
Description: 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.

Contents:
1. Executive Summary
2. Overview of NASH
   2.1 Possible targets for the treatment of NASH
   2.2 Drugs in the pipeline
   2.3 Key Milestones
   2.4 Drivers of M&A/ Licensing deals in NASH
   2.5 NASH disease market opportunity to 2025
3. Products in Development and Competitive Landscape
   3.1 Key Drugs/Companies Developing Drugs Against NASH
      3.1.1 Obeticholic Acid - Intercept Pharmaceuticals/ Dainippon Sumitomo
      3.1.2 Elafibranor - Genfit
      3.1.3 Multiple programs - Gilead
      3.1.4 Emricasan - Conatus Pharmaceuticals
      3.1.5 Aramchol - Galmed Pharmaceuticals
      3.1.6 Cenicriviroc - Tobira Therapeutics
      3.1.7 IMM-124E - Immuron
      3.1.8 GR-MD-02 - Galectin Therapeutics
      3.1.9 TD139 - Galecto Biotech
3.1.10 SHP626 - Shire  
3.1.11 PXS4728A - Boehringer Ingelheim  
3.2 Repurposed Drugs for NASH  
3.2.1 Remogliflozin etabonate - Islet Sciences/BHV pharma  
3.2.2 Lipaglyn (saroglitazar) - Cadila Healthcare  
3.2.3 Victoza (liraglutide) - Novo Nordisk  

4. NASH - Etiology, Pathogenesis, Diagnosis and Current Treatment  
4.1 Cause, Symptoms, Pathogenesis, Diagnosis  
4.2 Current treatment including Herbal Medicine  

5. Regulatory Pathway  
5.1 Challenges in trials using endpoints to define clinically meaningful benefits  
5.2 Potential Clinical Trial Design for NASH and Endpoints  

6. Annexure  

List of Tables:  
- Nonalcoholic steatohepatitis: Ongoing clinical trials  
- Pathways representing possible targets for the treatment of NASH  
- Drugs in Development  
- Failed/ Discontinued drugs  
- Select deals in the field of NASH  
- Potential licensing/ M&A opportunities  
- Drugs in development for NASH and Target  
- Noninvasive diagnostic methods for NAFLD  
- PIVENS trial: Primary outcomes after 96 weeks of treatment  
- PIVENS trial: Secondary outcomes after 96 weeks of treatment  
- PIVENS trial: Safety outcomes after 96 weeks of treatment  
- NASH disease market opportunity to 2025 in US, Europe, and Japan  

List of Figures:  
- Putative mechanisms underlying the contribution of NAFLD  
- Progression of NAFLD to NASH  
- Various modes of FXR gene regulation  
- Elafibranor: Mechanism of Action  
- Comparison GOLDEN/ FLINT/ PIVENS: Efficacy in the NAS > 4 Phase III target population  
  A. GOLDEN-505: Cardio-Metabolic protection  
  GOLDEN-505: Glycemic parameters in diabetics  
  Simtuzumab: LOXL2 pathway  
  GS-4997: ASK1 in insulin resistance  
  Emricasan: Phase II data @ EASL 2015  
  Emricasan: Phase II data @ AASLD 2015  
  Aramchol: Phase IIa data – relative change in liver-fat concentration  
  Cenicriviroc (CVC): A potent inhibitor of infiltration of pro-inflammatory monocytes  
  Cenicriviroc (CVC): Lipid Profile – Changes from Baseline  
  Results from PhIIa trial: Efficacy of IMM-124E  
  GR-MD-02: PhI study – Serum Biomarkers Evaluation  
  GR-MD-02: Preclinical data – Tx effect on NASH with fibrosis  
  LEAN study: Schematic of the trial design  
  Forms of fatty liver disease  
  Pivotal role of activated Kupffer cells in the pathogenesis of NASH and fibrogenesis  
  Companion diagnostics: The potential endpoints  
  Polyherbal therapeutic approaches available for the management of NASH  

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