ForPatients
by Roche

Type 2 Diabetes Mellitus

A study to see how well the body tolerates different dose levels of a new medicine for type 2 diabetes mellitus and non-alcoholic fatty liver disease called “BFKB8488A”.

A Multiple Ascending Dose Study to Evaluate Safety and Tolerability of BFKB8488A in Participants With Type 2 Diabetes Mellitus

Trial Status	Trial Runs In	Trial Identifier
Completed	2 Countries	NCT03060538 GC39547

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 Ib, randomized, blinded, placebo-controlled, multiple ascending-dose study of the safety, tolerability, pharmacokinetic (PK), and pharmacodynamic (PD) effects of BFKB8488A in participants with Type 2 diabetes mellitus (T2DM) and participants with non-alcoholic fatty liver disease(NAFLD). A maximum of approximately 160 participants will be enrolled across multiple sites in the United States. Participants will be randomly assigned to receive study drug (active BFKB8488A or placebo). The study will consist of a screening period (up to 8 weeks), a 12-week treatment period, and a 6-week follow-up period. Participants may come to clinic for an optional pre-screening visit.

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

NCT03060538 GC39547
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>= 18 Years & <= 75 Years	No

This clinical trial was done to study a new medicine called, “BFKB8488A”, for the treatment of patients with type 2 diabetes mellitus (T2DM) or non-alcoholic fatty liver disease (NAFLD). This study was done to find out how safe BFKB8488A was for patients with T2DM and NAFLD when given at different doses. One hundred and fifty-three patients took part in this study at 17 study centers in USA.