Single Ascending Dose Study of ALKS 6610 in healthy adults

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20667

Source
Nationaal Trial Register

Brief title
CHDR1921

Health condition

Single Ascending Dose Study

Sponsors and support

Primary sponsor: Alkermes, Inc.
Source(s) of monetary or material Support: Sponsor

Intervention

Outcome measures

Primary outcome

Tolerability / Safety Endpoints
Pharmacokinetic Endpoints

Secondary outcome

NA

Study description

Background summary

Subjects will be recruited in The Netherlands to participate in a Single Ascending Dose Study of ALKS 6610 in healthy adults. The study results may be used to support further clinical development of ALKS 6610.

Study objective

The objective of the study is to evaluate safety, tolerability, and pharmacokinetics (PK) of ALKS 6610 after single ascending oral doses in healthy adult subjects.

Study design

Baseline till EOS

Intervention

ALKS 6610 or placebo

Contacts

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Eligibility criteria

Inclusion criteria

1. Signed informed consent prior to any study-mandated procedure
2. Ability to communicate well with the Investigator in the Dutch language and willing to follow the procedures and comply with study restrictions as outlined in the protocol
3. Male or female age ≥18 years and ≤60 years old at the time of informed consent
4. Body mass index (BMI) ≥18 and <30 kg/m2 at Screening

Exclusion criteria

1. Clinically significant illness or disease within 8 weeks of dosing, or any clinically abnormal symptom or organ impairment, found by medical history, physical examinations, vital signs, electrocardiogram (ECG) finding, or either abnormal laboratory values or laboratory test results at Screening or Baseline
2. Females who are breastfeeding or pregnant at Screening or Baseline
3. Females of childbearing potential. NOTE: All females will be considered to be of childbearing potential unless they are postmenopausal or have been sterilized surgically
4. A prolonged QT/QTc interval (QTcF >450 ms in males, and QTcF >470 ms in females) demonstrated on ECG at Screening or Baseline
5. History of clinically significant arrhythmia or uncontrolled arrhythmia
6. Positive Hepatitis A antibodies (HAV IgM), Hepatitis B surface antigen (HBsAg), Hepatitis B antibodies (Anti-HBc), Hepatitis C antibodies (HCV Ab), or human immunodeficiency virus antibody (HIV Ab) at Screening
7. Use of nicotine containing products within 2 weeks before the first dose of study drug (Day 1)
8. Use of prescription and non-prescription medications, herbal and nutritional supplements within 2 weeks prior to dosing or 5 half-lives, whichever is longer.
9. Any history of lifetime suicidal ideation or behaviour, confirmed by a Columbia Suicide Severity Rating Scale (C-SSRS) response of “Yes” to questions 4 or 5 at Screening
10. Currently enrolled in another clinical study, used any investigational drug or device within 3 months prior to dosing, or having participated in more than 4 investigational drug studies within 1 year prior to Screening
11. Additional criteria may apply

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	05-02-2020
Enrollment:	56
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Plan description
NA

Ethics review

Positive opinion

Date:	29-01-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 50062
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8337
CCMO	NL71886.056.19
OMON	NL-OMON50062

Study results

Summary results
NA