

Phase I trial: Celerion code CA33748

Submission date 07/01/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 13/01/2025	Overall study status Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 13/01/2025	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

The Health Research Authority (HRA) has approved deferral of publication of the full details of the trial. The full details will be added to the study record within 30 months after the trial has ended.

Contact information

Type(s)

Principal investigator

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Public

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Additional identifiers

Clinical Trials Information System (CTIS)

2021-004177-32

Integrated Research Application System (IRAS)

1004078

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

IRAS 1004078; Celerion code: CA33748

Study information

Scientific Title

Phase I trial: Celerion code CA33748

Study objectives

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Ethics approval required

Ethics approval required

Ethics approval(s)

approved 14/12/2021, London - Harrow Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, United Kingdom; +44 (0)207 104 8137; harrow.rec@hra.nhs.uk), ref: 21/LO/0838

Study design

Pharmacokinetic pharmacodynamic safety and tolerability study in 189 healthy adult volunteers

Primary study design

Interventional

Study type(s)

Safety, Efficacy

Health condition(s) or problem(s) studied

Healthy volunteers

Interventions

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Intervention Type

Drug

Phase

Phase I

Drug/device/biological/vaccine name(s)

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Primary outcome(s)

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Key secondary outcome(s)

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Completion date

22/05/2024

Eligibility

Key inclusion criteria

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Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Sex

Male

Key exclusion criteria

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Date of first enrolment

10/01/2022

Date of final enrolment

30/08/2023

Locations**Countries of recruitment**

United Kingdom

England

Northern Ireland

Bulgaria

Poland

Study participating centre**Celerion GB Limited**

Suite 1, 7th Floor 50 Broadway

London

United Kingdom

SW1H 0BL

Study participating centre**MTZ Clinical Research powered by Pratia**

Pratia S.A., Gladka 22

Warszawa

Poland

02-172

Study participating centre

COMAC

3 Sv. Georgi Sofiyski str./13 Urvich str.

Sofia

Bulgaria

1606/1612

Sponsor information

Organisation

Alkem (India)

ROR

<https://ror.org/04kwy9224>

Organisation

Enzene BioSciences Ltd.

Funder(s)

Funder type

Industry

Funder Name

Alkem Laboratories Ltd.

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to the protection of commercially confidential information.

IPD sharing plan summary

Not expected to be made available