ForPatients
by Roche

Healthy Volunteers

A study to look at how safe different doses of GDC-0334 were for healthy people and how this medicine was processed through the body

A Study of the Safety, Tolerability, Pharmacokinetics and Pharmacodynamic Effects of Single and Multiple Ascending Doses of GDC-0334 and the Effect of Food on the Pharmacokinetics of GDC-0334 in Healthy Adult Participants

Trial Status	Trial Runs In	Trial Identifier
Terminated	1 Country	NCT03381144 2017-003498-33 GB40223

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 I, Randomised, Double-Blind, Placebo-Controlled, Single Centre, 3-Part, Study Designed to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamic Effects of Single and Multiple Ascending Doses of GDC-0334 and the Effect of Food on the Pharmacokinetics of GDC-0334 in Healthy Adult Subjects

Trial Summary:

This is a randomized, double-blind, placebo-controlled, single-center, three-part study designed to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamic effects of single and multiple ascending doses of GDC-0334 and the effect of food on the pharmacokinetics of GDC-0334 in healthy adult participants.

Genentech, Inc.
Sponsor

Phase 1
Phase

NCT03381144 2017-003498-33 GB40223
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 18 Years & # 55 Years	Accepts Healthy Volunteers

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GDC-0334 is a new medicine for the treatment of patients with severe asthma. This study was the first time that humans got GDC-0334. People (healthy volunteers) received different doses of the study medicine to find out which dose was safe.

Inclusion Criteria:

- Healthy males or non-pregnant, non-lactating healthy females. Females may be of non-childbearing potential or childbearing potential. Healthy females of childbearing potential must agree to use a highly effective method of contraception.
- Healthy males must agree to use an adequate method of contraception
- Body mass index of 18.0 to 32.0 kilograms per meter squared (kg/m^2) or, if outside the range, considered not clinically significant by the investigator
- Must be willing and able to communicate and participate in the whole study

Exclusion Criteria:

- Participants who have received any investigational medicinal product in a clinical research study within the previous 3 months
- Participants who are study site employees, or immediate family members of a study site or sponsor employee
- Participants who have previously been enrolled in this study. Participants who have enrolled in Part 1 are not permitted to enrol in Parts 2 or 3, and participants who have enrolled in Part 2 are not permitted to enroll in Part 3
- History of any drug or alcohol abuse in the past 2 years
- Regular alcohol consumption >14 units per week (1 unit = ½ pint beer, 25 milliliters (mL) of 40% spirit or a 125-mL glass of wine)
- Current smokers and those who have smoked within the last 12 months. A breath carbon monoxide reading of greater than 6 parts per million (ppm) at screening or admission
- Current users of e-cigarettes and nicotine replacement products and those who have used these products within the last 12 months
- Participants who do not have suitable veins for multiple venepunctures/cannulation as assessed by the investigator at screening
- Clinically significant abnormal biochemistry, hematology or urinalysis as judged by the investigator
- Positive drugs-of-abuse test result at screening or admission
- Positive hepatitis B surface antigen (HBsAg), hepatitis C virus antibody (HCV Ab), or human immunodeficiency virus (HIV) results
- Evidence of renal impairment at screening, as indicated by an estimated creatinine clearance of <70 milliliters per minute (mL/min) using the Cockcroft-Gault equation
- History of seizure
- History of clinically significant cardiovascular, renal, hepatic, chronic respiratory or gastrointestinal disease, or psychiatric disorder, as judged by the investigator
- Participants with a history of cholecystectomy or gall stones (applies to any regimen where food effect is being explored)
- History of serious adverse reaction or serious hypersensitivity to any drug or the formulation excipients
- Presence or history of active allergy requiring treatment, as judged by the investigator. History of hayfever is allowed unless it is active.
- Donation or loss of greater than 400 mL of blood within the previous 3 months
- Participants who are taking, or have taken, any prescribed or over-the-counter drug or herbal remedies in the 14 days or 5 half-lives, whichever is longer, before investigational medicinal product administration. Exceptions may apply on a case-by-case basis, if considered not to interfere with the objectives of the study, as agreed by the principal investigator and sponsor's medical monitor.

- History or presence of an abnormal electrocardiogram (ECG) that is clinically significant in the investigator's opinion, including complete left bundle branch block, second- or third-degree heart block, or evidence of prior myocardial infarction, at screening or admission
- QT interval corrected using Fridericia's formula (QTcF) > 450 milliseconds (msec) demonstrated by at least two ECGs >30 minutes apart
- History of ventricular dysrhythmias or risk factors for ventricular dysrhythmias such as structural heart disease, coronary heart disease (symptomatic or with ischemia demonstrated by diagnostic testing), clinically significant electrolyte abnormalities, or family history of sudden unexplained death or long QT syndrome
- Current treatment with medications that are well known to prolong the QT interval
- History of dermatographism
- Presence or history of clinically significant skin disorders, as judged by the investigator (Parts 1 and 3 only)
- History of trauma or surgery (laceration repair is not excluded) to the arm but not including wrist or hand injury/surgery (Parts 1 and 3 only)
- Failure to satisfy the investigator of fitness to participate for any other reason