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NASH Drugs: A Comprehensive Review Of Current Clinical Trials

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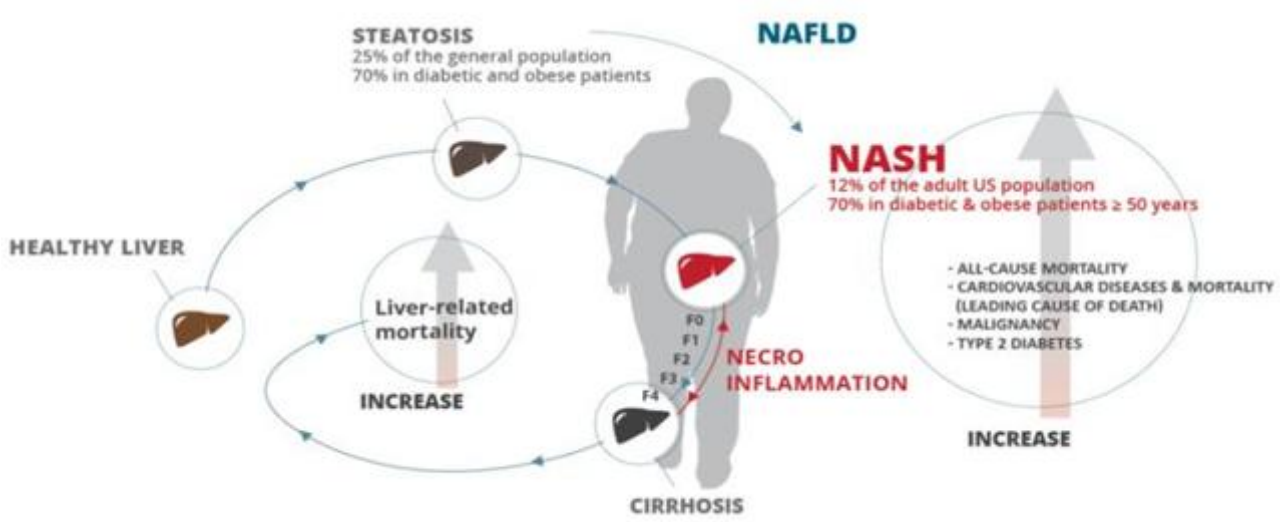
Summary

- NASH has no FDA-approved therapy and could represent a $35 billion market by 2025, prompting many biotechs to race for the approval of the first NASH-targeted drugs.
- The most advanced product candidates are Genfit's and Intercept's Phase 3 compounds, with many other biotechs currently conducting Phase 2 trials.
- This article aims to provide an updated and fairly comprehensive review of the current status and prospects of all major contenders in the NASH field.

Non-alcoholic steatohepatitis, or NASH, is a form of chronic liver disease caused by a build-up of fat in the liver (progressive fatty liver disease) affecting at least 2 to 5% of Americans, with some estimates going as high as a 17% prevalence rate in the U.S. population. There is currently no FDA-approved therapy for NASH, even though the disease can progress to cirrhosis and ultimately lead to hepatocellular carcinoma (liver cancer), which makes it one of the major unmet medical needs of the 21st century - NASH is now the second most common cause for liver transplantation in the U.S., and it is anticipated to become the leading cause by 2020.

Treating NASH is therefore a pressing matter of public health and the development of targeted therapies has been strongly supported by the FDA and EMA alike in the past years. The market for NASH drugs is currently estimated to reach $35 to $40 billion by 2025, a huge, mostly untapped market that could support several blockbuster drugs in the years to come.



Several companies are currently developing NASH-targeted drugs. Those with the most serious prospects include Genfit (OTCPK:GNFTF), Intercept (NASDAQ:ICPT), Gilead (NASDAQ:GILD), Novo Nordisk (NYSE:NVO), Tobira (NASDAQ:TBRA) and Galmed (NASDAQ:GLMD). Some other companies, such as Conatus (NASDAQ:CNAT), Galectin (NASDAQ:GALT) and MediciNova (NASDAQ:MNOV) have been granted Fast Track designations and are starting to explore the field. However, until now, only Intercept and Genfit have launched Phase 3 trials based on histological evidence (the current gold standard assessment of NASH) that their compounds are able to reverse or reduce NASH symptoms in randomized controlled trials.