ISRCTN23220202 https://doi.org/10.1186/ISRCTN23220202

Phase I trial HMR code: 23-006

Submission date 26/01/2024	**Recruitment status** Recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 09/02/2024	**Overall study status** Deferred	
Last Edited 09/02/2024	**Condition category** Other	

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.

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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
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.

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

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.

Secondary outcome measures
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.

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
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Sponsor information

Organisation
Gedeon Richter (Hungary)

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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