ISRCTN14891667 https://doi.org/10.1186/ISRCTN14891667

Phase I Trial: Quotient Code QSC300787

Submission date 18/06/2024	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 03/07/2024	**Overall study status** Deferred	[_] Statistical analysis plan [_] Results
Last Edited 17/07/2024	**Condition category** Other	[_] Individual participant data [_] 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 study. The full details will be added to the study records 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)
1009779

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 1009779, Quotient Code: QSC300787

Study information

Scientific Title
Phase I Trial: Quotient Code QSC300787

Study objectives
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Ethics approval required
Ethics approval required

Ethics approval(s)
approved 04/07/2024, London – Harrow REC (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8154; harrow.rec@hra.nhs.uk), ref: 24/LO/0336

Study design
Relative bioavailability, food effect, safety and tolerability study: Parts 1 & 2 - non-randomized repeated measures, Part 3 - randomized crossover, Part 4 - non-randomized

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)
The Sponsor has confirmed that the trial meets the criteria for deferral of publication of the full details of the study. The full details will be added to the study records within 30 months after the trial has ended.

Key secondary outcome(s))
The Sponsor has confirmed that the trial meets the criteria for deferral of publication of the full details of the study. The full details will be added to the study records within 30 months after the trial has ended.

Completion date
08/02/2027

Eligibility

Key inclusion criteria
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Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria

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Date of first enrolment
10/07/2024

Date of final enrolment
08/02/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Quotient Sciences Limited
Mere Way
Ruddington Fields
Ruddington
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United Kingdom
NG11 6JS

Sponsor information

Organisation
Alumis Inc.

Funder(s)

Funder type
Industry

Funder Name
Alumis Inc.

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the 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.

IPD sharing plan summary
Not expected to be made available