

A phase 1 trial evaluating the absorption, safety and tolerability of imlifidase after a single dose in healthy Japanese men

Submission date 19/05/2022	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 20/05/2022	Overall study status Deferred	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 27/05/2025	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Principal Investigator

Contact name

Dr David Steel

Contact details

Parexel Early Phase Clinical Unit
Level 7, Northwick Park Hospital
Watford Road
Harrow
London
United Kingdom
HA1 3UJ
+44 (0)808 134 6555
drugtrial@parexel.com

Type(s)

Scientific

Contact name

Dr David Steel

Contact details

Parexel Early Phase Clinical Unit
Level 7, Northwick Park Hospital
Watford Road
Harrow
London
United Kingdom
HA1 3UJ
+44 (0)808 134 6555
drugtrial@parexel.com

Type(s)

Public

Contact name

Dr David Steel

Contact details

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HA1 3UJ
+44 (0)808 134 6555
drugtrial@parexel.com

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

1005630

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

IRAS 1005630, PXL 272092

Study information

Scientific Title

A phase 1 trial evaluating the pharmacokinetics, pharmacodynamics, safety, and tolerability of imlifidase after administration of a single intravenous dose in healthy Japanese men

Study objectives

PK/PD in healthy Japanese volunteers

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Approved 05/05/2022, London-Brent REC (80 London Road, Skipton House, London, SE1 6LH, UK; +44(0)20 7104 8137; brent.rec@hra.nhs.uk), ref: 22/LO/0315
2. Approved 05/05/2022, MHRA (10 South Colonnade, Canary Wharf, London, E14 4PU, UK; +44 (0) 20 3080 6000; info@mhra.gov.uk), ref: CTA 46323/0005/001-0001

Study design

Pharmacokinetic pharmacodynamic safety and tolerability study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Healthy volunteers

Interventions

All subjects received an intravenous dose of 0.25 mg/kg imlifidase on Day 1, administered over 15 minutes. Follow up for 14 days.

Intervention Type

Drug

Pharmaceutical study type(s)

Pharmacokinetic, Pharmacodynamic

Phase

Phase I

Drug/device/biological/vaccine name(s)

Imlifidase

Primary outcome measure

PK was measured as concentration of imlifidase in serum from pre-dose until Day 14

Secondary outcome measures

1. Safety was assessed as adverse events (AEs) from obtaining the informed consent throughout the study. An AE is any untoward medical occurrence in a subject participating in the clinical trial. An AE could be any unfavourable and unintended sign, symptom or disease temporally associated with the treatment, whether or not considered related to the study drug
2. PD was assessed as concentration of IgG in serum throughout the study

Overall study start date

19/04/2022

Completion date

30/09/2022

Eligibility

Key inclusion criteria

1. Healthy man
2. Between 20 and 60 years old
3. Both parents and all 4 grandparents were ethnically Japanese

Participant type(s)

Healthy volunteer

Age group

Adult

Sex

Male

Target number of participants

8

Key exclusion criteria

1. Previous participation in this study
2. Present participation in another clinical trial, or use of any investigational drug or therapy, taking into account participation in a medical device study, within 90 days or 5 half-lives, whichever is longer, prior to administration of IMP
3. Presence or history of any clinically significant disease or disorder which, in the opinion of the Investigator, may either put the subject at risk because of participation in the study, or influence the results or the subject's ability to participate in the study

Date of first enrolment

29/06/2022

Date of final enrolment

30/09/2022

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Parexel Early Phase Clinical Unit

Level 7, Northwick Park Hospital

Watford Road

Harrow

London

United Kingdom

HA1 3UJ

Sponsor information

Organisation

Hansa Biopharma (Sweden)

Sponsor details

P.O. Box 785

Lund

Sweden

SE-220 07

+46 (0) 46 16 56 70

info@hansabiopharma.com

Sponsor type

Industry

Website

<http://www.hansabiopharma.com/>

ROR

<https://ror.org/001r0mk78>

Funder(s)

Funder type

Industry

Funder Name

Hansa Biopharma AB

Results and Publications

Publication and dissemination plan

Potential publication in a peer-reviewed journal

Intention to publish date

31/03/2025

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		23/05/2025	23/05/2025	No	No