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 | Trial Runs In | Trial Identifier |
|---|---|---|
| Completed | 1 Countries | GP43039 |

*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) | Phase 1 |
|---|---|
| Sponsor | Phase |

**GP43039**
Trial Identifiers

## *Eligibility Criteria:*

| Gender | Age | Healthy Volunteers |
|---|---|---|
| Male and female | 18 to 60 years old | Yes |

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

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