A study to assess the safety, tolerability, and pharmacokinetics of FM101 after single and multiple ascending dose administration to healthy subjects.

Gepubliceerd: 11-02-2019 Laatst bijgewerkt: 15-05-2024

This is a Phase I study (not a hypothesis-driven).

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27747

Bron
NTR

Verkorte titel
TBA

Aandoening

NASH (non-alcoholic steatohepatitis)

Ondersteuning

Primaire sponsor: Future Medicine Ltd.
Overige ondersteuning: Future Medicine Ltd.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Part 1, FM101-SAD: Safety as measured by Adverse events (TEAEs), clinical laboratory values, vital signs, ECGs, and physical examinations .
2. Part 3, FM101-MAD: Safety as measured by Adverse events (TEAEs), clinical laboratory values, vital signs, ECGs, and physical examinations
3. Part 1, Plasma PK assessment: Plasma concentrations of FM101, derived PK parameters
4. Part 3, Plasma PK assessment: Plasma concentrations of FM101, derived PK parameters
[Time Frame: from Day 1 to Day 10].

Toelichting onderzoek

Achtergrond van het onderzoek

This is a randomized, double-blinded, placebo-controlled, alternating single ascending dose (SAD), sequential multiple ascending dose (MAD) and food effect (FE) study in 50 healthy male and female volunteers.
The study is conducted in the Netherlands.

Doel van het onderzoek

This is a Phase I study (not a hypothesis-driven).

Onderzoeksopzet

SAD [Day 1 to Day 7]; FE [Day 1 to Day 4]; MAD [Day1 to Day 10]

Onderzoeksproduct en/of interventie

Drug: FM101 oral solution
Other: Placebo matching FM101 oral solution

Contactpersonen

Publiek

Future Medicine Ltd.
Seonah Ha

82222898690

Wetenschappelijk

Future Medicine Ltd.
Seonah Ha

82222898690

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Gender : male or female
2. Age : 18 - 50 years, inclusive, at screening
3. Body mass index (BMI) : 18.0 – 32.0 kg/m2 (inclusive)
4. Weight : ≥ 50 kg
5. Status : healthy subjects
6. At screening, females must be non-pregnant and non-lactating, or of non childbearing potential (either surgically sterilized or physiologically incapable of becoming pregnant, or at least 1 year post menopausal [amenorrhea duration of 12 consecutive months); non-pregnancy will be confirmed for all females by a serum pregnancy test conducted at screening, and a urine pregnancy test at each admission and at follow-up.
7. Female subjects of child-bearing potential, with a fertile male sexual partner, must agree to use adequate contraception from screening until 90 days after the follow up visit. Adequate contraception is defined as using hormonal contraceptives or an intrauterine device combined with at least 1 of the following forms of contraception: a diaphragm or cervical cap, or a condom. Also, total abstinence, in accordance with the lifestyle of the subject, is acceptable.
8. Male subjects, if not surgically sterilized, must agree to use adequate contraception and not donate sperm from first admission to the clinical research center until 90 days after the follow-up visit. Adequate contraception for the male subject (and his female partner) is defined as using hormonal contraceptives or an intrauterine device combined with at least 1 of the following forms of contraception: a diaphragm or cervical cap, or a condom. Also, total abstinence, in accordance with the lifestyle of the subject is acceptable.
9. All prescribed medication must have been stopped at least 14 days prior to (each) admission to the clinical research center. An exception is made for hormonal contraceptives, which may be used throughout the study.
10. All over-the-counter medication, vitamin preparations and other food supplements, or herbal medications (eg, St. John’s Wort) must have been stopped at least 7 days prior to (each) admission to the clinical research center. An exception is made for paracetamol, which is allowed up to admission to the clinical research center.
11. Ability and willingness to abstain from alcohol, methylxanthine-containing beverages or food (coffee, tea, cola, chocolate, energy drinks), grapefruit (juice), and tobacco products

from 48 hours prior to (each) admission to the clinical research center.
12. Good physical and mental health on the basis of medical history, physical examination, clinical laboratory, ECG, and vital signs, as judged by the Investigator.
13. Willing and able to sign the ICF.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Employee of CRO or the Sponsor.
2. History of relevant drug and/or food allergies.
3. Using tobacco products within 60 days prior to (the first) drug administration.
4. History of alcohol abuse or drug addiction (including soft drugs like cannabis products).
5. Positive drug and alcohol screen (opiates, methadone, cocaine, amphetamines [including ecstasy], cannabinoids, barbiturates, benzodiazepines, gamma hydroxybutyric acid [GHB], tricyclic antidepressants, and alcohol) at screening and (each) admission to the clinical research center.
6. Average intake of more than 24 units of alcohol per week (1 unit of alcohol equals approximately 250 mL of beer, 100 mL of wine, or 35 mL of spirits).
7. Positive screen for hepatitis B surface antigen (HBsAg), anti hepatitis C virus (HCV) antibodies, or anti human immunodeficiency virus (HIV) 1 and 2 antibodies.
8. Participation in a drug study within 60 days prior to (the first) drug administration in the current study. Participation in more than 3 other drug studies (for male subjects) / more than 2 other drug studies (for female subjects) in the 10 months prior to (the first) drug administration in the current study.
9. Donation or loss of more than 100 mL of blood within 60 days prior to (the first) drug administration. Donation or loss of more than 1.5 liters of blood (for male subjects) / more than 1.0 liters of blood (for female subjects) in the 10 months prior to (the first) drug administration in the current study.
10. Significant and/or acute illness within 5 days prior to (the first) drug administration that may impact safety assessments, in the opinion of the Investigator.
11. Non-willingness to consume the high-fat breakfast (Part B only).
12. Unsuitable veins for infusion or blood sampling.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind

Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	29-01-2019
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	11-02-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 48530
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7515
CCMO	NL68308.056.18
OMON	NL-OMON48530

Resultaten