ISRCTN90323813 https://doi.org/10.1186/ISRCTN90323813

Safety, tolerability, pharmacokinetics, and pharmacodynamics of single and multiple doses of ANB033 - Part 1c

Submission date 18/01/2026	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 27/01/2026	**Overall study status** Ongoing	
Last Edited 26/01/2026	**Condition category** Digestive System	

Plain English summary of protocol

Background and study aims
AnaptysBio, Inc. is developing the study treatment ANB033 as a potential new treatment for autoimmune and inflammatory diseases such as eosinophilic esophagitis (EoE). Thesediseases appear to be the result of an overreaction of a person's immune system which damages their own cells or organs.
ANB033 is an investigational monoclonal antibody, designed to reduce disease-causing immune cells and restore healthy immune balance. It is given by an injection under the skin. The purpose of this research study is to investigate ANB033 safety and tolerability when given to adult participants with symptomatic EoE and how this treatment is absorbed and processed by the human body.

Who can participate?
Part 1c of the study will enroll male and female participants ages 18 to 70 with a diagnosis of EoE.

What does the study involve?
Participants will be randomized to subcutaneous ANB033 or placebo in a 1:1 ratio, like flipping a coin.

What are the possible benefits and risks of participating?
Participation in this study may help develop important scientific knowledge that could contribute to the development of ANB033 as a potential new treatment for autoimmune and inflammatory diseases, potentially benefiting others in the future.

Where is the study run from?
This is a global study with clinical sites in Australia, Belgium, Canada, Finland, Germany, Italy, Netherlands, New Zealand, Norway, Spain, and the UK.

When is the study starting and how long is it expected to run for?
Part 1c is planned to start January 2026. The final participant's last visit is projected to be in November 2027.

Who is funding the study?
AnaptysBio (USA)

Who is the main contact?
Mark Rigby, MD, PhD, clinicaltrialinfo@anaptysbio.com

Contact information

Type(s)
Principal investigator

Contact name
Dr Robert Anderson

Contact details
87 Ipswich Road, QLD
Woolloongabba
Australia
4102
+61 0432491089
robertand@jmclinical.com

Type(s)
Public

Contact name
Dr Lewis Gryziewicz

Contact details
AnaptysBio, Inc.
10770 Wateridge Circle, Suite 210, CA
San Diego
United States of America
92121
+1 (0)4042746330
clinicaltrialinfo@anaptysbio.com

Type(s)
Scientific

Contact name
Dr Mark Rigby

Contact details
AnaptysBio, Inc.
10770 Wateridge Circle, Suite 210, CA

San Diego
United States of America
92121
+1 (0)4042746330
clinicaltrialinfo@anaptysbio.com

Additional identifiers

Integrated Research Application System (IRAS)
1013483

Protocol Number
ANB033-101

Study information

Scientific Title
A phase 1, randomized, double-blind, placebo-controlled study of the safety, tolerability, pharmacokinetics, and pharmacodynamics of single and multiple doses of ANB033 in adult participants- part 1c

Study objectives
Part 1c of the study will comprise a multicenter, double-blind, randomized, placebo-controlled, parallel arm design that compares the safety and tolerability of multiple SC (subcutaneous) doses of ANB033 versus placebo in participants with with symptomatic Eosinophilic Esophagitis (EoE).

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 16/01/2026, Bellberry Human Research Ethics Committee (123 Glen Osmond Road Eastwood, Adelaide, 5063, Australia; +61 (0)883613222; bellberry@bellberry.com.au), ref: 2024-11-1935-A-10

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Safety

Study type(s)

Health condition(s) or problem(s) studied
Eosinophilic Esophagitis (EoE)

Interventions
Part 1c of the study will comprise of a multicenter, double-blind, randomized, placebo-controlled, parallel arm design that compares the safety and tolerability of a single SC (subcutaneous) dose level of ANB033 or placebo in participants with symptomatic Eosinophilic Esophagitis (EoE). Part 1c will enroll participants every 2 weeks for 12 weeks for a total of 6 doses. Participants will be randomized to subcutaneous ANB033 or placebo in a 1:1 ratio.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
ANB033

Primary outcome(s)
1. The safety of ANB033 in participants with symptomatic EoE measured using Incidence, type, and severity of all adverse events (AEs) at Days 1, 15, 29, 43, 57, 71, 85, 99, 127, 155, 183, 211, 239.

2. The tolerability of ANB033 in participants with symptomatic EoE measured using Vital signs, ECGs, physical examinations, and clinical laboratory assessments at Days 1, 15, 29, 43, 57, 71, 85, 99, 127, 155, 183, 211, 239

Key secondary outcome(s)
1. Pharmacokinetic (PK) parameters measured using a fully validated ligand-binding assay and noncompartmental analysis at Days 1, 15, 29, 43, 57, 71, 85, 99, 127, 155, 183,

2. Incidence of confirmed positive anti-drug antibodies (ADAs) and titers measured using a fully validated ligand-binding assay at Days 1, 15, 29, 43, 57, 71, 99, 155, 239

Completion date
22/11/2027

Eligibility

Key inclusion criteria
1. Male or female aged 18 to 70 years old
2. Willing and able to provide informed consent
3. Female participants must not be pregnant or lactating
4. Male participants must be willing to comply with protocol contraceptive requirements

5. Prior histologic documentation of EoE diagnosis
6. Absence of histologic response to at least 6 weeks of proton pump inhibitors (PPI) or documented intolerance to PPI.
7. Histologic evidence of EoE with peak eosinophil count ≥15/hpf, from 2 of 3 levels of the esophagus at the Screening endoscopy.
8. History of at least 4 episodes of dysphagia in the 2 weeks prior to Screening.
9. Willing to comply with necessary tests and protocol requirements

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
70 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Has signs, symptoms, or current diagnosis of concerning, severe, progressive, or uncontrolled renal, cardiac, vascular, pulmonary, GI, endocrine, neurologic, hematologic, rheumatologic, psychiatric, or metabolic disturbances.
2. Participant has a BMI of <16 or >35 kg/m² or total body weight <45 kg (99 lb) (Note: BMI = weight (kg)/[height (m)]²).
3. Participant smokes cigarettes or has quit smoking within 3 months of screening.
4. History of clinically significant drug or alcohol abuse
5. Clinically significant, abnormal 12-lead ECG
6. Planned surgery within 4 weeks prior to the start of screening
7. History of drug allergy, suspected medical condition, including autoimmune or inflammatory conditions, that currently requires or may require systemic immunomodulatory or immune suppressive therapy.
8. Predisposed to develop an infection
9. Positive for hepatitis B, hepatitis C and HIV-1 or HIV-2 antibodies
10. Diagnosis of, suspected diagnosis of, or concerns of acquiring active TB or currently with untreated latent TB.

Date of first enrolment
28/02/2026

Date of final enrolment
28/02/2027

Locations

Countries of recruitment
United Kingdom

England

Australia

Belgium

Canada

Germany

Italy

Netherlands

Norway

Spain

United States of America

Study participating centre
Royal Liverpool University Hospital
Prescot Street
Liverpool
England
L7 8XP

Sponsor information

Organisation
AnaptysBio, Inc.

Funder(s)

Funder type

Funder Name
AnaptysBio, Inc.

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available