

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

Submission date 18/01/2026	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 27/01/2026	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 26/01/2026	Condition category Digestive System	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

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). These diseases 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

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Additional identifiers

Protocol Number

ANB033-101

Integrated Research Application System (IRAS)

1013483

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 $\geq 15/\text{hpf}$, 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 $>35 \text{ kg/m}^2$ or total body weight $<45 \text{ kg}$ (99 lb) (Note: $\text{BMI} = \text{weight (kg)}/[\text{height (m)}]^2$).
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