

Non Alcoholic Steato-HepatitisChronic Kidney Disease

## A study of a new medicine (fazpilodemab) in people with a type of liver disease called non-alcoholic steatohepatitis or NASH

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).

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|---------------------------------------------------------------------------|----------------|
| <b>Genentech, Inc. (A part of F. Hoffmann-La Roche Ltd., Switzerland)</b> | <b>Phase 2</b> |
| Sponsor                                                                   | Phase          |

**NCT04171765 GC41033**  
Trial Identifiers

### Eligibility Criteria:

|                      |                                      |                                 |
|----------------------|--------------------------------------|---------------------------------|
| <b>Gender</b><br>All | <b>Age</b><br>#18 Years & # 75 Years | <b>Healthy Volunteers</b><br>No |
|----------------------|--------------------------------------|---------------------------------|

### 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