ForPatients
by Roche

Healthy Volunteers

Study to Investigate the Effect of Formulation and Food on the Pharmacokinetics of GDC-0810

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Countries	NCT02722018 2015-003730-27 GP29826

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

Trial Summary:

This is a phase 1, randomized, open-label, single center, crossover study to investigate the effect of formulation and food on the pharmacokinetics of GDC-0810 in female healthy participants of non-childbearing potential. This study is divided into three parts. Participants in each part will be randomized to one of three treatment sequences. Part 1 study in 4 periods will investigate the effect of formulation on the pharmacokinetics (PK) of GDC-0810 administered with low-fat food. Each participant in this part will receive a single dose of GDC-0810 dose level A following consumption of a low fat meal (30 minutes after the start of the meal) in each treatment period. Part 2 is an optional Phase I study in 3 periods to investigate the effect of formulation on the PK of GDC-0810 administered with low-fat food in healthy female participants of non-childbearing potential. Part 3 study in three periods will compare the PK of a Phase III prototype tablet formulation selected from Parts 1 and 2 of the study with the Phase II tablet formulation (both administered 30 minutes after the start of a low fat meal) at dose level B and to investigate the PK of the Phase III prototype formulation administered in the fasted state.

Genentech, Inc.	Phase 1
Sponsor	Phase

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Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Female	>= 40 Years & <= 70 Years	Accepts Healthy Volunteers