ForPatients
by Roche

Healthy Volunteers

A study to find out if taking different forms of a medicine (GDC-9545) results in the same amount of medicine in your body – and the effect of food on the medicine

Evaluation of the Relative Bioavailability and Food Effect of GDC-9545 in Healthy Females of Non-Childbearing Potential

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	NCT04274075 GP42006

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, Single-Dose, Randomized, Three-Period Crossover Study to Evaluate the Relative Bioavailability and Food Effect of GDC-9545 in Healthy Female Subjects of Non-Childbearing Potential

Trial Summary:

This study will be an open-label, randomized, three-period, six-sequence crossover study of GDC-9545 administered to healthy females of non-childbearing potential to determine the relative bioavailability of the Phase 3 capsule formulation to the Phase 1 tablet formulation in the fasted state and the effect of food on the Phase 3 capsule formulation.

Genentech, Inc.	Phase 1
Sponsor	Phase

NCT04274075 GP42006
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Female	#18 Years & # 65 Years	Accepts Healthy Volunteers

This clinical trial was done to study a new medicine called, “GDC-9545”, for the treatment of patients with “ER+ breast cancer”. This study was done to find out how much medicine was present in the body after taking it in capsule form and in tablet form. The effect of

taking the medicine with and without food was also studied. Eighteen women took part in this study at one study center in the United States.

Inclusion Criteria:

- Females of non-childbearing potential including non-pregnant, non-lactating, and either postmenopausal or surgically sterile for at least 90 days prior to screening, as defined in the protocol
- Body mass index (BMI) from 18.5 to 30.0 kilograms per square metre of body surface area (kg/m^2) at screening
- In good health, determined by no clinically significant findings from medical history, 12-lead ECG, or vital signs
- Clinical laboratory evaluations within the reference range for the test laboratory, unless deemed not clinically significant by the investigator
- Negative test for selected drugs of abuse at Screening (does not include alcohol) and at Check-in (Day -1) for Period 1 (does include alcohol)
- Negative hepatitis panel (hepatitis B surface antigen and hepatitis C virus antibody) and negative human immunodeficiency virus (HIV) antibody screens
- Subject must receive an explanation of the mandatory Research Biosample Repository (RBR) component of the study and be able to comprehend and willing to sign an Informed Consent Form (ICF)

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 of significant hypersensitivity, intolerance, or allergy to any drug compound, food, or other substance, unless approved by the investigator
- History of allergy to GDC-9545 or any of its excipients
- History of stomach or intestinal surgery (including cholecystectomy) or resection that would potentially alter absorption and/or excretion of orally administered drugs (except that appendectomy and hernia repair will be allowed)
- History or presence of an abnormal ECG that, in the investigator's opinion, is clinically significant including complete left bundle branch block; right bundle branch block; first-, second-, or third-degree heart block; sick sinus syndrome; or evidence of prior myocardial infarction
- Having a QTc interval greater than (>)470 milliseconds (msec), PR interval >210 msec, or QRS complex >120 msec
- Confirmed (e.g., 2 consecutive measurements) baseline heart rate #50 beats per minute (bpm) prior to enrollment
- History of alcoholism or drug addiction within 1 year prior to Check-in (Day -1) of Period 1
- The use of tobacco- or nicotine-containing products within 6 months prior to Check-in (Day -1) of Period 1
- History of active or latent tuberculosis (TB), regardless of treatment history
- History of previous use of tamoxifen, aromatase inhibitors, or any other endocrine agent for the treatment of breast cancer
- The use of hormone replacement therapy or selective ER modulators (SERMs; e.g., raloxifene) within 1 year prior to Check-in (Day -1) of Period 1
- The use of oral antibiotics within 4 weeks or intravenous antibiotics within 8 weeks prior to Check-in (Day -1) of Period 1
- The use or intent to use any medications/products known to alter drug absorption, metabolism, or elimination processes, including St. John's wort, within 30 days prior to Check-in (Day -1) of Period 1

- The participation in any other investigational study drug trial in which receipt of an investigational study drug occurred within 5 half-lives or 30 days, whichever is longer, prior to Check-in (Day -1) of Period 1
- The use of drugs of abuse (including opioids) within 4 weeks of Screening
- The use of any prescription medications/products within 14 days prior to Check-in (Day -1) of Period 1, unless deemed acceptable by the investigator
- The use of any over-the-counter, non-prescription preparations (including vitamins; minerals; and phytotherapeutic-, herbal-, and plant-derived preparations) within 7 days prior to Check-in (Day -1) of Period 1, unless deemed acceptable by the investigator
- The use of poppy seed-containing foods or beverages within 7 days prior to Check-in (Day -1) of Period 1, unless deemed acceptable by the investigator
- The use of alcohol- or caffeine-containing foods or beverages within 72 hours prior to Check-in (Day -1) of Period 1, unless deemed acceptable by the investigator
- Not refraining from strenuous exercise from 7 days prior to Check-in (Day -1) of Period 1
- The need to follow a special diet and unable to consume the high-fat meal
- Poor peripheral venous access
- History of malignancy, except for appropriately treated carcinoma in situ of the cervix, non-melanoma skin carcinoma, or Stage I uterine cancer (must be cancer-free for at least 5 years)
- Donation of blood from 90 days prior to Screening through Follow-up, inclusive, or of plasma from 2 weeks prior to Screening
- Receipt of blood products within 2 months prior to Check-in (Day -1) of Period 1
- Any acute or chronic condition that, in the opinion of the investigator, would limit the subject's ability to complete and/or participate in this clinical study
- In the opinion of the investigator or Sponsor, are unsuitable for inclusion in the study