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Phase I Trial: RD 785.35736 (ADR-UK-23-1)

Submission date 12/04/2024	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 12/04/2024	**Overall study status** Deferred	
Last Edited 12/04/2024	**Condition category** Other	

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.

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
1008056

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
ADR-UK-23-1, IRAS 1008056

Study information

Scientific Title
Phase I Trial: RD 785.35736 (ADR-UK-23-1)

Acronym
ADR-UK-23-1

Study objectives
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Ethics approval required
Ethics approval required

Ethics approval(s)

approved 16/01/2024, Wales Research Ethics Committee 2 (Health and Care Research Wales, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, United Kingdom; +44 (0)2922 941119; Wales.REC2@wales.nhs.uk), ref: 23.WA.0204

Study design
Three-part open-label study in up to 90 healthy participants

Primary study design
Interventional

Study type(s)
Other, Safety

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
23/11/2024

Eligibility

Key inclusion criteria

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Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
60 years

Sex
All

Key exclusion criteria
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Date of first enrolment
30/04/2024

Date of final enrolment
17/11/2024

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Simbec Research Limited
Simbec House Merthyr Tydfil Industrial Park
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Pentrebach
Merthyr Tydfil

Mid Glamorgan
United Kingdom
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Sponsor information

Organisation
Theravia

Funder(s)

Funder type
Industry

Funder Name
Theravia

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes