A clinical study to evaluate the safety, tolerability, and pharmacokinetics of the MMP 12 inhibitor FP- 025 after multiple oral ascending dose administration, and to evaluate the effect of food after a single oral dose administration in healthy subjects

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Primary* To determine the safety and tolerability of multiple oral ascending doses of FP 025 in healthy subjects.Secondary* To determine the pharmacokinetics (PK) of FP 025 after multiple oral ascending doses of FP 025 in healthy subjects.* To...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON44633

Source
ToetsingOnline

Brief title
CS0284-170114

Condition

- Respiratory disorders NEC

Synonym
asthma, copd

Research involving
Human

Sponsors and support

Primary sponsor: Foresee Pharmaceuticals Co., Ltd.
Source(s) of monetary or material Support: Foresee Pharmaceuticals Co.;Ltd.

Intervention

Keyword: Foodeffect, Pharmacokinetics, Safety, Tolerability

Outcome measures

Primary outcome

Safety, tolerability and pharmacokinetics

Food Effect

Secondary outcome

Secondary

* To determine the pharmacokinetics (PK) of FP 025 after multiple oral

ascending doses of FP 025 in healthy subjects.

* To explore the effect of food on the PK of FP 025.

Study description

Background summary

FP 025 is a novel oral MMP-12 inhibitor currently being developed for the treatment of chronic asthma and/or COPD. FP 025 is a high affinity inhibitor of MMP-12 with 90-fold selectivity over the next closest family member (MMP-2) and 2-3 orders of magnitude selectivity over the seven other MMP family members (MMP-1, MMP-3, MMP-7, MMP-8, MMP-9, MMP-13, and MMP-14) that were tested. In an in vivo model of allergic asthma in mice, FP 025 demonstrated anti-inflammatory activity and improved airway function compared to control mice. These data suggest that FP 025 may be beneficial as a prophylactic therapeutic for the treatment of asthma.

Study objective

Primary
* To determine the safety and tolerability of multiple oral ascending doses of FP 025 in healthy subjects.
Secondary
* To determine the pharmacokinetics (PK) of FP 025 after multiple oral ascending doses of FP 025 in healthy subjects.
* To explore the effect of food on the PK of FP 025.

Study design

Single-center, Phase I study consisting of 2 parts. The first part is a multiple ascending dose (MAD) part with a randomized, double-blind, placebo-controlled design in 3 treatment groups of 8 subjects (6 active; 2 placebo). The second part is a food effect (FE) part with a randomized, open-label, 2-period, 2 way crossover, single dose design in 8 subjects.

Study burden and risks

The blood collection procedure is not dangerous, but may cause discomfort or bruising. Occasionally, fainting, bleeding or an infection at the blood sampling site can occur.
No related side effects were observed during the first trial in human subjects.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Males or females aged *18 and 65 years, with a BMI *18 kg/m2 and 30 kg/m2. Female subjects must be of non-childbearing potential, defined as pre-menopausal females with a documented tubal ligation, hysterectomy or bilateral oophorectomy; or as post-menopausal females defined as 12 months amenorrhoea and follicle stimulating hormone (FSH) levels >40 IU/L.
2. A resting pulse *40 bpm and *100 bpm at screening and on Day -1.
3. A resting systolic blood pressure of 150 mmHg and a resting diastolic blood pressure of 95 mmHg at screening and on Day -1.
4. Baseline laboratory test values within reference ranges based on the blood and urine samples taken at screening and on Day -1. Out of normal ranges values may be accepted by the Investigator, if not clinically significant.
5. The subject is, in the opinion of the Investigator, generally healthy based on assessment of medical history, physical examination, vital signs, electrocardiogram (ECG), and the results of the haematology, clinical chemistry, urinalysis, serology, and other laboratory tests.
6. The subject must use adequate contraception, if applicable, during the study and until 3 months after completion of the study.
7. Subjects participating in the FE part of the study must be willing and able to consume the entire high-fat, high-calorie breakfast in the designated timeframe.
8. Signed Informed Consent prior to any study related procedures.
9. Ability to communicate well with the Investigator, in the local language, and to understand and comply with the requirements of the study.

Exclusion criteria

1. The subject has taken prescription or non-prescription medication, herbal remedies, vitamins or minerals within 2 weeks prior to the first dose of study product (or within 5 half-lives prior to inclusion for any medication ingested, whichever is longer).
2. The subject has a substance abuse-related disorder or has a history of drug, alcohol and/or substance abuse deemed significant by the investigator.
3. The subject has taken any investigational products within 60 days prior to the first dose of study product.

4. The subject has a history of severe drug allergy or hypersensitivity or food allergy.
5. The subject has a history or presence of any clinically significant immunological, cardiovascular, respiratory, metabolic, renal, hepatic, gastrointestinal, endocrinological (in particular diabetes or pre-diabetes), haematological, dermatological, venereal, neurological, chronic infectious or psychiatric disease or other major disorder.
6. The subject has a history of cancer, other than basal cell or Stage 1 squamous cell carcinoma of the skin, which has not been in remission for at least 5 years prior to the first dose of study product.
7. The subject has a history of abdominal surgery (excluding laparoscopic cholecystectomy or uncomplicated appendectomy) or thoracic or non-peripheral vascular surgery within 6 months prior to the first dose of study product.
8. The subject has any concurrent illness that may affect the particular target or absorption, distribution, and elimination of the study product.
9. The subject has had a clinically significant illness within 4 weeks prior to the first dose of study product.
10. The subject has had surgery or trauma with significant blood loss within the last 3 months prior to the first dose of study product.
11. The subject has donated blood more than 250 mL within 2 months prior to the first dose of study product.
12. The subject has tested positive for human immunodeficiency virus (HIV), hepatitis B surface antigen (HBsAg), or hepatitis C virus antibody (anti-HCV).
13. The subject is a current smoker or uses other nicotine containing products. Ex-smokers must have ceased smoking at least 6 months prior to the first dose of study product.
14. The subject has tested positive at screening or on Day 1 for drugs of abuse or alcohol.
15. A female subject who has a positive pregnancy test at screening or on Day 1.
16. The subject*s corrected QT interval (QTcF) (Fridericia*s correction) is >450 ms as read on the printout of the ECG produced by the ECG equipment and evaluated by the Investigator at screening and on Day -1. An out-of-range or abnormal ECG may be repeated. In total, 3 ECGs should be recorded consecutively and the Investigator must evaluate the triplicate ECG. If the subject*s QTcF is >450 ms on at least 2 ECGs, the subject must be excluded.
17. In general, subjects should refrain from excessive physical exercise and strenuous sports activities (endurance sports) for at least 4 days before screening and Day -1.
18. The subject is, in the opinion of the Investigator, unlikely to comply with the clinical study protocol or is unsuitable for any other reason.
19. Legal incapacity or limited legal capacity at screening and on Day -1.
20. Employees of the Investigator or study centre, as well as first degree family members of the employees or the Investigator.

Study design

Design

Study type:	Observational invasive

Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-07-2017
Enrollment:	32
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	placebo
Generic name:	placebo

Ethics review

Approved WMO

Date:	04-07-2017
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO

Date:	10-07-2017
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
EudraCT	EUCTR2017-002458-35-NL
CCMO	NL62287.056.17