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Name of Study: **EmricasaN, a Caspase inhibitOR, for Evaluation in Subjects with Non-Alcoholic Steatohepatitis (NASH) Fibrosis (ENCORE-NF)-(Conatus Pharmaceuticals)**

PI: Adam Zivony, MD

LINK: https://clinicaltrials.gov/ct2/show/NCT02686762?term=conatus+nash&rank=1&submit_fld_opt=

Enrollment Begins: May 2016

Enrollment Ends: 2017 with extension

Study Coordinator: Susan Westcott x 3580 or Direct 828-350-3667

Summary: A Multicenter, Randomized, Double-blind, Placebo-Controlled 72 week Trial of Emricasan, an Oral Caspase Inhibitor, in Subjects with Non-alcoholic Steatohepatitis (NASH) Fibrosis

To assess whether treatment with emricasan compared to matching placebo in subjects with NASH fibrosis improves fibrosis on liver biopsy by at least one stage without worsening of steatohepatitis using the NASH Clinical Research Network (CRN) Histologic Scoring System

Inclusion:

1. Male or female subjects 18 years or older
2. Histological evidence of definite NASH based on diagnostic classification, as confirmed by the central histopathologist, on a liver biopsy obtained no more than 90 days prior to the start of Screening
3. NAFLD Activity Score (NAS) of 4 or greater with a score of at least 1 in each component of the NAS (steatosis scored 0-3, lobular inflammation scored 0-3, ballooning scored 0-2)
4. Fibrosis stage 1 (limited to 20% of subjects), stage 2, or stage 3 using the NASH CRN Histologic Scoring System
5. Willingness to utilize effective contraception (for both males and females of childbearing potential) from Screening to 4 weeks after the last dose of study drug
6. If on vitamin E or pioglitazone, subjects must have been on a stable dose for at least 3 months prior to the biopsy (whether historical or qualifying biopsy)

Exclusion:

1. Current or history of significant alcohol consumption, defined as more than 20 g/day for females and more than 30 g/day in males on average, or inability to reliably quantify alcohol consumption based on investigator's judgement
2. Uncontrolled diabetes (HbA1c ≥ 9%) within 60 days prior to Day 1
3. Presence of cirrhosis on liver biopsy (fibrosis stage 4 based on the central histopathologist reading)
4. A platelet count below 100,000/mm3
5. Evidence of hepatic decompensation
a. serum albumin < 3.2 g/dL
b. INR > 1.4
c. direct bilirubin > 1.3 mg/dL
d. History of esophageal varices, ascites, or hepatic encephalopathy
6. Evidence of other forms of chronic liver disease
7. Symptoms of biliary colic, e.g. due to symptomatic gallstones, within the last 6 months
8. Any subject who has made a significant lifestyle change to their diet and/or exercise regimens within 3 months prior to Day 1 or plans to do so during the study
9. History of or active malignancies, other than curatively treated skin cancer (basal cell or squamous cell carcinoma), unless disease-free for at least 5 years and believed to be cured
10. Significant systemic or major illness other than liver disease that in the opinion of the investigator would preclude the subject from participating in and completing the study, including but not limited to acute coronary syndrome or stroke within 6 months of screening or major surgery within 3 months of screening
11. History or presence of clinically concerning cardiac arrhythmias, or prolongation of Screening (pre-treatment) QTcF interval > 480 milliseconds (msec)
12. If female: planned or known pregnancy, positive urine or serum pregnancy test, or lactating/breastfeeding