ForPatients
by Roche

Healthy Volunteers

A study to find out what happens to a new medicine inside women's bodies – and to look at different forms of the medicine (giredestrant)

Study to Investigate the Absorption, Metabolism, and Excretion of [14C]-GDC-9545 Following a Single Oral Dose (Part 1) and to Evaluate the Absolute and Relative Bioavailability of Oral Capsule Formulations of GDC-9545 (Part 2) in Healthy Female Subjects of Non-Childbearing Potential

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	NCT04680273 2020-004650-29 GP42662

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, Single Center, Open-Label, Partially Randomized, Two Part Study to Investigate the Absorption, Metabolism, and Excretion of [14C]-GDC-9545 Following a Single Oral Dose (Part 1) and to Evaluate the Absolute Bioavailability of Oral Capsule Formulations of GDC-9545 F12 and F18 and the Relative Bioavailability of F18 Compared to F12 (Part 2) in Healthy Female Subjects of Non-Childbearing Potential

Trial Summary:

This is an open-label, single-center, two part study in healthy female subjects of non-childbearing potential to investigate the absorption, metabolism, and excretion of [14C]-GDC-9545 (Part 1), the absolute bioavailability of formulations F12 and F18 (i.e., GDC-9545/F12 capsule, 30 mg and GDC-9545/F18 capsule, 30 mg) and relative bioavailability of GDC-9545 oral capsule F18 to the F12 formulation (Part 2). It is planned that Part 1 will begin prior to Part 2 of the study, and that the two parts of the study will partially overlap.

Genentech, Inc.
Sponsor

Phase 1
Phase

NCT04680273 2020-004650-29 GP42662
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers

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Female	#30 Years & # 65 Years	Accepts Healthy Volunteers

This clinical trial was done to study a new medicine called, “giredestrant”, for the treatment of patients with ER+ breast cancer. This study was done to take a detailed look at what happens to giredestrant in the body of healthy women who were not pregnant, unable to have children, and were not breastfeeding. Sixteen healthy women took part in this study at one study center in one country – The United Kingdom.

Inclusion Criteria:

- Healthy female subjects of non-childbearing potential that are non-pregnant, non-lactating females, who are either postmenopausal or surgically sterile, aged 30 to 65 years, inclusive, at time of signing the Informed Consent Form (ICF)
- A body mass index (BMI) between 18.5 and 32.0 kg/m^2, inclusive, at screening
- Ability to comply with the study protocol
- Must have regular bowel movements (i.e., average stool production of #1 and #3 stools per day) (Part 1 only)

Exclusion Criteria:

- Women of childbearing potential, women who are pregnant or breastfeeding
- Subjects who have received any investigational medicinal product (IMP) in a clinical research study within the 90 days prior to Day 1 (Part 1) or Day 1 of Period 1 (Part 2)
- History of serious adverse reaction or serious hypersensitivity to any drug or allergy to the study drug formulation excipients
- Subjects who are, or are immediate family members of, a study site or Sponsor employee
- Subjects who have previously been administered IMP in this study. Subjects who have taken part in Part 1 are not permitted to take part in Part 2.
- Evidence of current severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2; i.e., the virus that causes COVID-19) infection
- Positive for hepatitis C virus (HCV) antibody, hepatitis B surface antigen (HBsAg), or human immunodeficiency virus (HIV) antibody at screening
- History of any drug or alcohol abuse in the past 2 years
- Regular alcohol consumption >14 units per week
- A confirmed positive alcohol breath test at screening or admission
- Current smokers and those who have smoked within the last 12 months
- Current users of e-cigarettes and nicotine replacement products and those who have used these products within the last 12 months
- Confirmed positive drugs of abuse test result at screening or admission
- Radiation exposure, including that from the present study, excluding background radiation but including diagnostic x-rays and other medical exposures, exceeding 5 mSv in the last 12 months or 10 mSv in the last 5 years. No occupationally exposed worker, as defined in the Ionising Radiation Regulations 2017, shall participate in the study (Part 1 only)
- Subjects who do not have suitable veins for multiple venipunctures/cannulation as assessed by the Investigator or delegate at screening
- Clinically significant abnormal clinical chemistry, hematology, coagulation or urinalysis as judged by the Investigator
- Evidence of renal impairment at screening, as indicated by an estimated creatinine clearance (CLcr) of <70 mL/min using the Cockcroft-Gault equation

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- History of clinically significant cardiovascular, renal, hepatic, dermatological, chronic respiratory or gastrointestinal (GI) disease (especially peptic ulceration, GI bleeding, ulcerative colitis, Crohn's Disease or Irritable Bowel Syndrome), neurological or psychiatric disorder, as judged by the Investigator
- Presence or history of clinically significant allergy requiring treatment, as judged by the Investigator
- Donation of blood or plasma within the previous 3 months or loss of greater than 400 mL of blood
- Subjects who are taking, or have taken, any medication (e.g., prescription drugs, over-the-counter drugs, hormone replacement therapy [HRT], vaccines, topical medications, herbal or homeopathic remedies, nutritional supplements), other than up to 4 g of paracetamol per day, in the 14 days before IMP administration. Exceptions may apply on a case by case basis, if considered not to interfere with the objectives of the study, as determined by the Investigator.
- Subjects who are taking, or have taken, oral antibiotics within 4 weeks or IV antibiotics within 8 weeks prior to admission
- Subjects who are taking, or have taken, any medications/products known to alter drug absorption, metabolism, or elimination processes, including St. John's wort, within 30 days prior to admission
- History of GI surgery (with the exception of appendectomy unless it was performed within the previous 12 months) (Part 1 only)
- Acute diarrhea or constipation in the 7 days before the predicted Day 1. If screening occurs >7 days before the Day 1, this criterion will be determined on Day 1. Diarrhea will be defined as the passage of liquid feces and/or a stool frequency of greater than 3 times per day. Constipation will be defined as a failure to open the bowels for 3 days (Part 1 only)
- Malabsorption syndrome or other condition that would interfere with enteral absorption
- History or presence of an abnormal ECG that is clinically significant in the Investigator's opinion, including complete left bundle branch block, second- or third-degree atrioventricular heart block, or evidence of prior myocardial infarction
- QT interval corrected through use of Fridericia's formula (QTcF) >440 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 (e.g., severe left ventricular systolic dysfunction, left ventricular hypertrophy), coronary heart disease (symptomatic or with ischemia demonstrated by diagnostic testing), clinically significant electrolyte abnormalities (e.g., hypokalemia, hypomagnesemia, hypocalcemia), or family history of sudden unexplained death or long QT syndrome
- Confirmed (e.g., 2 consecutive measurements) baseline heart rate #50 bpm prior to enrollment
- Current treatment with medications that are well known to prolong the QT interval
- Absolute neutrophil count <1.3 x 10^9/L (1300/µL)
- Failure to satisfy the Investigator of fitness to participate for any other reason

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