ForPatients
by Roche

Healthy Volunteers

A Study to Evaluate the Relative Bioavailability of Two Tablet Formulations Compared to Capsule Formulation and the Effect of Food and Proton Pump Inhibitor on ZN-A-1041 Tablet(s) in Healthy Participants

Trial Status	Trial Runs In	Trial Identifier
Recruiting	1 Country	NCT07051993 GP45607

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A Phase 1, Open-Label, Randomized, Crossover, Two-Part Study to Evaluate the Relative Bioavailability of Two ZN-A-1041 Tablet Formulations Compared to Capsule Formulation and the Effect of Food and Proton Pump Inhibitor on the Pharmacokinetics of ZN-A-1041 Tablet(s) in Healthy Subjects

Trial Summary:

This is a Phase 1, open-label, randomized, two-part study to evaluate the relative bioavailability (rBA) of two tablet formulations compared to the capsule formulation of ZN-A-1041 (Part 1). Part 2 of the study will evaluate the effect of food and rabeprazole on the ZN-A-1041 tablet formulation.

Genentech, Inc.
Sponsor

Phase 1
Phase

NCT07051993 GP45607
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years & # 75 Years	Accepts Healthy Volunteers

Inclusion Criteria:

- Body mass index (BMI) within the range of 18 to 32 kg/m^2, inclusive
- Negative hepatitis panel and negative HIV antibody screens

- Negative screening test for latent Mycobacterium tuberculosis infection
- Able to consume the high-fat meal within the protocol-specified time period and willing to consume 100% of the high-fat meal
- Able to fast for 8 hours prior to dosing

Exclusion Criteria:

- Significant history or clinical manifestation of any metabolic, allergic, dermatological, hepatic, renal, hematological, pulmonary, cardiovascular, GI, neurological, or psychiatric disorder
- Personal or family history of congenital long QT syndrome
- History of significant hypersensitivity, intolerance, or allergy to any drug
- History of acute GI symptoms
- History of ophthalmological disease or clinically significant abnormality in the ophthalmic examination
- Have significantly impaired hepatic function
- Female who is pregnant or breastfeeding or intending to become pregnant during the study or within 90 days following the final ZN-A-1041 administration
- Have a QTc interval corrected through use of Fredericia's formula >450 millisecond (msec), PR interval >210 msec, QRS complex >120 msec, or heart rate <50 beats per minute (bpm)
- Use of any drugs known to be moderate or strong inhibitors or inducers of CYP3A or CYP2C8
- Poor peripheral venous access
- History of malignancy within 5 years prior to enrollment