Nonalcoholic Steatohepatitis (NASH) | Niche and Rare Pharmacor | G7 | 2015

Nonalcoholic fatty liver disease (NAFLD) is caused by a buildup of fat in the liver. A proportion of NAFLD sufferers will also experience injury to their hepatocytes, which can lead to nonalcoholic steatohepatitis (NASH). NAFLD and NASH are the fastest-growing liver diseases in the United States and Europe. Patients with NASH are at high risk for further liver damage, including fibrosis, cirrhosis, and even hepatocellular carcinoma (HCC). No FDA-approved treatments for NAFLD or NASH are currently available. Interviewed physicians state that they are limited to providing exercise and nutrition advice, using vitamin E, or attempting to recruit patients into clinical trials. A very high unmet need remains for the development of novel treatment for NAFLD and NASH. This report provides an overview of the NASH market, including a comprehensive analysis of patient populations, current therapies and medical practice, and opportunities for emerging therapies. The findings described in this report derive from detailed interviews with expert and European specialists, secondary research, and best-in-class epidemiological analysis. This report provides deep insights into this complex and evolving clinical space, and it includes a detailed analysis of specific opportunities for current and emerging therapies, including experts’ views on which unmet needs have not yet been addressed by developers of new therapies.

Questions Answered in This Report:

- **NASH is a disease with high prevalence.** What is the size of the U.S. and EU5 (France, Germany, Italy, Spain, and the United Kingdom) diagnosed prevalent population for NASH? How will these populations change over the ten-year forecast period? How many diagnosed prevalent NASH cases have advanced fibrosis, now and through 2024?

- **The pathogenesis of NASH is complex and involves multiple steps.** What new insights are informing experts’ understanding of NASH? What are the key avenues of preclinical and clinical research and development for NASH? What are the current gaps in knowledge with respect to disease progression and etiology? What are the current obstacles and barriers to diagnosis and treatment?

- **The expected market entry of Intercept’s obeticholic acid (OCA) and Genfit’s elafibranor will usher a new era of specific treatment for NASH, resulting in expansion of the treated population.** How will OCA and elafibranor reshape the NASH treatment paradigm? Which patients are most likely to be treated with these emerging NASH agents? What are physician perceptions about these emerging therapies? What considerations will drive physician choice between these two agents?
NASH represents an area with untapped market opportunities and significant unmet need that span a range of challenging issues. What are the emerging therapies in late-stage development, and which emerging therapies are poised to address unmet needs in the NASH market and see uptake in the next ten years? What unmet needs are expected to remain unaddressed? What are the opportunities for new product development? How can drug companies optimize drug development and capitalize on commercial opportunities in the NASH space?

Scope:
Market covered: United States, France, Germany, Italy, Spain, and the United Kingdom.
Primary research: Eight country-specific interviews with thought-leading NASH specialists.
Epidemiology: Prevalence of NASH, NASH with obesity, and NASH with advanced fibrosis. Diagnosed prevalent cases of NASH and NASH with advanced fibrosis.
Emerging therapies: Phase III: 1, Phase II: 11; Phase I: 3.

Report Details
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