

# Phase I trial: Celerion code CA33748

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

### Contact name

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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

### Study outputs

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

