

Non Alcoholic Steato-HepatitisChronic Kidney Disease

A Study to Evaluate the Efficacy, Safety, and Pharmacokinetics of BFKB8488A Compared With Placebo in Participants With Non-Alcoholic Steatohepatitis

Trial Status
Terminated

Trial Runs In
5 Countries

Trial Identifier
NCT04171765 GC41033

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 II, Randomized, Parallel-Group, Double-Blind, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy, Safety, and Pharmacokinetics of BFKB8488A Compared With Placebo in Patients With Non-Alcoholic Steatohepatitis

Trial Summary:

This study will evaluate the efficacy, safety, and pharmacokinetics of BFKB8488A compared to placebo in participants with non-alcoholic steatohepatitis (NASH).

Genentech, Inc. (A part of F. Hoffmann-La Roche Ltd., Switzerland)	Phase 2
Sponsor	Phase

NCT04171765 GC41033
Trial Identifiers

Eligibility Criteria:

Gender All	Age #18 Years & # 75 Years	Healthy Volunteers No
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Inclusion Criteria:

- Confirmed diagnosis of NASH as documented through liver biopsy performed no more than 6 months before randomization, defined according to NASH CRN criteria along with a NASH CRN fibrosis score between F2 and F3
- Hepatic steatosis on MRI ($\geq$ 8% average PDFF) prior to randomization

Exclusion Criteria:

- History of any liver disease other than NASH, except for resolved, self-limited illnesses such as Hepatitis A or E, and previous Hepatitis C
- Weight gain > 10% or loss > 5% within 3 months prior to randomization
- History of liver transplantation
- Current or history of significant alcohol consumption