

# Phase I trial: Fortrea Clinical Pharmacology Services 1006539

<b>Submission date</b> 06/12/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 07/12/2022	<b>Overall study status</b> Deferred	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 19/01/2026	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> 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, Principal investigator

### Contact name

Dr Clinical Trials Information

### Contact details

Hegenheimermattweg 91  
Allschwil  
Switzerland  
4123  
+41 58 844 1977  
idorsiaclinicaltrials@idorsia.com

### Type(s)

Principal investigator

### Contact name

Dr Jim Bush

### Contact details

Fortrea Clinical Research Unit Ltd  
Drapers Yard  
Marshall Street  
Holbeck

Leeds  
United Kingdom  
LS11 9EH  
+44 113 394 5200  
jim.bush@fortrea.com

## **Additional identifiers**

### **Clinical Trials Information System (CTIS)**

Nil known

### **Integrated Research Application System (IRAS)**

1006539

### **Protocol serial number**

IRAS 1006539

## **Study information**

### **Scientific Title**

Phase I trial: Fortrea Clinical Pharmacology Services 1006539

### **Study objectives**

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### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 24/11/2022, North East – York Research Ethics Committee, NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ; +44 (0)207 104 8079; york.rec@hra.nhs.uk; ref: 22/NE/0204.

The HRA has approved deferral of publication of trial details.

### **Study design**

First-in-man safety, pharmacokinetics and pharmacodynamics trial in 106 healthy volunteers.

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

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## **Interventions**

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### **Intervention Type**

Drug

### **Phase**

Phase I

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

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### **Primary outcome(s)**

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### **Key secondary outcome(s)**

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### **Completion date**

04/06/2024

## **Eligibility**

### **Key inclusion criteria**

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### **Participant type(s)**

Healthy volunteer

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

All

### **Total final enrolment**

0

### **Key exclusion criteria**

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### **Date of first enrolment**

06/12/2022

### **Date of final enrolment**

03/05/2024

## **Locations**

### **Countries of recruitment**

United Kingdom

England

### **Study participating centre**

#### **Fortrea Clinical Research Unit Limited**

Draper's Yard Marshall Street

Holbeck

Leeds

England

LS11 9EH

## **Sponsor information**

### **Organisation**

Idorsia Pharmaceuticals Ltd

## **Funder(s)**

### **Funder type**

Industry

### **Funder Name**

Idorsia Pharmaceuticals Ltd

# Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not expected to be made available

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			28/06/2023	No	No