Call Toll-free 1-800 856-7842 or 828-254-0881 with Extension listed

Name of Study: Randomized Global Phase 3 Study to Evaluate the Impact on NASH with Fibrosis of Obeticholic Acid Treatment (REGENERATE)-(Intercept Pharmaceuticals)

Link:
https://clinicaltrials.gov/ct2/show/NCT02548351?term=Intercept+Pharmaceuticals&type=Intr&cond=NASH&state1=NA%3AUS%3ANC&age=12&phase=123&rank=1

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Study Coordinator: Chris Childres x 3417 or Direct 828-255-2471

Enrollment Begins: June 2016

Enrollment Ends: 2017 with extension TBD

Summary: The primary objectives of this study are to evaluate the effect of Obeticholic Acid treatment compared to placebo on 1) histological improvement and 2) liver-related clinical outcomes in patients with non-cirrhotic nonalcoholic steatohepatitis (NASH) with liver fibrosis.

Inclusion:

1. Histologic evidence of NASH following a liver biopsy obtained no more than 6 months before Day 1.
2. Histologic evidence of fibrosis stage 1, stage 2 or stage 3.
3. Is either not taking or is on stable doses of :
   - TZDs or vitamin E
   - Therapies for diabetes
   - Allowed concomitant medications
4. Stable body weight.
5. Age ≥18 years.
6. Female subjects of childbearing potential must use ≥1 effective method of contraception during the study and until 4 weeks following the last dose of investigational product or at study termination.

7. Must provide written informed consent and agree to comply with the study protocol.

Exclusion:

8. Current or history of significant alcohol consumption.
9. Prior or planned (during the study period) bariatric surgery or ileal resection.
10. HbA1c ≥9.0% within 60 Days before Day 1.
11. Evidence of other forms of chronic liver disease including:
12. Positive test result for hepatitis B surface antigen or hepatitis C antibody
13. Primary biliary cirrhosis, primary sclerosing cholangitis, autoimmune hepatitis, or overlap syndrome
14. Alcoholic liver disease
15. Wilson's disease, hemochromatosis, or iron overload
16. Alpha-1-antitrypsin (A1AT) deficiency
17. Prior known drug-induced liver injury
18. Known or suspected HCC
19. History of liver transplant, current placement on a liver transplant list, or current MELD score >12
20. Histological presence of cirrhosis.
21. Total bilirubin >1.5 mg/dL.
22. AST >10× ULN, international normalized ratio (INR) >1.3, or serum creatinine ≥1.5 mg/dL.
23. Creatinine Phospho Kinase > 5xULN
24. Platelet count <100,000/mm3.
25. LDL ≥190mg/dL and already on statin therapy.
26. Inability to safely undergo a liver biopsy.
27. History of biliary diversion.
28. Known positivity for human immunodeficiency virus infection.
29. Recent history of specific types of cardiovascular disease.
30. Other medical conditions that may diminish life expectancy to <2 years, including known cancers.
31. Known substance abuse.
32. Pregnancy, planned pregnancy, potential for pregnancy or current or planned breast feeding.
33. Participated in a clinical research study with any investigational product being evaluated for the treatment of diabetes, weight loss, or NASH in the 6 months before Day 1.

34. Received any investigational product not being evaluated for the treatment of diabetes, weight loss, or NASH within 30 days before Day 1.
35. Previous exposure to Obeticholic Acid.
36. Mental instability or incompetence, such that the validity of informed consent or ability to be compliant with the study, is uncertain.
37. History of known or suspected clinically significant hypersensitivity to Obeticholic Acid or any of its components.
38. Any other condition that, in the opinion of the Investigator, would impede compliance or hinder completion of the study