

# Phase I trial HMR code: 23-007

<b>Submission date</b> 17/01/2024	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 22/01/2024	<b>Overall study status</b> Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 22/01/2024	<b>Condition category</b> 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

### Type(s)

Principal investigator

### Contact name

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## **Additional identifiers**

### **Clinical Trials Information System (CTIS)**

Nil known

### **Integrated Research Application System (IRAS)**

1008807

### **ClinicalTrials.gov (NCT)**

Nil known

### **Protocol serial number**

IRAS 1008807 HMR code: 23-007

## **Study information**

### **Scientific Title**

Phase I trial HMR code: 23-007 [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)**

approved 12/01/2024, South Central – Oxford A REC (Ground Floor, Temple Quay House, 2 The Square, Bristol, BS1 6PN, United Kingdom; +44 (0)207 1048171; oxforda.rec@hra.nhs.uk), ref: 23/SC/0316

### **Study design**

First-in-human safety, pharmacokinetics, and pharmacodynamics trial in up to 176 healthy volunteers

### **Primary study design**

Interventional

### **Study type(s)**

Other

### **Health condition(s) or problem(s) studied**

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### **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)**

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.

### **Completion date**

25/07/2025

## **Eligibility**

**Key inclusion criteria**

Healthy human volunteer

**Participant type(s)**

Healthy volunteer

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

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**Date of first enrolment**

24/01/2024

**Date of final enrolment**

25/04/2025

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**

**HMR**

Cumberland Avenue

Park Royal

London

United Kingdom

NW10 7EW

**Sponsor information**

**Organisation**

Gedeon Richter (Hungary)

**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****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