ForPatients
*by Roche*

Healthy Volunteers

# A study to find out if taking different forms of GDC-0134 gives you the same amount of medicine in your body

A Study to Determine the Bioavailability of Various Formulations of GDC-0134 in Healthy Female Participants of Non-Childbearing Potential

| Trial Status | Trial Runs In | Trial Identifier |
|---|---|---|
| Completed | 1 Country | NCT03807739 GP40957 |

*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 I Study to Determine the Relative Bioavailability of Various Formulations of GDC-0134 in Healthy Female Subjects of Non-Childbearing Potential

## *Trial Summary:*

This is a two-part study to determine the relative bioavailability of two different prototype capsules of GDC-0134 to that of an existing reference capsule of GDC-0134 under both fed and fasted conditions. The study is open to healthy female participants of non-childbearing potential.

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|---|---|
| **Genentech, Inc.**<br>Sponsor | **Phase 1**<br>Phase |

**NCT03807739 GP40957**
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-0134”, for the treatment of patients with “amyotrophic lateral sclerosis” – also known as “ALS” and “Lou Gehrig’s disease”. This study was done to find out whether taking three different forms (different formulations) of GDC-0134 gave you the same amount of medicine in your body. The effect of taking the medicine with and without food was also studied. The impact of the

medicine on patients with ALS was not studied. Twenty-nine healthy people participated in this study at two study centers in USA.

## *Inclusion Criteria:*

- Body mass index (BMI) range 18.5 to 35 kilograms per square meter (kg/m2)
- In good health, determined by no clinically significant findings from medical history, physical examination, 12-lead ECG, and vital signs;
- Clinical laboratory evaluations within the reference range for the test laboratory, unless deemed not clinically significant by the principal investigators (PIs)
- Females of non-childbearing potential only

## *Exclusion Criteria:*

- History or clinical manifestation of any significant medical condition as determined by the PI (or designee)
- History of significant hypersensitivity, intolerance, or allergy to any drug compound, food, or other substance, unless approved by the PI (or designee)
- History of stomach or intestinal surgery or resection that would potentially alter absorption and/or excretion of orally administered drugs
- Use of any prescription medications/products within 14 days prior to Check-in (Day -1) for their first treatment period and during the entire study duration, unless deemed acceptable by the PI
- Use of oral antibiotics within 4 weeks or intravenous antibiotics within 8 weeks prior to the Screening evaluation and during the entire study duration
- Use of any over-the-counter, non-prescription preparations within 14 days prior to Check-in (Day -1) for their first treatment period and during the entire study duration, unless deemed acceptable by the PI
- Use of acid reducing medications (proton pump inhibitors [PPIs], histamine H2-receptor antagonists [H2RAs]) within 14 days prior to Check-in (Day -1) for their first treatment period and during the entire study duration. As an alternative, antacids may be allowed at least 4 hours before or after dose
- Use of any vaccines (including seasonal flu and H1N1 vaccines) within 14 days prior to Check-in (Day -1) for their first treatment period
- Use of tobacco- or nicotine-containing products within 6 months prior to Check-in (Day -1) for their first treatment period and during the entire study
- Any acute or chronic condition or any other reason that, in the opinion of the PI, would limit the subject's ability to complete and/or participate in this clinical study