A Phase 3 Study Evaluating Efficacy and Safety of Lanifibranor Followed by an Active Treatment Extension in Adult Patients With (NASH) and Fibrosis Stages F2 and F3 (NATiV3)

Status: Recruiting

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Prescreening Criteria:

• Diagnosed with NASH on prior liver biopsy

• Type 2 diabetes with high waist circumference or obesity or hepatic steatosis on ultrasound

• At least 3 of the components of metabolic syndrome

Inclusion Criteria:

1. Male or female, aged ≥18 years at the time of signing informed consent 2. Upon central biopsy reading process: diagnosis of NASH according to the Steatosis-Activity-Fibrosis (SAF): 1. Steatosis score ≥1 2. Activity score: A3 or A4 3. Fibrosis score: F2 or F3 3. No qualitative change in dose for the drugs listed below: 1. Antidiabetic treatment if glucagon-like peptide-1 receptor agonists (GLP1 receptor agonists) or sodium-glucose co-transporter-2 inhibitors (SGLT2 inhibitors): for at least 3 months 2. Vitamin E (if at a dose ≥400 IU/day): for at least 6 months 3. Statins: for at least 3 months 4. No qualitative change in dose for all other chronically administered drugs for at least 3 months prior to Screening 5. Weight stable for 6 months prior to Screening and between the qualifying liver biopsy and Baseline (no more than 5% change for both periods) 6. Negative serum pregnancy test at study Screening for females of childbearing potential confirmed by central laboratory. Females of childbearing potential must practice a consistent and proper use of highly effective method of contraception throughout the study and for 1 month after treatment discontinuation.

Exclusion Criteria:

Liver-related: 1. Documented causes of chronic liver disease other than NASH 2. Histologically documented liver cirrhosis (fibrosis stage F4) 3. History or current diagnosis of hepatocellular carcinoma (HCC) 4. History of or planned liver transplant 5. Positive human immunodeficiency virus (HIV) serology 6. ALT or AST >5 × ULN 7. AST<0.6 ULN if the liver biopsy has to be performed in the scope of the study 8. Abnormal synthetic liver function as defined by Screening central laboratory evaluation 9. Haemoglobin <110 g/L (11 g/dL) for females and <120 g/L (12 g/dL) for males 10. Patient currently receiving any approved treatment for NASH or obesity 11. Current or recent history (<5 years) of significant alcohol consumption 12. Treatment with drugs that may cause non-alcoholic fatty liver disease (NAFLD) administered for at least 2 weeks within 12 months prior to qualifying liver biopsy Glycaemia related: 13. HbA1c >9% at Screening 14. Diabetes mellitus other than type 2 15. Current treatment with insulin 16. Treatment with PPAR-gamma agonists (thiazolidinediones [TZDs]) 12 months before screening or historical biopsy. Obesity related: 17. Bariatric surgery: Restrictive procedures are allowed, if performed >6 months prior to the qualifying liver biopsy; malabsorptive procedures and procedures combining both restrictive and malabsorptive methods are not allowed within 5 years of the qualifying liver biopsy. Cardiovascular related: 18. History of heart failure with reduced left ventricular ejection fraction (LVEF) 19. Atrial fibrillation requiring anticoagulation 20. Unstable heart failure 21. Uncontrolled hypertension at Screening (values >160/100 mm Hg) General safety: 22. Women currently breastfeeding 23. Previous exposure to lanifibranor 24. Participation in any clinical trial investigational medicinal product/device within 3 months from Screening or 5 half-lives from Screening, whichever is longer 25. Concomitant treatment with PPAR-alpha agonists (fibrates)

Conditions & Interventions

Interventions:
Drug: IVA337, Drug: Placebo
Conditions:
NASH - Nonalcoholic Steatohepatitis
Keywords:
Phase III, Nonalcoholic Steatohepatitis, NASH, Peroxisome proliferator-activated receptor (PPAR), Liver Diseases, Fibrosis

More Information

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IRB
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