Clinical trial results:
Placebo-Controlled Proof of Concept Study to Investigate ANB020 Activity upon House Dust Mite Skin Challenge in Patients Suffering from Moderate to Severe Atopic Dermatitis

Summary

EudraCT number	2016-002539-14
Trial protocol	GB
Global end of trial date	04 December 2017

Results information

Result version number	v1 (current)
This version publication date	13 October 2021
First version publication date	13 October 2021

Trial information

Trial identification

Sponsor protocol code	ANB020-002

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	AnaptysBio Inc.
Sponsor organisation address	10421 Pacific Center Court, Suite 200, San Diego, CA, United States, 92121
Public contact	AnaptysBio Clinical Trials Info, AnaptysBio Inc, +1 8583626387, clinicaltrialinfo@anaptysbio.com
Scientific contact	AnaptysBio Clinical Trials Info, AnaptysBio Inc, +1 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	04 December 2017
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	04 December 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

• To measure the decrease of cytokines within interstitial fluid, where saline and house dust mite (HDM) have been administered, in patients receiving ANB020 compared to placebo.
• To assess the effect of ANB020 on differential white blood cell (WBC) counts.
• To assess the safety and tolerability of single dose administration of ANB020 in patients with atopic dermatitis (AD).

Protection of trial subjects:

The study was conducted in accordance with the protocol, the ethical principles derived from international guidelines including the Declaration of Helsinki and Council for International Organizations of Medical Sciences International Ethical Guidelines, applicable International Council for Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines, and applicable laws and regulations.
The study protocol, all study protocol amendments, written study patient information, informed consent form (ICF), Investigator's Brochure and any other relevant documents were reviewed and approved by an independent ethics committee (IEC) at the study center.
An informed consent document approved by the study center's IEC was signed by the patient or their legally authorized representative and the authorized person obtaining the informed consent before the participant was entered in the study.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	06 March 2017
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: 14
Worldwide total number of subjects	14
EEA total number of subjects	0

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)	14
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 14 (100%) patients were screened in the study. Of these, 12 (85.7%) patients received placebo and ANB020. Two (14.3%) patients discontinued the study prior to ANB020 or placebo administration with the reported reason as patient withdrew consent.

Pre-assignment period milestones

Number of subjects started	14
Number of subjects completed	12

Pre-assignment subject non-completion reasons

Reason: Number of subjects	Consent withdrawn by subject: 2

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	ANB020

Arm description:

Participants received an intravenous (IV) dose of placebo saline on Day 1. On Day 4, participants returned to the study center for a skin challenge test with saline control and house dust mite (HDM) allergen. Approximately 1 hour after the HDM skin challenge, suction blister cups were applied to the site of injection to generate a blister.
On Day 8, participants with a positive response to the HDM skin challenge test received 300 mg ANB020 IV. On Day 11 participants returned to the study center for the skin challenge with saline and HDM. Approximately 1 hour after the HDM skin challenge, suction blister cups were applied to the site of injection to generate a blister.

Arm type	Experimental
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Sterile normal saline (0.9% NaCl) for injection.

Investigational medicinal product name	ANB020
Investigational medicinal product code	ANB020
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

ANB020 was administered as a single IV dose of 300 mg/100 mL.

Number of subjects in period 1[1]	ANB020
Started	12
Completed	12

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: Two patients discontinued the study prior to ANB020 or placebo administration.

Baseline characteristics

Reporting groups	
Reporting group title	ANB020

Reporting group description:

Participants received an intravenous (IV) dose of placebo saline on Day 1. On Day 4, participants returned to the study center for a skin challenge test with saline control and house dust mite (HDM) allergen. Approximately 1 hour after the HDM skin challenge, suction blister cups were applied to the site of injection to generate a blister.
On Day 8, participants with a positive response to the HDM skin challenge test received 300 mg ANB020 IV. On Day 11 participants returned to the study center for the skin challenge with saline and HDM. Approximately 1 hour after the HDM skin challenge, suction blister cups were applied to the site of injection to generate a blister.

Reporting group values	ANB020	Total	
Number of subjects	12	12	
Age categorical Units: Subjects			
18 - 65 years	12	12	
Age continuous Units: years			
arithmetic mean	40.4		
standard deviation	± 13.45	-	
Gender categorical Units: Subjects			
Female	1	1	
Male	11	11	
Race Units: Subjects			
White	12	12	

End points

End points reporting groups

Reporting group title	ANB020

Reporting group description:

Participants received an intravenous (IV) dose of placebo saline on Day 1. On Day 4, participants returned to the study center for a skin challenge test with saline control and house dust mite (HDM) allergen. Approximately 1 hour after the HDM skin challenge, suction blister cups were applied to the site of injection to generate a blister.
On Day 8, participants with a positive response to the HDM skin challenge test received 300 mg ANB020 IV. On Day 11 participants returned to the study center for the skin challenge with saline and HDM. Approximately 1 hour after the HDM skin challenge, suction blister cups were applied to the site of injection to generate a blister.

Subject analysis set title	Placebo
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received a placebo IV infusion on Day 1.

Subject analysis set title	ANB020
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received 300 mg ANB020 by IV infusion on Day 8.

Primary: Interleukin-4 (IL-4) Concentration in Blister Fluid

End point title	Interleukin-4 (IL-4) Concentration in Blister Fluid[1]

End point description:

Within 24 hours of the saline and HDM skin challenge (Days 5 and 12), blister fluid was aspirated with a 30-gauge needle. Cytokine concentrations were measured using validated assay methods. The lower limit of quantitation (LLOQ) for IL-4 is 6.46 pg/mL.

End point type	Primary

End point timeframe:

Day 5 (4 days after placebo infusion) and Day 12 (4 days after infusion with ANB020)

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: Inferential statistical analysis of cytokine concentrations in blister fluid was not performed due to < 5 paired data points.

End point values	Placebo	ANB020		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	0[2]	0[3]		
Units: pg/mL				
arithmetic mean (standard deviation)				
Saline control	()	()		
House dust mite extract	()	()		

Notes:

[2] - All participants had concentrations below lower limit of quantification

[3] - All participants had concentrations below lower limit of quantification

Statistical analyses

No statistical analyses for this end point

Primary: Interleukin-5 (IL-5) Concentration in Blister Fluid

End point title	Interleukin-5 (IL-5) Concentration in Blister Fluid[4]

End point description:

Within 24 hours of the saline and HDM skin challenge (Days 5 and 12), blister fluid was aspirated with a 30-gauge needle. Cytokine concentrations were measured using validated assay methods. The LLOQ for IL-5 is 1.16 pg/mL.
"99999" indicates values that were below the LLOQ or could not be calculated.

End point type	Primary

End point timeframe:

Day 5 and Day 12

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: Inferential statistical analysis of cytokine concentrations in blister fluid was not performed due to < 5 paired data points.

End point values	Placebo	ANB020		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	12[5]	12[6]		
Units: pg/mL				
arithmetic mean (standard deviation)				
Saline control	1.88 (± 2.462)	99999 (± 99999)		
House dust mite extract	1.73 (± 1.648)	2.47 (± 2.583)		

Notes:

[5] - 4 and 5 subjects had concentrations ≥ LLOQ after saline and HDM challenge, respectively.

[6] - 1 and 5 subjects had concentrations ≥ LLOQ after saline and HDM challenge, respectively.

Statistical analyses

No statistical analyses for this end point

Primary: Interleukin-13 (IL-13) Concentration in Blister Fluid

End point title	Interleukin-13 (IL-13) Concentration in Blister Fluid[7]

End point description:

Within 24 hours of the saline and HDM skin challenge (Days 5 and 12), blister fluid was aspirated with a 30-gauge needle. Cytokine concentrations were measured using validated assay methods. The LLOQ for IL-13 is 90.96 pg/mL.

End point type	Primary

End point timeframe:

Day 5 and Day 12

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: Inferential statistical analysis of cytokine concentrations in blister fluid was not performed due to < 5 paired data points.

End point values	Placebo	ANB020		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	12[8]	12[9]		
Units: pg/mL				
arithmetic mean (standard deviation)				
Saline control	131.90 (± 122.626)	160.84 (± 136.219)		
House dust mite extract	137.13 (± 110.450)	135.99 (± 168.476)		

Notes:

[8] - 5 and 6 subjects had concentrations ≥ LLOQ after saline and HDM challenge, respectively.

[9] - 6 and 4 subjects had concentrations ≥ LLOQ after saline and HDM challenge, respectively.

Statistical analyses

No statistical analyses for this end point

Primary: Interleukin-33 (IL-33) Concentration in Blister Fluid

End point title	Interleukin-33 (IL-33) Concentration in Blister Fluid[10]

End point description:

Within 24 hours of the saline and HDM skin challenge (Days 5 and 12), blister fluid was aspirated with a 30-gauge needle. Cytokine concentrations were measured using validated assay methods. The LLOQ for IL-33 is 4.44 pg/mL.

End point type	Primary

End point timeframe:

Day 5 and Day 12

Notes:

[10] - 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: Inferential statistical analysis of cytokine concentrations in blister fluid was not performed due to < 5 paired data points.

End point values	Placebo	ANB020		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	0[11]	0[12]		
Units: pg/mL				
arithmetic mean (standard deviation)				
Saline control	()	()		
House dust mite extract	()	()		

Notes:

[11] - All participants had concentrations < LLOQ

[12] - All participants had concentrations < LLOQ

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants with Treatment-emergent Adverse Events

End point title	Number of Participants with Treatment-emergent Adverse Events[13]

End point description:

Treatment emergent adverse events (TEAEs) are AEs that started or worsened in severity on or after the date and time of the study drug infusion or if the event represents an exacerbation of a condition observed pre-treatment.
A serious AE is any untoward medical occurrence that at any dose:
- Resulted in death;
- Was life-threatening;
- Required inpatient hospitalization or prolongation of existing hospitalization;
- Resulted in persistent or significant disability/incapacity;
- Was a congenital abnormality/birth defect.
- Other: Medically significant events, which did not meet any of the criteria above, but may have jeopardized the patient and may have required medical or surgical intervention to prevent one of the other serious outcomes listed above.

A severe AE is defined as an event that interrupted the patient's usual daily activity.

End point type	Primary

End point timeframe:

For Placebo, Day 1 to Day 8; For ANB020 from Day 8 to Day 148.

Notes:

[13] - 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: Inferential statistical analysis of safety data were not planned.

End point values	Placebo	ANB020		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	12	12		
Units: participants				
Any treatment-emergent adverse event (TEAE)	8	11		
Any treatment-emergent serious AE (TESAE)	0	1		
TEAE leading to study drug discontinuation	0	0		
TEAE leading to study drug interruption	0	0		
TEAE leading to study drug dose reduction	0	0		
TEAE leading to discontinuation of study	0	0		
Related TEAEs	0	10		
Severe TEAEs	0	0		
Deaths due to TEAE	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Longest Wheal Diameter

End point title	Longest Wheal Diameter

End point description:

Urticarial response (longest wheal diameter) was measured 30 minutes after the HDM skin challenge test.

End point type	Secondary

End point timeframe:

Day 4 (placebo) and Day 11 (ANB020), 30 minutes after the saline and HDM challenge.

End point values	Placebo	ANB020		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	12	12		
Units: mm				
arithmetic mean (standard deviation)				
Saline control	0.1 (± 0.29)	0.0 (± 0.00)		
House dust mite extract	8.3 (± 2.96)	7.9 (± 3.23)		

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum Observed Concentration (Cmax) of ANB020

End point title	Maximum Observed Concentration (Cmax) of ANB020

End point description:

End point type	Secondary

End point timeframe:

Day 8 at predose, 0.5 hours after the start of infusion, end of infusion, and 3 hours and 6 hours after the end of infusion.

End point values	ANB020			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: µg/mL				
geometric mean (geometric coefficient of variation)	115.6 (± 39.9)			

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Maximum Observed Concentration (Tmax) of ANB020

End point title	Time to Maximum Observed Concentration (Tmax) of ANB020

End point description:

End point type	Secondary

End point timeframe:

Day 8 at predose, 0.5 hours after the start of infusion, end of infusion, and 3 hours and 6 hours after the end of infusion.

End point values	ANB020			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: hours				
median (full range (min-max))	1.180 (1.00 to 7.03)			

Statistical analyses

No statistical analyses for this end point

Secondary: Area Under the Concentration-time Curve in Serum from Time Zero (Predose) Extrapolated to Infinite Time (AUC0-inf) of ANB020

End point title	Area Under the Concentration-time Curve in Serum from Time Zero (Predose) Extrapolated to Infinite Time (AUC0-inf) of ANB020

End point description:

End point type	Secondary

End point timeframe:

Day 8 at predose, 0.5 hours after the start of infusion, end of infusion, and 3 hours and 6 hours after the end of infusion.

End point values	ANB020			
Subject group type	Reporting group			
Number of subjects analysed	9[14]			
Units: h × µg/mL				
geometric mean (geometric coefficient of variation)	21110 (± 32.4)			

Notes:

[14] - Three subjects excluded due to percentage of AUC(0-inf) obtained by extrapolation > 20.0%

Statistical analyses

No statistical analyses for this end point

Secondary: Area Under the Serum Concentration-time Curve from Time Zero to the Time of the Last Quantifiable Concentration (AUClast) for ANB020

End point title	Area Under the Serum Concentration-time Curve from Time Zero to the Time of the Last Quantifiable Concentration (AUClast) for ANB020

End point description:

End point type	Secondary

End point timeframe:

Day 8 at predose, 0.5 hours after the start of infusion, end of infusion, and 3 hours and 6 hours after the end of infusion.

End point values	ANB020			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: h × µg/mL				
geometric mean (geometric coefficient of variation)	13740 (± 90.5)			

Statistical analyses

No statistical analyses for this end point

Secondary: Apparent Terminal Half-life (t1/2) of ANB020

End point title	Apparent Terminal Half-life (t1/2) of ANB020

End point description:

End point type	Secondary

End point timeframe:

Day 8 at predose, 0.5 hours after the start of infusion, end of infusion, and 3 hours and 6 hours after the end of infusion.

End point values	ANB020			
Subject group type	Reporting group			
Number of subjects analysed	10[15]			
Units: hours				
geometric mean (geometric coefficient of variation)	241.7 (± 52.8)			

Notes:

[15] - Two subjects excluded due to a goodness-of-fit statistic for calculation of λZ (Rsq) < 0.800

Statistical analyses

No statistical analyses for this end point

Secondary: Systemic Clearance (CL) of ANB020

End point title	Systemic Clearance (CL) of ANB020

End point description:

End point type	Secondary

End point timeframe:

Day 8 at predose, 0.5 hours after the start of infusion, end of infusion, and 3 hours and 6 hours after the end of infusion.

End point values	ANB020			
Subject group type	Reporting group			
Number of subjects analysed	9[16]			
Units: L/h				
geometric mean (geometric coefficient of variation)	0.01422 (± 32.3)			

Notes:

[16] - Three subjects excluded due to percentage of AUC(0-inf) obtained by extrapolation > 20.0%

Statistical analyses

No statistical analyses for this end point

Secondary: Volume of Distribution at Steady State Following IV Dosing of ANB020 (Vss)

End point title	Volume of Distribution at Steady State Following IV Dosing of ANB020 (Vss)

End point description:

End point type	Secondary

End point timeframe:

Day 8 at predose, 0.5 hours after the start of infusion, end of infusion, and 3 hours and 6 hours after the end of infusion.

End point values	ANB020			
Subject group type	Reporting group			
Number of subjects analysed	9[17]			
Units: liters				
geometric mean (geometric coefficient of variation)	5.354 (± 37.2)			

Notes:

[17] - Three subjects excluded due to percentage of AUC(0-inf) obtained by extrapolation > 20.0%

Statistical analyses

No statistical analyses for this end point

Secondary: Serum IL-4 Concentration

End point title	Serum IL-4 Concentration

End point description:

Cytokine concentrations were measured using validated assay methods. The lower limit of quantitation (LLOQ) for IL-4 is 6.46 pg/mL.

End point type	Secondary

End point timeframe:

Baseline (Day 1 for Placebo and Day 8 for ANB020) and 5 days after study drug administration (Day 5

End point values	Placebo	ANB020		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	0[18]	0[19]		
Units: pg/mL				
arithmetic mean (standard deviation)				
Baseline	()	()		
5 days after study drug administration	()	()		

Notes:

[18] - All participants had concentrations below lower limit of quantification

[19] - All participants had concentrations below lower limit of quantification

Statistical analyses

No statistical analyses for this end point

Secondary: Serum IL-5 Concentration

End point title	Serum IL-5 Concentration

End point description:

Cytokine concentrations were measured using validated assay methods. The LLOQ for IL-5 is 1.16 pg/mL.

End point type	Secondary

End point timeframe:

Baseline and 5 days after study drug administration

End point values	Placebo	ANB020		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	0[20]	0[21]		
Units: pg/mL				
arithmetic mean (standard deviation)				
Baseline	()	()		
5 days after study drug administration	()	()		

Notes:

[20] - All participants had concentrations less than the LLOQ

[21] - All participants had concentrations less than the LLOQ

Statistical analyses

No statistical analyses for this end point

Secondary: Serum IL-13 Concentration

End point title	Serum IL-13 Concentration

End point description:

Cytokine concentrations were measured using validated assay methods. The LLOQ for IL-13 is 90.96 pg/mL.

End point type	Secondary

End point timeframe:

Baseline and 5 days after study drug administration

End point values	Placebo	ANB020		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	0[22]	0[23]		
Units: pg/mL				
arithmetic mean (standard deviation)				
Baseline	()	()		
5 days aafter study drug administration	()	()		

Notes:

[22] - All participants had concentrations < LLOQ

[23] - All participants had concentrations < LLOQ

Statistical analyses

No statistical analyses for this end point

Secondary: Serum IL-33 Concentration

End point title	Serum IL-33 Concentration

End point description:

Cytokine concentrations were measured using validated assay methods. The LLOQ for IL-33 is 4.44 pg/mL.

End point type	Secondary

End point timeframe:

Baseline and 5 days after study drug administration

End point values	Placebo	ANB020		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	0[24]	0[25]		
Units: pg/mL				
arithmetic mean (standard deviation)				
Baseline	()	()		
5 days after study drug administration	()	()		

Notes:

[24] - All participants had concentrations < LLOQ

[25] - All participants had concentrations < LLOQ

Statistical analyses

No statistical analyses for this end point

Secondary: Serum Soluble Specific Cell-surface Receptor (sST2) Concentration

End point title	Serum Soluble Specific Cell-surface Receptor (sST2) Concentration

End point description:

The concentration of sST2 in serum was measured using a quantitative sandwich monoclonal enzyme-linked immunosorbant assay (ELISA). The LLOQ for sST2 was determined to be 3.13 ng/mL.

End point type	Secondary

End point timeframe:

Baseline and 5 days after study drug administration

End point values	Placebo	ANB020		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	12	12		
Units: µg/L				
arithmetic mean (standard deviation)				
Baseline	34.04 (± 8.531)	33.99 (± 9.089)		
5 days after study drug administration	34.90 (± 8.800)	35.67 (± 10.417)		

Statistical analyses

No statistical analyses for this end point

Secondary: Ex-Vivo Induced Interferon-gamma (IFN-y) Levels

End point title	Ex-Vivo Induced Interferon-gamma (IFN-y) Levels

End point description:

Whole blood samples were stimulated with interleukin-12 and interleukin-33 to determine the affect of ANB020 on inhibition of cytokine-induced interferon gamma. IFN-y concentrations were measured using validated assay methods. The LLOQ of IFN-y was 146.56 ng/L. "99999" indicates values below the LLOQ.

End point type	Secondary

End point timeframe:

Days 1, 11, 64, 120 and 148

End point values	ANB020			
Subject group type	Reporting group			
Number of subjects analysed	12[26]			
Units: ng/L				
arithmetic mean (standard deviation)				
Day 1 (Baseline)	4379.77 (± 4221.941)			
Day 11	99999 (± 99999)			
Day 64	629.65 (± 923.419)			
Day 120	3210.27 (± 2963.587)			

Day 148	3107.01 (± 2420.356)			

Notes:

[26] - The number of subjects with levels ≥ LLOQ was 12, 0, 8, 11, and 11 at each time point respectively

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Anti-drug Antibodies

End point title	Number of Participants with Anti-drug Antibodies

End point description:

End point type	Secondary

End point timeframe:

Samples for ADA detection were collected on Days 1, 11, 64, 120, and 148

End point values	ANB020			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: participants				
Day 1 (Baseline)	1			
Day 11	0			
Day 64	2			
Day 120	3			
Day 148	3			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: Placebo: Day 1 to Day 8 ANB020: Day 8 to Day 148	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	19.1

Reporting groups	
Reporting group title	Placebo
Reporting group description: Participants received a placebo IV infusion on Day 1.	
Reporting group title	ANB020
Reporting group description: Participants received 300 mg ANB020 by IV infusion on Day 8.	

Serious adverse events	Placebo	ANB020	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Placebo	ANB020	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 12 (66.67%)	11 / 12 (91.67%)	
Investigations			
Haemoglobin decreased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Monocyte count decreased			

subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Neutrophil count decreased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Injury, poisoning and procedural complications			
Accident			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Arthropod bite			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Clavicle fracture			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Contusion			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Vascular disorders			
Hot flush			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Hypertension			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Peripheral coldness			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Nervous system disorders			
Dizziness			
subjects affected / exposed	3 / 12 (25.00%)	4 / 12 (33.33%)	
occurrences (all)	3	5	
Headache			
subjects affected / exposed	0 / 12 (0.00%)	3 / 12 (25.00%)	
occurrences (all)	0	3	
Migraine			

subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Paraesthesia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Presyncope			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
General disorders and administration site conditions			
Peripheral swelling			
subjects affected / exposed	0 / 12 (0.00%)	2 / 12 (16.67%)	
occurrences (all)	0	2	
Chest pain			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Fatigue			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Infusion site pain			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Gastrointestinal disorders			
Dyspepsia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Nausea			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	3	
Vomiting			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Respiratory, thoracic and mediastinal disorders			

Cough			
subjects affected / exposed	1 / 12 (8.33%)	1 / 12 (8.33%)	
occurrences (all)	1	1	
Nasal congestion			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Oropharyngeal pain			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Skin and subcutaneous tissue disorders			
Urticaria			
subjects affected / exposed	0 / 12 (0.00%)	2 / 12 (16.67%)	
occurrences (all)	0	2	
Psychiatric disorders			
Stress			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Bursitis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Pain in extremity			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	0 / 12 (0.00%)	2 / 12 (16.67%)	
occurrences (all)	0	2	
Urinary tract infection			
subjects affected / exposed	0 / 12 (0.00%)	2 / 12 (16.67%)	
occurrences (all)	0	2	
Skin infection			

subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 12 (8.33%) 1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
08 November 2016	Amendment 1 implemented the following changes: • Secondary objectives updated to include: o Assess ex vivo PD activity of ANB020 on IFN-γ levels. o Test for immunogenicity to ANB020. • Summary of study design updated regarding additional PK draws, PD/ADA, and clinical assessments. • Schematic of study design updated to reflect the changes in protocol design. • Schedule of Events was updated to reflect changes in study conduct which includes: o Update of additional study center visits at Day 85, 120, and 148. o Additional telephone contact visit at Day 99. o Additional PK draws on Day 120 and Day 148. o Whole blood sampling for ex vivo IFN-γ (Day 1, 11, 64, 120 and 148). o Serum sampling for ADA (Day 1, 11, 64, 120, and 148). o EASI, IGA, SCORAD, DLQI, 5Ditch, corticosteroid use obtained on Day 85, 120, 148. o Urinalysis and safety laboratory assessments to Day 85, 120, and 148. o Moved physical examination and pregnancy test to Day 148 from Day 64. o Diary checked at Day 85, 99, 120, and 148. o Concomitant medications/AEs at each new time point. • Inclusion criteria and Patient restrictions modified to describe methods and duration of contraception for women of childbearing potential and male patients to ensure all patients are using highly effective methods of contraception throughout the study. • Section 4.3.5 modified to account for EOS to be Day 148 for AEs/SAE follow-up to reflect the changes in study conduct. • Blinding modified to accurately reflect the study is not blinded and changes in the study conduct. • Excluded medications modified to include: Any live attenuated vaccine within 4 weeks of screening and for the duration of the study (Day 148) or for 140 days post last dose of study drug. • Table of blood volume updated. • Pharmacodynamics, safety analyses, vital signs measurements, physical findings and clinical laboratory evaluation were updated to reflect the changes in study conduct.
01 December 2016	Amendment 2 implemented the following changes: • HIV criteria were added in the Exclusion criteria and the list of abbreviations was updated. • Exclusion Criteria was updated with text regarding enrollment of patients with positive blood screen for hepatitis C antibody, hepatitis B surface antigen, or HIV 1 and 2 antibodies at screening to ensure the safety of potential patients that were to be enrolled.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported