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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.

Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
1009779

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 1009779, Quotient Code: QSC300787

Study information

Scientific Title
Phase I Trial: Quotient Code QSC300787

Study objectives
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.

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

Secondary study design
Parts 1 & 2 - non-randomized repeated measures, Part 3 - randomized crossover, Part 4 - non-randomized

Study setting(s)
Pharmaceutical testing facility

Study type(s)
Other, Safety

Participant information sheet

Health condition(s) or problem(s) studied
Healthy volunteers

Interventions
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.

Intervention Type
Drug

Pharmaceutical study type(s)
Pharmacokinetic, Relative bioavailability, food effect, safety and tolerability study

Phase
Phase I

Drug/device/biological/vaccine name(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.

Primary outcome measure
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.

Secondary outcome measures
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.

Overall study start date
06/05/2024

Completion date
08/02/2027

Eligibility

Key inclusion criteria
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Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
84

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
England

United Kingdom

Study participating centre
Quotient Sciences Limited
Mere Way
Ruddington Fields
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Sponsor information

Organisation
Alumis Inc.

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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Alumis Inc.

Results and Publications

Publication and dissemination plan
Full trial details will be published up to 30 months after the end of the study. Publication of some study 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 on or after the date of publication of full trial details.

Intention to publish date
08/08/2027

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