

Nonalcoholic Steatohepatitis (NASH) - Market Insights, Epidemiology and Market Forecast-2028

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Abstracts

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DelveInsight's 'Nonalcoholic Steatohepatitis (NASH) - Market Insights, Epidemiology and Market Forecast-2028' report delivers an in-depth understanding of the disease, historical & forecasted epidemiology as well as the market trends of NASH in the United States, EU5 (Germany, Spain, Italy, France and United Kingdom), and Japan.

The Report provides the current treatment practices, emerging drugs, market share of the individual therapies, current and forecasted market size of Nonalcoholic Steatohepatitis from 2016 to 2028 segmented by seven major markets. The Report also covers current treatment practice/algorithm, market drivers, market barriers and unmet medical needs to curate best of the opportunities and assess underlying potential of the market.

Geography Covered

The United States

EU5 (Germany, France, Italy, Spain and the United Kingdom)

Japan

Study Period: 2016-2028

Nonalcoholic Steatohepatitis - Disease Understanding and Treatment Algorithm

Nonalcoholic Steatohepatitis (NASH) is the progressive form of liver injury that carries a risk of progressive fibrosis, cirrhosis, and end-stage liver disease. It is an advanced form of non-alcoholic fatty liver disease (NAFLD), caused by buildup of fat in the liver. When this buildup causes inflammation and damage, it is known as NASH, which can lead to scarring of the liver. Scarring of the liver is a potentially life-threatening condition called cirrhosis. NASH usually comes under the category of silent diseases that has very few or no symptoms typically because it doesn't cause any symptoms until it's too late.

The classification of fibrosis stages of NASH is as follows: No Fibrosis (F0), NASH Fibrosis (F1, F2 and F3), and NASH Cirrhosis (F4). According to various studies, such as Schuppan D et.al. [2019], Siddharth Singh et.al. [2014], and others NASH has been defined to keep progressing from early stages (F0 and F1) to advanced stages (F2, F3, F4) over time. The development of NASH with cirrhosis increases the risk of NASH Decompensated Cirrhosis and ultimately to death.

The DelveInsight Nonalcoholic Steatohepatitis (NASH) market report gives the thorough understanding of the NASH by including details such as disease definition, classification, symptoms, etiology, pathophysiology, diagnostic trends. It also provides treatment algorithms and treatment guidelines for NASH in the US, Europe, and Japan.

Nonalcoholic Steatohepatitis - Epidemiology

The Nonalcoholic Steatohepatitis epidemiology division provide the insights about historical and current patient pool and forecasted trend for every 8 major countries. It helps to recognize the causes of current and forecasted trends by exploring numerous studies and views of key opinion leaders. This part of the DelveInsight report also provides the diagnosed patient pool and their trends along with assumptions undertaken.

The disease epidemiology covered in the report provides historical as well as forecasted epidemiology [segmented by Total Prevalent Cases of Non-Alcoholic Fatty Liver Disease, Total Prevalent cases of Nonalcoholic Steatohepatitis and Nonalcoholic Steatohepatitis Segmentation by Fibrosis Stage] scenario of Nonalcoholic Steatohepatitis in the 7MM countries covering United States, EU5 countries (Germany, Spain, Italy, France and United Kingdom), and Japan from 2016-2028.

According to DelveInsight, increase in obesity, diabetes population will significantly

increase the prevalent cases of NAFLD with the CAGR of 1.02% for the study period i.e. 2016-2028 in the 7MM. Of all the prevalent cases of NAFLD in the 7MM, approximately 19% of the population fulfilled the criteria for NASH. These cases are expected to increase throughout the study period [2016-2028], reaching nearly 47 million cases in 2028. We estimate highest prevalence of NASH in the United States, accounting for almost 50% of the total prevalent cases, followed by Japan. On the other hand, it is assessed that among the European countries, Germany accounted for the highest prevalent population, followed by Italy. Among all the 7MM countries, Spain had the lowest prevalent population.

Nonalcoholic Steatohepatitis - Drug Chapters

This segment of the Nonalcoholic Steatohepatitis (NASH) report encloses the detailed analysis of marketed drugs and late stage (Phase-III and Phase-II) pipeline drugs. It also helps to understand the clinical trial details, expressive pharmacological action, agreements and collaborations, approval and patent details, advantages and disadvantages of each included drug and the latest news and press releases.

The treatment of NASH depends on the stage of the disease. Currently, there is no approved therapy for the treatment of NASH, yet doctors prescribe certain off-label drugs (supportive therapies) for its management. Lifestyle modifications are however the first line treatment. Lifestyle modifications include going for weight loss combined with active exercise program. Diet is also planned accordingly.

Medications are then prescribed in the later stages when lifestyle modifications do not produce significant results. Insulin sensitizing agents are prescribed in certain cases, however, metformin produced good results but on a temporary basis, due to which it is not recommended much. Pioglitazone is recommended in selected cases for patients already suffering with type II diabetes.

Vitamin E produces very significant results and is prescribed in most cases. Vitamin E is a first line therapy only for patients without diabetes. It is not recommended for patients with diabetes, NASH cirrhosis or cryptogenic cirrhosis. Statins are also prescribed in cases when a person has the cardiovascular risk associated with NASH. Statins are not recommended until histologic data are available.

Detailed chapters of upcoming therapies such as Elafibranor (Genfit), OCA (Intercept Pharmaceuticals), Selonsertib (Gilead Sciences), Cenicriviroc (Allergan- Tobira), GS-9674 (Gilead Sciences), Aramchol_005 (Galmed), MSDC-0602K (Cirius

Therapeutics), Emricasan (Conatus Pharmaceuticals), and others which are expected to launch during the forecast period [2019-2028] have also been covered in the report.

Nonalcoholic Steatohepatitis Market Outlook

The Nonalcoholic Steatohepatitis (NASH) market outlook of the report helps to build the detailed comprehension of the historic, current and forecasted trend of the market by analyzing the impact of current therapies on the market, unmet needs, drivers and barriers and demand of better technology.

This segment gives a through detail of market trend of each marketed drug and late-stage pipeline therapy by evaluating their impact based on annual cost of therapy, inclusion and exclusion criteria's, mechanism of action, compliance rate, growing need of the market, increasing patient pool, covered patient segment, expected launch year, competition with other therapies, brand value, their impact on the market and view of the key opinion leaders. The calculated market data are presented with relevant tables and graphs to give a clear view of the market at first sight.

The market for the treatment of Nonalcoholic Steatohepatitis (NASH) will experience significant annual growth over the 2016-2028 study period, as major-market sales increase up to USD 30,096.1 million by 2028. As the number of effective treatment for the NASH increases during the forecast period, the supportive therapies (off-label) market share will start to decrease, from a peak of 100% in 2016 to ~11% in 2028. Elafibranor (Genfit) will be the first drug for the treatment of NASH which will targeting the NASH Fibrosis (F1, F2 & F3) patients and Obeticholic acid (OCA; Intercept Pharmaceutical) will give competition to Elafibranor. Intercept's OCA is expected to grab maximum market share, owing to its development to target all stages of NASH (F1 to F4), except F0 and with the increasing demand for therapies to treat advanced stage of NASH, i.e. cirrhosis.

Nonalcoholic Steatohepatitis Drugs Uptake

This section focusses on the rate of uptake of the potential drugs recently launched in the market or will get launched in the market during the study period from 2016-2028. The analysis covers market uptake by drugs; patient uptake by therapies and sales of each drug.

This helps in understanding the drugs with the most rapid uptake, reasons behind the maximal use of new drugs and allows the comparison of the drugs on the basis of

market share and size which again will be useful in investigating factors important in market uptake and in making financial and regulatory decisions.

Key players in the market of NASH are Genfit, Intercept Pharmaceuticals, Gilead Sciences, Allergan (Tobira Therapeutics), Galmed Pharmaceuticals, Bristol-Myers Squibb, Cirius Therapeutics, Conatus Pharmaceuticals, Galectin Therapeutics, Immuron, NGM Biopharmaceuticals, Akcea Therapeutics and others. We expect that the launch of emerging therapies will fill the treatment void in the near future. The targeted therapies will have stronger penetration than the off-label therapies and the market is expected to reach in billions.

Intercept's Obeticholic Acid (OCA) is expected to grab maximum market share, owing to its development to target all stages of NASH (F1 to F4), except F0 and with the increasing demand for therapies to treat advanced stage of NASH, i.e. cirrhosis, this drug is expected to influence the market size with a greater percentage.

Apart from OCA, Selonsertib, and Emricasan, two other drugs which are expected to enter the NASH therapeutic market targeting cirrhosis stage of NASH, include GR-MD-02 by Galectin Therapeutics and Immuron's IMM-124E. Both of these drugs are expected will grab a significant proportion in the market size.

Furthermore, the expected launch of drugs, which are in the Phase II stage of clinical development shall significantly drive the market size forward. Emricasan (IDN-6556; Conatus Pharmaceuticals) is one of the drugs currently in Phase II, which will occupy more share in the therapeutic market of NASH as compared to two of the drugs in the Phase III, i.e. Cenicriviroc and Selonsertib.

It is expected that the market size of currently available off-label therapies for the treatment of NASH shall decrease, owing to the launch of upcoming therapies in forecast period [2019-2028]. Moreover, the ratio of drugs that will target all the NASH stages (F1 to F4) to those that are restricted towards the treatment of only one-or two of the stages, will be significant. Overall, the increasing prevalence, awareness of the disease and promising emerging pipeline therapies will fuel the market size during the forecasted period of 2019-2028.

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Key Benefits

This DelveInsight report will help to develop Business Strategies by understanding the trends shaping and driving Nonalcoholic Steatohepatitis

market

Organize sales and marketing efforts by identifying the best opportunities for Nonalcoholic Steatohepatitis market

To understand the future market competition in the Nonalcoholic Steatohepatitis market.

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