

Non-Alcoholic SteatoHepatitis (NASH): An Analysis of Disease Prevalence, Drugs in development, Regulatory guidelines and Market opportunity in Various Geographies

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Abstracts

Sales of Hepatitis C drugs crossed ~\$10bn in 2014 proving that treatments for liver disease could become mega-blockbusters and Non-Alcoholic SteatoHepatitis (NASH) is expected to be equally lucrative. Improved diagnosis rate and change in treatment guidelines along with defined clinical trials endpoint are the concerns for the emerging therapy. US FDA is expected to release guidelines for the clinical trial in CY16 and this should accelerate the development of the drugs targeting NASH.

NASH is the progressive form of Non-Alcoholic Fatty Liver Disease – NAFLD. While NASH can reverse itself, in many cases, the resulting liver scarring causes a patient's liver to harden and failure to work properly. It is estimated that NASH affects 2 to 5% of the US population. Other developed countries such as Europe and Japan also have similar or higher incidence of NASH disease. Due to the varying physical and metabolism traits across various geographies, development of drugs for NASH is facing difficulty. In Japan, the prevalence of NASH is rising although the population is not typically overweight. Countries like India and China with bigger population and changes in lifestyles face a greater risk of NASH along with other lifestyle diseases like Diabetes and Cardiovascular related complexities.

As per the US Association of Liver Disease, of those who develop NASH, ~15-25% will progress to end stage liver disease (ESLD) and hepatocellular carcinoma (HCC) over 10-20 years. Today, 1/3rd of Liver transplants and HCC are caused by NASH and the total cost burden of this on US is over ~\$5 billion per year. Only new treatments in NASH could lead to a cut in this major cost burden along with improving quality of life.

Since a new innovation in NASH has been enlightened, the interest in companies developing drugs for NASH has also gone up. In Jan. 2015, Gilead Sciences (GILD) acquired Phenex Pharma's Farnesoid X Receptor (FXR) program comprising small molecule FXR agonists for the treatment of liver diseases including nonalcoholic steatohepatitis (NASH) and other Liver Diseases. Merck-NGM Biopharma and Boehringer Ingelheim - Pharmaxis also entered into an exclusive agreement for the pipeline products which are being developed for NASH with a potential deal value of ~\$450-600mn.

This report will provide detailed analysis on NASH disease and Drugs in development in broader pharma market. This report list all the drugs in clinical trial and their design and the population recruited, also tells about the pathways representing possible targets for the treatment of NASH.

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COMPANIES COVERED

Intercept Pharmaceuticals/ Daiippon Sumitomo

Genfit

Gilead

Conatus Pharmaceuticals

Galmed Pharmaceuticals

Tobira Therapeutics

Immuron

Galectin Therapeutics

Galecto Biotech

Shire
Boehringer Ingelheim
Islet Sciences/BHV pharma
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