

Phase I trial HMR code: 23-006

Submission date 26/01/2024	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 09/02/2024	Overall study status Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 09/02/2024	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

The sponsor has confirmed that the trial meets the criteria for 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
Nil known

IRAS number
1008812

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 1008812, HMR code: 23-006

Study information

Scientific Title
Phase I trial HMR code: 23-006 [The full scientific title will be published within 30 months after the end of the trial]

Study objectives
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Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 21/12/2023, Harrow Research Ethics Committee (2 Redman Place, Stratford , London, E20 1JQ , United Kingdom; +44 (0)207 1048154; harrow.rec@hra.nhs.uk), ref: 23/LO /0809

2. Approved 04/01/2024, MHRA (10 South Colonnade, Canary Wharf, London , E14 4PU, United Kingdom; +44 (0)20 3080 6000; info@mhra.gov.uk), ref: CTA 04854/0225/001-0001

Study design

First-in-human safety, pharmacokinetics, and pharmacodynamics trial in up to 168 healthy volunteers

Primary study design

Interventional

Secondary study design

Randomized controlled trial; open-label cross-over trial

Study setting(s)

Other

Study type(s)

Other

Participant information sheet

Not available in web format

Health condition(s) or problem(s) studied

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Interventions

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Intervention Type

Drug

Pharmaceutical study type(s)

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Phase

Phase I

Drug/device/biological/vaccine name(s)

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Primary outcome measure

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Secondary outcome measures

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Overall study start date

06/11/2023

Completion date

08/11/2025

Eligibility

Key inclusion criteria

Healthy human volunteer

Participant type(s)

Healthy volunteer

Age group

Adult

Sex

Both

Target number of participants

Up to 168

Key exclusion criteria

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Date of first enrolment

13/02/2024

Date of final enrolment

08/08/2025

Locations

Countries of recruitment

England

United Kingdom

Study participating centre**HMR**

Cumberland Avenue

Park Royal

London

United Kingdom

NW10 7EW

Sponsor information**Organisation**

Gedeon Richter (Hungary)

Sponsor details

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Sponsor type

Industry

ROR<https://ror.org/0033rtn64>**Funder(s)****Funder type**

Industry

Funder Name

Gedeon Richter

Alternative Name(s)**Funding Body Type**

Private sector organisation

Funding Body Subtype

For-profit companies (industry)

Location

Hungary

Results and Publications

Publication and dissemination plan

Full trial details will be published up to 30 months after the end of the trial. 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 will be posted after the end of the Phase II trial.

Intention to publish date

08/05/2028

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study are not expected to be made available because of their high commercial sensitivity and the negligible benefit to the public of publication of results of non-therapeutic clinical trials.

IPD sharing plan summary

Not expected to be made available