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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	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 20/05/2022	**Overall study status** Deferred	
Last Edited 27/05/2025	**Condition category** Other	

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
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

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. Prescence 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