ForPatients
by Roche

Healthy Volunteers

A phase I, open-label, single-dose randomized, two-period crossover study to evaluate the relative bioavailability of single oral doses of two different formulations of divarasib (GDC-6036; 200-mg tablet and 400-mg tablet) in healthy subjects

Trial Status	Trial Runs In	Trial Identifier
Recruiting	1 Countries	GP45240

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

Trial Summary:

A study to compare how much divarasib is absorbed after a single oral dose of two different tablet formulations in healthy participants

Genentech Inc.
Sponsor

GP45240
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Both	18 to 60 years of age	Yes

Background and study aims:

Cancer is a disease caused when cells divide uncontrollably and spread into surrounding tissues. Changes or alterations in some genes can cause cancer or promote its growth. Despite significant breakthroughs in the understanding, prevention, and treatment of cancer, the disease continues to affect millions of people worldwide.

This study is testing a medicine called divarasib. It is being developed for the treatment of certain cancers. Divarasib is an experimental medicine. This means health authorities (like the US Food and Drug Administration and European Medicines Agency) have not approved divarasib for the treatment of cancer. Divarasib will be given to people by mouth as a single tablet or two tablets of the same dose under fasted conditions. This is to

compare how much of the divarasib enters the blood and how long it takes for blood levels of divarasib to decrease with time.

Who can participate?

Healthy people (males and females) of 18-60 years of age can take part in the study. Females who are pregnant, have the potential to become pregnant, or are currently breastfeeding cannot take part in the study.

What does the study involve?

People will be screened to check if they can participate in the study. The screening period will take place about 28 days before the start of the treatment. Everyone who joins this study will be split into 2 groups randomly (like flipping a coin) to receive divarasib in one of two treatment sequences.

Sequence 1: A single tablet of divarasib taken by mouth (orally) on an empty stomach followed by two tablets of divarasib taken orally after a period of 7 days.
Sequence 2: Two tablets of divarasib taken by mouth (orally) on an empty stomach followed by one single tablet of divarasib taken orally after a period of 7 days. Participants will have a 1:1 chance of being placed in any of the groups.

This is an open-label study. This means everyone involved, including the participant and the study doctor, will know the study treatment the participant has been given. During screening visit study participants will be required to stay at the clinic for 13 days and 12 nights (from check-in on Day -1 of Period 1 of the study to discharge on Day 5 of Period 2 of the study). Study doctors will check on the participants to see if there are any unwanted effects. Participants will have two follow-up visits on Days 14 and 28 of Period 2, during which the study doctor will check on the participant’s well-being. The total duration of participation in the study will be about 5 weeks, not including the screening visit. Participants have the right to stop study treatment and leave the study at any time if they wish to do so.

What are the possible benefits and risks of participating?

Taking part in the study will not provide any benefit to healthy participants but the information collected in the study can help other people with health conditions in the future. It may not be fully known at the time of the study how safe the study treatment is in healthy volunteers. The study involves some risks to the participant, but these risks are generally mild and easily monitored. People interested in taking part will be informed about the risks, as well as procedures or tests they may need to undergo. All details of the study will be described in an informed consent document. This includes information about possible side effects. Participants may have unwanted effects of the drug used in this study. These unwanted effects can be mild to severe, even life-threatening, and vary from person to

person. During this study, participants will have regular check-ups to see if there are any unwanted effects. Participants will be told about the known unwanted effects of divarasib and possible unwanted effects based on human and laboratory studies or knowledge of similar medicines.

Where is the study run from?

Genentech Inc. (Switzerland)

Who is funding the study?

Genentech Inc. (Switzerland)

Who is the main contact?

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