ISRCTN68610794 https://doi.org/10.1186/ISRCTN68610794

Phase I trial: Celerion code CA33748

Submission date 07/01/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 13/01/2025	**Overall study status** Deferred	[_] Statistical analysis plan [_] Results
Last Edited 13/01/2025	**Condition category** Other	[_] Individual participant data [X] 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

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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)
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.

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
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SW1H 0BL

Study participating centre
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Study participating centre
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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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
	Participant information sheet				

Participant information sheet	11/11/2025	11/11/2025	No	Yes