

# ForPatients

by Roche

Non-Small Cell Lung Cancer (NSCLC)

## A study to find out if taking different forms of a medicine (GDC-6036) results in the same amount of medicine in your body – and the effect of food on the medicine

A Phase 1, Open-Label, Single-Dose, Randomized, Three-Period Crossover Study to Evaluate the Relative Bioavailability and Food Effect of GDC-6036 in Healthy Subjects

**Trial Status**  
Completed

**Trial Runs In**  
1 Countries

**Trial Identifier**  
GP43039

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*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 clinical trial was done to study “GDC-6036”, a medicine for the treatment of patients with cancer. This phase 1 study investigated how much medicine was delivered to the body by the capsule and tablet forms – the relative bioavailability of GDC-6036. It also investigated whether there was a difference if GDC-6036 was taken after eating or on an empty stomach – the food effect on GDC-6036. Seventeen healthy men took part in this study at one study center in one country – the USA.

**Genentech, Inc. (Part of F. Hoffmann-La Roche Ltd., Switzerland)**

Sponsor

**Phase 1**

Phase

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**GP43039**

Trial Identifiers

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### ***Eligibility Criteria:***

**Gender**

**Male and female**

**Age**

**18 to 60 years old**

**Healthy Volunteers**

**Yes**

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Healthy volunteers were enrolled at one study site in USA to evaluate the relative bioavailability of tablet and capsule formulations, and the effect of food, on GDC-6036. Seventeen participants enrolled in the phase 1, open-label, randomized, three-period crossover, single-dose study. Results showed the capsule and tablet formulations to have similar bioavailability. Taking GDC-6036 after a meal slowed down the absorption rate and lowered the peak concentration reached – in comparison to taking GDC-6036 on an

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empty stomach. Study results will support other ongoing studies on GDC-6036, a *KRAS* G12C inhibitor.