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Phase I Trial: Quotient Code QSC300687

Submission date 28/05/2024	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 31/05/2024	**Overall study status** Deferred	
Last Edited 21/06/2024	**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.

Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
1008711

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 1008711, Quotient Code: QSC300687

Study information

Scientific Title
Phase I Trial: Quotient Code QSC300687

Study objectives
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Ethics approval required
Ethics approval required

Ethics approval(s)
Submitted 30/04/2024, London - Surrey Borders REC (Equinox House, City Link, Nottingham, NG2 4LA, United Kingdom; + 44 (0) 20 7104 8057; surreyborders.rec@hra.nhs.uk), ref: 24/LO /0231

Study design
Mass balance recovery pharmacokinetic metabolite profiling and identification and safety and tolerability study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Pharmaceutical testing facility

Study type(s)
Other

Participant information sheet
No participant information sheet available

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 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)
Not Applicable

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
30/04/2024

Completion date
18/01/2025

Eligibility

Key inclusion criteria
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Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Male

Target number of participants
8

Key exclusion criteria
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Date of first enrolment
02/07/2024

Date of final enrolment
18/01/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Quotient Sciences Limited
Mere Way, Ruddington
Nottingham
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Sponsor information

Organisation
Tarsus Pharmaceuticals, Inc.

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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Tarsus Pharmaceuticals, Inc.

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 on or after the date of publication of full trial details.

Intention to publish date
18/07/2027

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