# Phase 1 Trial: Fortrea

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

#### 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

#### Contact name

Dr Clinical Trial Disclosure and Transparency Clinical Trial Disclosure and Transparency

#### Contact details

3170 Porter Drive Palo alto United States of America 94304

-

ClinicalTrialDisclosure@jazzpharma.com

## Type(s)

Principal Investigator

#### Contact name

Dr Jim Bush

#### Contact details

Drapers Yard, Marshall Street Leeds United Kingdom LS11 9EH +441133013644 jim.bush@fortrea.com

## 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

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.

#### 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**

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.

#### Intervention Type

Drug

#### Pharmaceutical study type(s)

Pharmacokinetic, Dose response

#### Phase

Phase I

## Drug/device/biological/vaccine name(s)

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.

#### 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

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.

## Participant type(s)

Healthy volunteer

#### Age group

Adult

#### Sex

Both

## Target number of participants

96

## Key exclusion criteria

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.

#### 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 Leeds United Kingdom LS11 9EH

# Sponsor information

#### Organisation

JAZZ Pharmaceuticals Research UK Ltd

#### Sponsor details

Building 730, Kent Science Park, Sittingbourne Kent United Kingdom ME9 8AG ClinicalTrialDisclosure@jazzpharma.com

## 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