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

EudraCT/CTIS number
2021-004177-32

IRAS number
1004078

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised parallel trial

Study setting(s)
Pharmaceutical testing facility

Study type(s)
Safety, Efficacy

Participant information sheet
Not available in web format

Health condition(s) or problem(s) studied
Healthy volunteers

Interventions
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Intervention Type
Drug

Pharmaceutical study type(s)
Pharmacokinetic, Pharmacodynamic

Phase
Phase I

Drug/device/biological/vaccine name(s)
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Primary outcome measure
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.

Secondary outcome measures
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.

Overall study start date
19/10/2021

Completion date
22/05/2024

Eligibility

Key inclusion criteria
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Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Male

Target number of participants
189

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
Bulgaria

England

Northern Ireland

Poland

United Kingdom

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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Sponsor information

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Sponsor type
Industry

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Sponsor type
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Funder(s)

Funder type
Industry

Funder Name
Alkem Laboratories Ltd.

Results and Publications

Publication and dissemination plan
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. Publication of some trial details is deferred because of the high commercial sensitivity of this Phase I study and the negligible benefit to the public of Phase I information. Results may be posted on or after the date of publication of full trial details.

Intention to publish date
22/11/2026

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