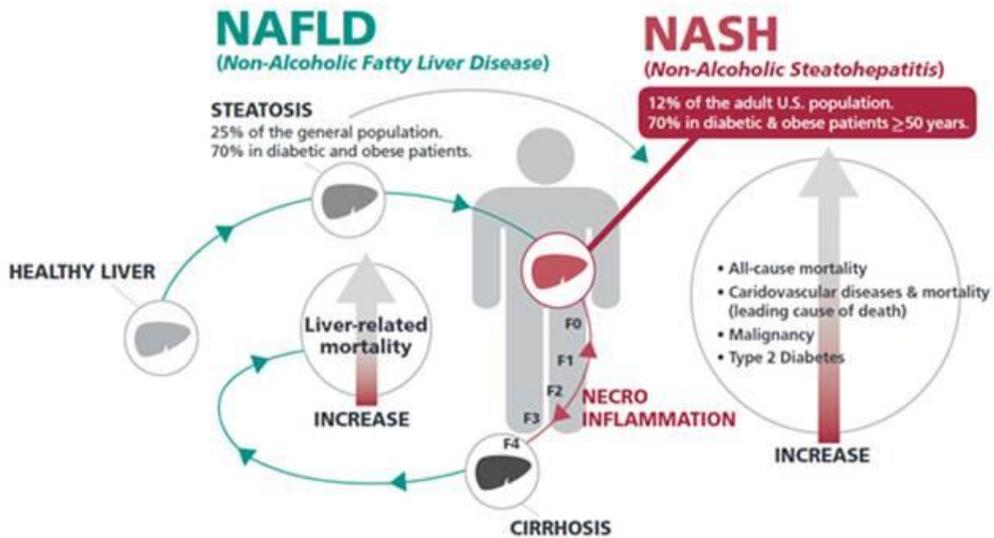




Yesterday, Intercept’s drug, Ocaliva, was the first one to pass its Phase 3 trial for Non-alcoholic Steatohepatitis (NASH, a \$22B to \$35B market).

NASH is a **chronic, silent disease** that can evolve for many years without visible symptoms. Fat and inflammation in the liver can lead to fibrosis and possibly cirrhosis. Currently, no treatment is approved and the disease could require liver transplant, increase the risk of cardiovascular diseases and lead to liver cancer.

### What is NASH?



Seeking Alpha. NASH Drugs: A Comprehensive Review of Current Clinical Trials. April, 6, 2016. Accessed at: <http://seekingalpha.com/article/3963505-nash-drugs-comprehensive-review-current-clinical-trials> on 01.19.2017.

After the recent failure in Phase 3 of Gilead’s drug a week ago, Intercept’s **Ocaliva may be the only treatment for NASH for at least a year.**

Intercept shares went up yesterday following the clinical results but failed to sustain double-digits gains as investors see a more difficult route to the **commercialization of the first NASH drug**.

In fact, the Phase 3 data on more than 900 patients with liver fibrosis caused by NASH was positive on one out of two criteria. On the first criterion, decrease in fibrosis, 23.1% of the treated patients at the highest dose (25mg) showed a significant decrease in their fibrosis (vs. 11.9% in the placebo arm). On the second criterion, NASH resolution, data was not statistically met as 11.7% of the patients on maximal dose (vs. 8% in the placebo arm).

Intercept had to meet at least one of the two criteria in order to have a chance to get the FDA approval. Therefore, **Intercept plans to submit its application for approval in the second half of 2019**.

While the results were not perfect (failure of the second criterion in addition to side effects such as pruritis and higher LDL-cholesterol levels), the FDA is likely to be flexible as there is no current treatment in the market.

As **NASH is a tricky disease** (multifaceted disease with various variables correlated to the NASH progression), we believe that a **combination therapy is the way to go for this disease**. Thus, the (partial) success of Intercept does not disqualify its main competitors, Genfit and Gilead. Genfit is currently conducting a Phase 3 trial on NASH with its molecule, Elafibranor. The results are to be published by the end of 2019.

**As NASH carries a huge market potential opportunity for any of the larger Pharma players (Allergan, Pfizer, Gilead notably), we believe that the possibility of seeing someone swallowing Intercept and possibly Genfit is very high and we keep our current exposure to the name.**

Viking Therapeutics (Phase 2) and Madrigal Pharmaceuticals (to initiate Phase 3 this year), which are often cited as key competitors and buyout candidates, target a different mechanism of action than other NASH drugs and thus do not represent as much interest as Intercept or Genfit in our view.