ForPatients
by Roche

Amyotrophic Lateral Sclerosis

A study to look at a new medicine called, “GDC-0134”, for treating patients with amyotrophic lateral sclerosis (ALS)

A Study of GDC-0134 to Determine Initial Safety, Tolerability, and Pharmacokinetic Parameters in Participants With Amyotrophic Lateral Sclerosis

Trial Status	Trial Runs In	Trial Identifier
Completed	3 Countries	NCT02655614 2017-002931-41 GN29823

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, Double-Blind, Randomized, Placebo-Controlled, Multicenter, Single- and Multiple-Ascending-Dose Study to Determine Initial Safety, Tolerability, and Pharmacokinetics of GDC-0134 in Patients With Amyotrophic Lateral Sclerosis

Trial Summary:

This first-in-human, double-blind, placebo-controlled Phase I study will be conducted in participants with amyotrophic lateral sclerosis (ALS) to explore safety, tolerability, and pharmacokinetic (PK) properties of GDC-0134. It will include three components: a Single-Ascending-Dose (SAD) stage, a Multiple-Ascending-Dose (MAD) stage, and an Open-Label Safety Expansion (OSE) stage.

Genentech, Inc. Sponsor	**Phase 1** Phase

NCT02655614 2017-002931-41 GN29823
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 18 Years	No

This clinical trial was done to study a new medicine called, “GDC-0134”, for the treatment of patients with amyotrophic lateral sclerosis (ALS). This study was done to find out how

safe was it for patients with ALS to be treated with a new study medicine. Forty-nine patients took part in this study at 10 study centers in 3 countries.

Inclusion Criteria:

- Male or female participants with a diagnosis of possible, laboratory-supported probable, probable, or definite ALS according to modified El Escorial criteria
- Upright forced vital capacity of at least 50 percent (%)
- Ability to fast from food for 8 hours prior to dosing and 2 hours after dosing

Exclusion Criteria:

- Currently taking riluzole unless on a stable dose for the 3 months prior to Day -1 and without current liver enzyme or liver function abnormalities
- Currently taking edaravone unless after completion of at least the second 14-day drug-treatment period, as long as Day 1 occurs during a drug-free period at least 24 hours after the last edaravone dose and at least 5 days prior to the first dose of the next cycle
- Positive for hepatitis C antibody, hepatitis B surface antigen, or human immunodeficiency virus (HIV) antibody
- Clinically significant thrombocytopenia
- Currently taking nutritional/herbal supplements, except for over-the-counter vitamins that are within Recommended Dietary Allowance (RDA), unless discontinued at least 7 days prior to Day -1, except upon approval of both the investigator and Sponsor
- For participants participating in a designated drug-drug interaction (DDI) cohort in the MAD stage of the study, who require midazolam/caffeine administration: known allergy, religious prohibition, or other condition limiting midazolam or caffeine administration