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A study to evaluate the safety, tolerability, processing by the body, and response of the body to the drug VK2735 in healthy adults

Submission date
08/12/2021

Recruitment status
No longer recruiting

Registration date
10/12/2021

Overall study status
Completed

Last Edited
07/12/2022

Condition category
Digestive System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
This is a study to investigate the safety and tolerability of single and multiple doses of VK2735. The study also assesses how much VK2735 is in the blood (called pharmacokinetics or PK) and what VK2735 does to the body (called pharmacodynamics or PD). Viking Therapeutics Inc. is developing VK2735 as a potential treatment for nonalcoholic steatohepatitis (NASH). NASH is more prevalent in patients with metabolic disease and obesity and progresses to cirrhosis in approximately 20% of cases. Currently, there are no approved therapies for the treatment of NASH and therefore, there is a substantial unmet medical need for the development of effective treatments. VK2735 is a drug delivered by an injection that increases the activity of a receptor in the body which reduces appetite and inhibits another receptor which contributes to blocking the accumulation of fat within the body. It is hoped that these effects will make VK2735 a useful drug for NASH.
This study will be the first time the test medication, VK2735 is given to humans. VK2735 is experimental and has not been approved by the TGA (Therapeutic Goods Administration) in Australia, or any other Regulatory Agency responsible for approving study drugs for general medical use.

Who can participate?
Healthy volunteers, and otherwise healthy volunteers who have an increased body mass index, between the ages of 18 and 65 years.

What does the study involve?
The study will be conducted in two parts:
Part A: single ascending dose (SAD)
Up to 48 participants will be enrolled into 6 groups (8 participants in each) who will receive a single dose of the drug. Participants in each of the 6 groups will receive a dose higher than the previous group. Some participants will get an injection containing VK2735 and others will get a placebo injection (a similar-looking injection without VK2735).
Part B: multiple ascending dose (MAD)
Up to 40 participants will be enrolled into 5 groups (8 participants in each) to receive 1 dose of

VK273 each week for four weeks. Each group (cohort) will receive a dose higher than the previous cohort. Some participants will get an injection containing VK2735 and others will get a placebo injection (a similar-looking injection without VK2735).

What are the possible benefits and risks of participating?
Participants are not expected to receive any direct medical benefits from their participation in the study. The information developed in this study may help other people with Non-Alcoholic Steatohepatitis (NASH) in the future. As participants will be healthy volunteers who do not require treatment, their alternative is to not participate in this study.

Medical procedures often have side effects. Participants may have none, some, or all of the effects listed below, and they may be mild, moderate, or severe. If they have any of these side effects or are worried about them, or have any new or unusual symptoms, participants will be encouraged to talk with their study doctor. The study doctor will also be looking out for side effects. There may also be side effects that the researchers do not expect or do not know about and that may be serious. Many side effects go away shortly after the intervention ends. However, sometimes side effects can be serious, long-lasting, or permanent. If a severe side effect or reaction occurs, the study doctor may need to stop the procedure. The study doctor will discuss the best way of managing any side effects with participants. There is always a chance that an unexpected or serious side effect may happen. This can happen to people who take this or any other drug. VK2735 has not been given to people before.

Where is the study run from:
Cmax Clinical Research Pty Ltd (Australia)

When is the study starting and how long is it expected to run for?
December 2021 to December 2022

Who is funding the study?
Viking Therapeutics, Inc. (USA)

Who is the main contact?
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Contact information

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Public

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Additional identifiers

Protocol serial number
VK2735-101

Study information

Scientific Title
A Phase I, randomized, double-blind, placebo-controlled, single and multiple ascending dose study to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of VK2735, a dual glucagon-like peptide-1 and gastric inhibitory polypeptide receptor agonist, in healthy adults and otherwise healthy adults who have an increased body mass index

Study objectives
The purpose of the present study is to evaluate safety, tolerability, pharmacokinetics (PK), and pharmacodynamics (PD) of VK2735 administered subcutaneously (SC) in healthy adults and otherwise healthy adults who have an increased body mass index.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/11/2021, Bellberry Limited (123 Gen Osmond Road, Eastwood, South Australia, 5063, AU; +61 (0)8 8361 3222; bellberry@bellberry.com.au), ref: 2021-09-1038

Primary study design
Interventional

Study design
Single-center randomized double-blind placebo-controlled single and multiple ascending dose study

Study type(s)
Other

Health condition(s) or problem(s) studied

Non-alcoholic steatohepatitis (NASH)

Interventions
Approximately 48 Part A (SAD) participants will enroll into one of 6 SAD cohorts (SAD Cohort 1 through SAD Cohort 6, N = 8 per cohort) and will be randomized to receive either VK2735 (at doses: 0.25 mg, 0.5 mg, 1.0 mg, 2.5 mg, 5 mg, 7.5 mg, 10 mg, or 15 mg) or VK2735 matching placebo at a ratio of 3:1 (6 VK2735:2 placebo per cohort). Part A (SAD) participants will be domiciled at the Clinical Research Unit (CRU) from Day -1 through to Day 8 (inclusive).

Participants in Part A (SAD) (ie, SAD Cohort 1 through SAD Cohort 6) will receive a single dose SC injection in any upper quadrant of the abdomen of VK2735 or placebo on Day 1 after a minimum 8 hour fast.

Approximately 40 Part B (MAD) participants will enrol into one of 5 MAD cohorts (MAD Cohort 1 through MAD Cohort 5, N = 8 per cohort) and will be randomized to receive either VK2735 or matching VK2735 placebo at a ratio of 3:1 (6 VK2735:2 placebo per cohort). Part B (MAD) participants will be domiciled in the CRU from Day 1 through to 6 hours post-dose Day 8 (inclusive), from Day 14 through to 6 hours post-dose on Day 15 (inclusive), and Day 21 through to Day 29 (inclusive).

Participants in Part B (MAD) cohorts will receive a single SC injection of VK2735 or matching VK2735 placebo administered once weekly for 4 consecutive weeks. Doses will be administered clockwise around the abdomen following a minimum 8 hour fast on Day 1, Day 8, Day 15, and Day 22.

Intervention Type
Biological/Vaccine

Phase
Phase I

Drug/device/biological/vaccine name(s)
VK2735

Primary outcome(s)
Safety measured as the incidence of treatment-emergent adverse events (TEAEs) and treatment-emergent serious AEs (TESAEs) measured between baseline and 16 days for part A of the study, and between baseline and 43 days for part B of the study

Key secondary outcome(s)
Plasma pharmacokinetic analysis of VK2735 measured using Cmax, Tmax, AUC, and other plasma PK analysis of VK2735 from blood samples taken between 30 min pre-dose and 168 h post-dose for part A and part B of the study

Completion date
01/12/2022

Eligibility

Key inclusion criteria

1. Participants must be capable of giving signed informed consent
2. Participants must be medically healthy, with no significant medical history, have no clinically significant abnormalities on physical examination at Screening and/or before administration of the initial dose of IP in the opinion of the Investigator
3. Participant body weight must have been stable (no change greater than 5%) for a minimum 8 weeks prior to Screening
4. Willing and able to comply with scheduled visits, treatment plan, laboratory tests and other clinical study procedures
5. Willing to comply with contraception requirements

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Participants with any level of disease or organ system dysfunction as identified during physical examination, medical history or laboratory testing, as assessed by the PI
2. Any surgical or medical condition (active or chronic) that may interfere with IP distribution, metabolism, excretion, or drug absorption
3. Participants may be excluded from the study if they have conditions that might compromise safety or other endpoints in the study as judged by the Sponsor (or designee) or Investigator
4. History or presence of clinically significant acute or unstable cerebrovascular (stroke), hepatic, renal, gastrointestinal, pulmonary, immunological, endocrine, diabetes, hematological, oncological, or central nervous disorder that in the opinion of the Investigator would pose a significant risk for the participant
5. Use of any investigational drug or product, or participation in an investigational drug study within 30 days prior to dosing or 5 half-lives of the drug (whichever is longest)
6. Active smoker and/or user of nicotine-containing products unless the participant agrees to discontinue smoking/use of nicotine-containing products from 2 weeks before first IP dose administration through to study completion, including the follow-up period
7. Have serum triglycerides >5.65 mmol/l (500 mg/dl) at Screening
8. Positive serology for hepatitis B surface antigen (HBsAg), hepatitis C antibodies, or HIV

Date of first enrolment
01/12/2021

Date of final enrolment
01/06/2023

Locations

Countries of recruitment

Australia

Study participating centre
Cmax Clinical Research Pty Ltd
Level 5, 18a North Terrace
Adelaide
Australia
5000

Sponsor information

Organisation
Viking Therapeutics, Inc.

Funder(s)

Funder type
Industry

Funder Name
Viking Therapeutics, Inc.

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date