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

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

Samenvatting

ID

NL-OMON26146

Bron
Nationaal Trial Register

Aandoening

Healthy human volunteers (preliminary safety study)
Cancer

Ondersteuning

Primaire sponsor: FLX Bio, Inc.
PRA Health Sciences located at Van Swietenlaan 6, 9728 NZ Groningen, in The Netherlands.
Overige ondersteuning: FLX Bio, Inc. in South San Francisco, California, USA.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Onderzoeksopzet

Throughout the study

Onderzoeksproduct en/of interventie

FLX475

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	17-11-2017
Aantal proefpersonen:	104
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	15-08-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7240
NTR-old	NTR7439
Ander register	EudraCT number: 2017-003952-22 (Stichting BEBO) : FLX475-01

Resultaten