A First-in-Human Study of FLX475 in Healthy Volunteers

No registrations found.

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

Summary

ID

NL-OMON26146

Source
Nationaal Trial Register

Health condition

Healthy human volunteers (preliminary safety study)
Cancer

Sponsors and support

Primary sponsor: FLX Bio, Inc.
PRA Health Sciences located at Van Swietenlaan 6, 9728 NZ Groningen, in The Netherlands.
Source(s) of monetary or material Support: FLX Bio, Inc. in South San Francisco, California, USA.

Intervention

Outcome measures

Primary outcome

Safety and tolerability of single and multiple oral ascending doses of FLX475 administered to healthy male and female subjects

Secondary outcome

Pharmacokinetics of FLX475 (capsule and tablet formulation)
Food effect

Study description

Background summary

This study is a first-in-human, 2-part, single-center, Phase 1, randomized, double-blind, placebo-controlled study in up to 136 healthy male and female subjects of FLX475. FLX475 is an orally-available, potent, and selective antagonist of CCR4, a chemokine receptor found on the surface of regulatory T cells responsible for their recruitment into the tumor microenvironment. In preclinical models of cancer, FLX475 has been shown to inhibit the recruitment of regulatory T cells into tumors, and to improve tumor control and eradication in combination with checkpoint inhibitor drugs. This first-in-human study will examine the safety, pharmacokinetics, and pharmacodynamics in healthy volunteers of single and repeat dosing. It will also examine the relative bioavailability of an alternative tablet formulation, and food effect on PK.

Study design

Throughout the study

Intervention

FLX475

Contacts

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Eligibility criteria

Inclusion criteria

Healthy Male or Female

18-55 years of age, inclusive

At least 50 kg in weight

BMI: 18.0-30.0 kg/m2, inclusive

Non-smoking

Exclusion criteria

Use of tobacco products within 60 days prior to drug administration

History of alcohol abuse or drug addiction

Positive drug and alcohol screen

Participation in a drug study within 60 days prior to drug administration

Donation or loss of more than 100 mL of blood within 60 days prior to 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 drug administration.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-11-2017
Enrollment:	104
Type:	Anticipated

Ethics review

Positive opinion

Date:	15-08-2018
Application type:	First submission

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
NTR-new	NL7240
NTR-old	NTR7439
Other	EudraCT number: 2017-003952-22 (Stichting BEBO) : FLX475-01

Study results