Health testing with all subjects who participated in any phase I clinical study and received at least one dose of HTL0018318/AGN-242071 to date.

Published: 21-05-2019
Last updated: 10-01-2025

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Ethical review	Approved WMO
Status	Completed
Health condition type	Hepatic and hepatobiliary disorders
Study type	Observational invasive

Summary

ID

NL-OMON48060

Source
ToetsingOnline

Brief title
HTL0018318/AGN-242071 Health Testing Programme

Condition

- Hepatic and hepatobiliary disorders

Synonym
General Health

Research involving
Human

Sponsors and support

Primary sponsor: Heptares Therapeutics Ltd.

Source(s) of monetary or material Support: Heptares Therapeutics Ltd.

Intervention

Keyword: Health test, HTL0018318

Outcome measures

Primary outcome

Liver Ultrasound

Clinical Laboratory Assessments

Optional genetics & biomarkers

Secondary outcome

N.A.

Study description

Background summary

This programme is designed to provide targeted health testing procedures to all subjects who participated in any phase 1 clinical studies with HTL0018318/AGN-242071 and received at least one dose of active HTL0018318/AGN-242071 to date.
This testing is being provided by the Sponsor following emerging non-clinical safety findings (liver abnormalities) from a 9-month toxicology study, in non-human primates, with HTL0018318/AGN-242071.

Study objective

Because the risk of liver abnormalities for subjects who previously took HTL0018318/AGN-242071 is unknown the sponsor has decided that it is prudent to offer this initial 6-month health testing programme while further investigation of the toxicity findings and their translatability to humans is being investigated.

This programme will provide targeted health testing, including blood tests for indicators of general health and liver ultrasound (the liver was the primary target in the 9-month monkey study), for individual qualifying subjects who are only those previously exposed to at least one dose of HTL0018318/AGN-242071.

The primary aim of the programme is to establish an initial baseline as soon as possible, followed by another assessment after at least 6-months, to observe each subject*s general health and the status of their liver via blood and abdominal ultrasound tests. The secondary aim of the surveillance will be to establish any discernible patterns in the subjects* health which may have relevance to the non-clinical safety findings.

Test results will be used to assess each individual and, where abnormalities are identified, refer them for further testing and/or treatment per local standard of care.

This programme is focused on tracking the health of individual subjects over a period of at least 6-months and is not intended as a cohort study and there is no prospective intention to do any group/sub-group analyses.

Study design

This is a programme to provide health assessments, on 2 occasions, at least 6-months apart (no less than 6-months and no longer than 8-months), to all subjects who received at least one dose of active study medication in any prior HTL0018318/AGN-242071 clinical study, and to document the findings in individual subject narratives.

Study burden and risks

This testing programme does not involve the provision of any medication or other experimental procedure and so participation will involve minimal additional risk to the participants. It is anticipated that some subjects may experience psychological distress or anxiety when the non-clinical safety findings are disclosed to them. Investigators will be advised on providing this information to subjects and also advised to provide adequate support for subjects so as to minimize this risk.

While there will also be no direct therapeutic benefit to subjects they may benefit from earlier detection of previously undetected health issues as a result of this health testing programme

Contacts

Public
Heptares Therapeutics Ltd.

Steinmetz building, Granta Park, Great Abington .
Cambridge CB21 6 AL

GB
Scientific
Heptares Therapeutics Ltd.

Steinmetz building, Granta Park, Great Abington .
Cambridge CB21 6 AL
GB

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

All subjects who received at least one dose of active study medication in any prior HTL0018318/AGN-242071 clinical study.

Exclusion criteria

None

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	25-06-2019
Enrollment:	170
Type:	Actual

Ethics review

Approved WMO

Date:	21-05-2019
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL69506.056.19

Study results

Date completed:	27-10-2020
Results posted:	07-04-2022

First publication
14-03-2022