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

Submission date 10/07/2025	**Recruitment status** Not yet recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 04/09/2025	**Overall study status** Ongoing	
Last Edited 03/09/2025	**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 celiac disease (CeD). 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 subcutaneous injection.
The purpose of this research study is to investigate ANB033 safety and tolerability when given to adult participants with CeD and how this treatment is absorbed and processed by the human body.

Who can participate?
Adults aged 18-70 years old with CeD

What does the study involve?
This study is testing the safety, tolerability of both single and multiple doses of a new experimental treatment called ANB033.

What are the possible benefits and risks of participating?
ANB033 is an experimental medication so the risks to human participants have not been fully evaluated.
The benefits, risks and side effects that may occur in participants treated with ANB033 are based on the results from nonclinical investigations of ANB033 and information available from the same class of compound effects.

Where is the study run from?
Australia, New Zealand and the Netherlands

When is the study starting and how long is it expected to run for?
October 2024 to July 2026

Who is funding the study?
AnaptysBio, Inc. (USA)

Who is the main contact?
clinicaltrialinfo@anaptysbio.com

Contact information

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

Type(s)
Principal Investigator

Contact name
Dr Nah Yeon (Tina) Baik

Contact details
Level 2, 97 Grafton Road, Grafton
Grafton Auckland
New Zealand

1010
(+649) 303-4987
tina@optimalclinicaltrials.com

Type(s)
Principal Investigator

Contact name
Dr Oscar Walsh

Contact details
Suite 9, 6/230 Blackshaws Road, VIC
Altona North
Australia
3025
+61 (0)1300903512
owalsh@altonaclinicalresearch.com

Additional identifiers

EudraCT/CTIS number
2024-520409-38-00

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
ANB033-101

Study information

Scientific Title
A Phase I, randomized, double-blind, placebo-controlled study of the safety, tolerability, pharmacokinetics, and pharmacodynamics of single and multiple doses of ANB033 in adult participants - Part 1b

Study objectives
Part 1b 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 celiac disease (CeD). Exploratory assessments of the effect of ANB033 on gastrointestinal (GI) symptoms and on intestinal histology will be conducted.

Ethics approval required
Ethics approval required

Ethics approval(s)

1. Approved 21/01/2025, Bellberry Human Research Ethics Committee (123 Glen Osmond Road Eastwood, Adelaide, 5063, Australia; +61 (0)883613222; bellberry@bellberry.com.au), ref: 2024-11-1935

2. Approved 25/03/2025, Southern Health and Disability Ethics Committee (Ministry of Health, PO Box 5013, Wellington, 6140, New Zealand; +64 (0)800 855 066; hdecs@health.govt.nz), ref: 2025 FULL 21884

Study design
Multicenter double-blind randomized placebo-controlled parallel-arm trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other, Safety

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Celiac disease

Interventions
Part 1b of the study will comprise 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 CeD. Part 1b will enroll adults with CeD every 2 weeks for a total of three doses. Part 1b of the study will enroll adults with CeD.

Participants will be randomized to subcutaneous ANB033 or placebo in a 1:1 ratio.

Intervention Type
Drug

Pharmaceutical study type(s)
Pharmacokinetic, Pharmacodynamic

Phase
Phase I

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

Primary outcome measure

The safety and tolerability of ANB033 in participants with celiac disease:
1. Incidence, type, and severity of all adverse events (AEs) recorded at Days 1, 15, 29, 36, 43, 57, 71, 85, 99, 127, 155, and 183
2. Vital signs, ECGs, physical examinations, and clinical laboratory assessments measured at Days 1, 15, 29, 36, 43, 57, 71, 85, 99, 127, 155, and 183

Secondary outcome measures
1. Pharmacokinetic (PK) parameters measured using a fully validated ligand-binding assay and noncompartmental analysis at Days 1, 15, 29, 36, 43, 57, 85, 99, 127
2. Incidence of confirmed positive anti-drug antibodies (ADAs) and titers measured using a fully validated ligand-binding assay at Days, 1, 15, 29, 36, 43, 57, 71, 85, 127

Overall study start date
30/10/2024

Completion date
01/07/2026

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. Have an established diagnosis of Celiac Disease, including diagnostic findings from a duodenal biopsy AND have had this diagnosis at least 12 months prior to Screening
6. Adhered to a gluten-free diet and willing to comply with a gluten-free diet
7. Willing to comply with necessary tests and protocol requirements

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
60

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 months 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
20/10/2025

Date of final enrolment
28/02/2026

Locations

Countries of recruitment
Australia

Netherlands

New Zealand

Study participating centre
Site 1
Altona North
Australia
3025

Study participating centre
Site 2
Taringa
Australia
4068

Study participating centre
Site 3
Auckland
New Zealand
1010

Study participating centre
Site 4
Waikanae Beach
New Zealand
5036

Study participating centre
Site 5
Auckland
New Zealand
0622

Study participating centre
Site 6
Wellington
New Zealand
5010

Study participating centre
Site 7
Arnhem
Netherlands
6815 AD

Study participating centre
Site 8
Amsterdam
Netherlands
1081 HV

Sponsor information

Organisation
AnaptysBio, Inc.

Sponsor details
10770 Wateridge Circle, Suite 21, CA
San Diego
United States of America
92121
+1 (0)4042746330
clinicaltrialinfo@anaptysbio.com

Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
AnaptysBio, Inc.

Results and Publications

Publication and dissemination plan
There is no plan to publish

Intention to publish date
13/01/2027

Individual participant data (IPD) sharing plan
The researchers do not plan to share participant level data as the primary and secondary endpoints are safety and pharmacodynamic related and the celiac disease endpoints are exploratory in nature. All participant level data will be used for internal decision making for future development planning.

IPD sharing plan summary
Not expected to be made available