ForPatients
by Roche

Healthy Volunteers

A Study to Evaluate the Effect of Food and Proton Pump Inhibitor on the Pharmacokinetics of ZN-A-1041 in Healthy Participants

Trial Status	Trial Runs In	Trial Identifier
Recruiting	1 Country	NCT07329972 GP46367

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 Study to Evaluate the Effect of Food and Proton Pump Inhibitor on the Pharmacokinetics of ZN-A-1041 Tablet(s) in Healthy Participants

Trial Summary:

This study is a phase 1, open-label, randomized, four-period crossover study to evaluate the effect of food and rabeprazole on the ZN-A-1041 tablet formulation in healthy male and female participants.

Genentech, Inc.
Sponsor

Phase 1
Phase

NCT07329972 GP46367
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/m2, inclusive
- In good health, determined by no clinically significant findings from medical history, physical examination, 12-lead ECG, and vital signs, as determined by the investigator, at Screening and Check-in, as applicable
- Clinical laboratory evaluations (including chemistry panel, CBC, and UA with complete microscopic analysis) within the normal reference ranges for the certified test laboratory at Screening and Check-in
- Negative test for selected drugs of abuse at Screening and Check-in (includes alcohol)

- Negative hepatitis panel (hepatitis B surface antigen, hepatitis B core antibody, hepatitis B surface antibody [unless consistent with vaccination or immunity due to natural infection], and hepatitis C virus antibody) and negative HIV antibody screens
- For women of childbearing potential: agreement to remain abstinent or use contraception
- For men: agreement to remain abstinent or use contraceptive methods, and agreement to refrain from donating sperm
- Negative screening test for latent Mycobacterium tuberculosis infection
- Able to swallow and retain multiple tablets without chewing or crushing
- 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, gastrointestinal (GI), neurological, or psychiatric disorder, as determined by the investigator
- History or concurrent clinically significant hemorrhagic, bleeding abnormalities, as determined by the investigator
- Personal or family history of congenital long QT syndrome
- History of significant hypersensitivity, intolerance, or allergy to any drug compound, food, or other substance, unless approved by the investigator
- History of GI surgery or resection that would potentially alter absorption and/or excretion of orally administered drugs except that uncomplicated appendectomy and hernia repair will be allowed
- History of myocardial infarction
- History of febrile illness within 10 days prior to the first dose of study drug, or participants with evidence of active systemic infection, as determined by the investigator
- History of acute GI symptoms (e.g., nausea, vomiting, diarrhea, heartburn) as determined by the investigator (or designee) at Screening or Check-in
- History of ophthalmological disease or clinically significant abnormality in the ophthalmic examination as determined by the investigator, optometrist, or ophthalmologist
- Risk for suicidal behavior at Screening as determined by the investigator's clinical assessment and an answer "Yes" to item 4 or 5 within 2 years of Screening, or to suicidal behavior items on the Baseline/ Screening version C-SSRS or suicide attempt within 2 years of screening. Non-suicidal self-injurious behavior is not exclusionary.
- Have significantly impaired hepatic function (at Screening or Check-in)
- 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 corrected QT (QTc) interval corrected through use of Fredericia's formula >450 msec for males or >470 for females, PR interval >210 msec, QRS complex >120 msec, or heart rate <50 bpm (at Screening or Check-in)
- History or presence of an abnormal ECG that, in the investigator's opinion, is clinically significant, such as symptomatic bradyarrhythmias, bradycardia, or heart block as determined from 12-lead ECG (at Screening, Check-in, or Day 1 predose). Abnormal results can be confirmed by one repeat 12-lead ECG
- History of alcoholism or drug addiction within 1 year prior to Check-in, use of drugs of abuse (including opioids) within 4 weeks of Screening, and/or positive alcohol breath test and/or urinary drug screen at Screening or Check-in
- Participation in any other investigational study drug trial in which receipt of an investigational study drug occurred within 5 half-lives or 90 days, whichever is longer, prior to Check-in
- Treatment with intravenous (IV) antibiotics within 8 weeks prior to Screening and/or treatment with oral antibiotics within 4 weeks prior to Screening

- Use of any drugs known to be moderate or strong inhibitors or inducers of CYP3A or CYP2C8 within 30 days prior to Check-in
- Use of any other prescription medications/products or vaccines (including seasonal flu, H1N1, and coronavirus 2019 [COVID-19] vaccines) other than oral, implantable, transdermal, and injectable contraceptives or medications administered during the ophthalmic examination within 14 days prior to Check-in, unless deemed acceptable by the investigator
- Use of therapeutic anticoagulation or thrombolytic anticoagulants within 14 days prior to Check-in
- Use of any over-the-counter, non-prescription medications (including vitamins; minerals; and phytotherapeutic-, herbal-, and plant-derived preparations) within 7 days prior to Check-in, unless deemed acceptable by the investigator
- Use of tobacco- or nicotine-containing products (including, but not limited to, cigarettes, e-cigarettes, pipes, cigars, chewing tobacco, nicotine patches, nicotine lozenges, or nicotine gum) within 3 months prior to Check-in or a positive cotinine test
- Use of poppy seed-, grapefruit-, star fruit-, pomegranate-, pawpaw-, or Seville orange-containing foods or beverages within 7 days prior to Check-in
- Use of alcohol- or caffeine-containing foods or beverages within 48 hours prior to Check-in, unless deemed acceptable by the investigator
- Participant is not willing to minimize or avoid exposure to natural or artificial sunlight (tanning beds or ultraviolet (UV) A/B treatment) following administration of study drug through 5 days following the final ZN-A-1041 administration
- Participant is not willing to refrain from strenuous exercise from 7 days prior to Check-in and during the period of confinement at the study site (e.g., will not begin a new exercise program or participate in any unusually strenuous physical exertion)
- Poor peripheral venous access as determined by the investigator
- History of malignancy within 5 years prior to enrollment, with the exception of those with a negligible risk of metastasis or death (such as adequately treated carcinoma in situ of the cervix or basal cell skin cancer)
- Donation of blood within 3 months prior to Screening through study completion, donation of plasma within 2 weeks prior to Screening through study completion, or donation of platelets within 6 weeks prior to Screening through study completion
- Receipt of blood products within 2 months prior to Screening and during the entire study duration
- Participants who, in the opinion of the investigator (or designee), should not participate in this clinical study