ISRCTN40371122 https://doi.org/10.1186/ISRCTN40371122

Phase 1 Trial: Fortrea

Submission date 26/06/2024	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 27/06/2024	**Overall study status** Deferred	[ ] Statistical analysis plan [ ] Results
Last Edited 27/06/2024	**Condition category** Other	[ ] Individual participant data [ ] Record updated in last year

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.

Contact information

Type(s)
Public, Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
1006698

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 1006698

Study information

Scientific Title
Phase 1 Trial: Fortrea

Study objectives
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Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 19/01/2023, London-Brent Research Ethic Committee (80 London Road, Skipton House, London, SE1 6LH, United Kingdom; +44 (0)20 3080 6456; brent_rec@hra.nhs.uk), ref: 22/LO/0850

2. Approved 07/03/2023, MHRA (10 South Colonnade, Canary Wharf, London, E14 4PU, United Kingdom; +44 (0)20 3080 6456; clintrialhelpline@mhra.gov.uk), ref: CTA 36772/0031/001-0001

Study design
Phase I safety tolerability and pharmacokinetics in 96 healthy volunteers

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Safety

Participant information sheet
Not available in web format

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

Interventions
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Intervention Type
Drug

Pharmaceutical study type(s)
Pharmacokinetic, Dose response

Phase
Phase I

Drug/device/biological/vaccine name(s)
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Primary outcome measure
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.

Secondary outcome measures
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.

Overall study start date
17/11/2022

Completion date
12/01/2024

Eligibility

Key inclusion criteria
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Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
96

Key exclusion criteria
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Date of first enrolment
18/04/2023

Date of final enrolment
12/01/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Fortrea Clinical Research Unit Limited
Draper's Yard Marshall Street
Holbeck
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United Kingdom
LS11 9EH

Sponsor information

Organisation
JAZZ Pharmaceuticals Research UK Ltd

Sponsor details
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Sponsor type
Industry

Funder(s)

Funder type
Not defined

Funder Name
JAZZ Pharmaceuticals Research UK Ltd

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
24/07/2026

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 nontherapeutic clinical trials.

IPD sharing plan summary
Not expected to be made available