (0.00%)	
occurrences (all)	1	0	

Neuralgia			
subjects affected / exposed	1 / 29 (3.45%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Sciatica			
subjects affected / exposed	1 / 29 (3.45%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Ear and labyrinth disorders			
Ear discomfort			
subjects affected / exposed	0 / 29 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Vertigo			
subjects affected / exposed	0 / 29 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Eye disorders			
Blepharospasm			
subjects affected / exposed	1 / 29 (3.45%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	0 / 29 (0.00%)	2 / 30 (6.67%)	
occurrences (all)	0	3	
Dental caries			
subjects affected / exposed	0 / 29 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Vomiting			
subjects affected / exposed	0 / 29 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Duodenogastric reflux			
subjects affected / exposed	1 / 29 (3.45%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Toothache			
subjects affected / exposed	4 / 29 (13.79%)	0 / 30 (0.00%)	
occurrences (all)	4	0	
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 29 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	

Diffuse alopecia			
subjects affected / exposed	0 / 29 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Palmoplantar pustulosis			
subjects affected / exposed	5 / 29 (17.24%)	1 / 30 (3.33%)	
occurrences (all)	6	1	
Skin lesion			
subjects affected / exposed	0 / 29 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Eczema asteatotic			
subjects affected / exposed	1 / 29 (3.45%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Pustular psoriasis			
subjects affected / exposed	1 / 29 (3.45%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	1 / 29 (3.45%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	1 / 29 (3.45%)	1 / 30 (3.33%)	
occurrences (all)	1	1	
Myalgia			
subjects affected / exposed	0 / 29 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	2	
Neck pain			
subjects affected / exposed	0 / 29 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	2	
Osteoarthritis			
subjects affected / exposed	0 / 29 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Pain in extremity			
subjects affected / exposed	2 / 29 (6.90%)	1 / 30 (3.33%)	
occurrences (all)	2	2	
Arthralgia			

subjects affected / exposed	1 / 29 (3.45%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Spinal pain			
subjects affected / exposed	1 / 29 (3.45%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	4 / 29 (13.79%)	4 / 30 (13.33%)	
occurrences (all)	6	4	
Pharyngitis			
subjects affected / exposed	0 / 29 (0.00%)	2 / 30 (6.67%)	
occurrences (all)	0	3	
COVID-19			
subjects affected / exposed	2 / 29 (6.90%)	1 / 30 (3.33%)	
occurrences (all)	3	1	
Otitis externa			
subjects affected / exposed	0 / 29 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Rhinitis			
subjects affected / exposed	0 / 29 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Tinea pedis			
subjects affected / exposed	0 / 29 (0.00%)	1 / 30 (3.33%)	
occurrences (all)	0	1	
Bacterial pyelonephritis			
subjects affected / exposed	1 / 29 (3.45%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Bronchitis viral			
subjects affected / exposed	1 / 29 (3.45%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Conjunctivitis			
subjects affected / exposed	1 / 29 (3.45%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Folliculitis			
subjects affected / exposed	1 / 29 (3.45%)	0 / 30 (0.00%)	
occurrences (all)	1	0	

Gastrointestinal infection			
subjects affected / exposed	1 / 29 (3.45%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Impetigo			
subjects affected / exposed	1 / 29 (3.45%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Urinary tract infection			
subjects affected / exposed	2 / 29 (6.90%)	0 / 30 (0.00%)	
occurrences (all)	2	0	
Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed	1 / 29 (3.45%)	0 / 30 (0.00%)	
occurrences (all)	1	0	
Hyperuricaemia			
subjects affected / exposed	1 / 29 (3.45%)	0 / 30 (0.00%)	
occurrences (all)	1	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
17 October 2019	Changes included: - Moved immunogenicity endpoint to secondary objectives. - Increased the screening period from 28 days (4 weeks) to 48 days. - Removed the reference to the Patient Global Assessment (PGA) of disease activity and replaced with Patient Assessment of Palmoplantar Pustulosis Disease Activity. - Increased the number of study centers from 10 to 25. - Increased the upper age limit of subjects from 70 years to 75 years. - Inclusion Criteria, criterion 3, revised to remove reference to lack of response to prior topical or corticosteroid therapy. - Added a caveat that out-of-range screening values may be assessed by the Investigator and subjects may be enrolled at the discretion of the Investigator following consultation with the Medical Monitor and Sponsor. Removed the clause allowing one repeat test for abnormal laboratory results. - Exclusion Criteria, criterion 13 revised to allow squamous cell carcinoma as determined by the Investigator to be fully treatable. - Added a criterion to exclude subjects for inability to tolerate SC drug administration. - Clarified the appearance description of ANB019 and placebo. - Added a paragraph to describe the study procedures for early withdrawal. - Added an additional urine pregnancy text collection at the Week 20 study visit. - For FSH collection, removed the criteria in the definition of postmenopausal that stated women must be 45 years of age. - Added the endpoint for ADA assessment.
19 December 2019	Changes included: - Revised the duration allowed for previous chest x-ray from 6 months to 12 months. - Removed the following sentence: "If any laboratory results are outside the upper or lower limits listed above, final determination of eligibility will be after Investigator assessment following consultation with the Medical Monitor and Sponsor. - Administrative changes for consistency with other AnaptysBio protocols.
23 June 2020	Changes included: - Removed Week 4 from the primary analysis of PPASI50. - Revised text describing primary efficacy analysis with respect to analysis factors and use of 2-sided exact 95% test for the analysis of treatment differences. - Revised the wording of the exclusion criteria to permit enrollment of subjects with localized oral and genital herpes simplex that is well controlled. - Revised description of logistic regression model to identify factors used for analysis of 2 secondary efficacy endpoints (proportion of subjects achieving PPPASI50 and PPPASI75 at all study centers and proportion of patients with clear or almost clear assessment score on PPPIGA at all study center visits).
11 August 2020	Changes included: - Updated Benefit/Risk Assessment to include ANB019-005 final TEAE results and 26-week toxicology study in cynomolgus monkeys
29 October 2020	Changes included: - Changed the primary endpoint to mean change from Baseline in PPPASI at Week 16. Moved proportion of subjects achieving PPPASI50 at Week 16 from primary to secondary objective. - Changed description of statistical methods for analysis of primary efficacy endpoint. - Minor editorial changes for accuracy and formatting.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported