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 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 Ib, Randomized, Blinded, Placebo-Controlled, Multiple Ascending-Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of Subcutaneous BFKB8488A in Patients With Type 2 Diabetes Mellitus and Patients With Non-Alcoholic Fatty Liver Disease

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

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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.

Inclusion Criteria:

For T2DM Cohort only:

- Body mass index (BMI) # 27 kg/m2 and # 40 kg/m2.
- A confirmed diagnosis of Type 2 diabetes # 6 months at screening
- Current stable treatment (at least 3 months) for diabetes
- Hemoglobin A1c (HbA1c) # 6.8% and # 9.0%.
- For women of childbearing potential, agreement to remain abstinent or use reliable contraception during treatment period and for at least 42 days after last dose of study drug
- For men, agreement to remain abstinent or use reliable contraception and agree to refrain from donating sperm
- For NAFLD cohort only:
- BMI # 25 kg/m2 and # 40 kg/m2
- At screening, confirmed liver fat by ultrasound OR calculated Liver Fat # 10% using variables from the NAFLD liver fat score
- Hepatic steatosis on magnetic resonance imaging (MRI; # 10% average liver proton density fat fraction [PDFF]) prior to randomization.

Exclusion Criteria:

- Pregnant, lactating, or intending to become pregnant within 42 days after the last dose of study drug is administered
- Suspected or confirmed diagnosis of Type 1 diabetes
- Significant cardiac disease
- Any psychiatric illness that increases the risk of participation in the study
- History of severe allergic, anaphylactic, or other hypersensitivity reactions, or severe systemic bacterial, fungal, or parasitic infections
- Poor peripheral venous access
- Received blood products within 2 months before dosing
- Donation or loss of blood within 30-56 days prior to study drug administration
- Positive for hepatitis C virus (HCV) antibody, hepatitis B surface antigen (HBsAg), or human immunodeficiency virus (HIV) antibody
- Liver enzymes greater than acceptable limits
- History of eating disorders or surgical procedures for weight loss
- Active participation in a structured weight loss or dietary program
- Treatment with investigational therapy or exposure to any biological therapy
- Illicit drug use, marijuana use, or alcohol abuse
- Current use of more than one pack of cigarettes a day or equivalent nicotine- containing products
- Any serious medical condition or abnormality in clinical laboratory tests