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North America Metabolic Dysfunction-Associated Steatohepatitis (MASH) Treatment Market - 2025-2033

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Abstracts

Overview

The North America metabolic dysfunction-associated steatohepatitis (MASH) treatment market size reached US$ 3.70 billion in 2024 and is expected to reach US$ 17.15 billion by 2033, growing at a CAGR of 19.3% during the forecast period 2025-2033.

Metabolic Dysfunction-Associated Steatohepatitis (MASH), formerly known as Nonalcoholic Steatohepatitis (NASH), is a disease caused by a build-up of fat in the liver, not caused by alcohol consumption. As a result of fat deposition, the liver becomes inflamed (hepatitis). The inflammation and liver damage from MASH can cause fibrosis and scarring, and can lead to cirrhosis, where the liver is scarred and significantly damaged, often permanently. The development of MASH is linked with underlying conditions such as metabolic syndrome, obesity, and type 2 diabetes.

The obesity rate is rising continuously in North America, with about 38 million people having diabetes, which is about 1 in every 10 people, creating a direct risk factor for NASH/MASH. Currently, there is only one FDA-approved drug for NASH/MASH, which is Rezdiffra (resmetirom), making these diseases an area of high unmet medical need, which drives company focus for new therapies.

For instance, on March 14, 2024, Madrigal Pharmaceuticals, Inc. cleared the U.S. Food and Drug Administration (FDA) accelerated approval for Rezdiffra (resmetirom) in conjunction with diet and exercise for the treatment of adults with noncirrhotic NASH with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis). Continued approval for this indication may be contingent upon verification and description of clinical benefit in ongoing confirmatory trials.

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Market Dynamics: Drivers & Restraints

The rising prevalence of underlying conditions is significantly driving the metabolic dysfunction-associated steatohepatitis (MASH) treatment market growth.

The rising prevalence of underlying conditions such as obesity, type 2 diabetes, and other metabolic syndromes contributes significantly to the development of liver diseases, particularly NASH and MASH, which are increasingly recognized as public health concerns in North America. For instance, according to the Centers for Disease Control and Prevention, the prevalence of obesity among adults was 40.3% during August 2021–August 2023. The prevalence was 39.2% in men and 41.3% in women.

Obesity is a major risk factor for both NASH and MASH. The obesity rate has surged over the past few decades in North America, especially in the United States, contributing directly to an increase in liver-related diseases. In obese individuals, excess fat accumulation in the liver (known as NAFLD, Non-Alcoholic Fatty Liver Disease) can progress to more severe stages such as NASH. About 20-30% of people with NAFLD will eventually develop NASH, increasing the demand for effective treatments.

Type 2 diabetes is another major risk factor for NASH/MASH. The prevalence of type 2 diabetes in North America is increasing at an alarming rate, with more than 38 million Americans having diabetes (about 1 in 10), and about 90% to 95% of them have type 2 diabetes. Type 2 diabetes leads to insulin resistance, a metabolic dysfunction that is strongly linked to fat accumulation in the liver (a hallmark of NASH/MASH). Additionally, the fatty liver associated with diabetes can exacerbate insulin resistance, creating a vicious cycle. The prevalence of underlying conditions leads to the high prevalence of MASH, which further accelerates the market for better treatment.

The growing prevalence of these underlying conditions has prompted pharmaceutical companies to accelerate the development of novel therapies for NASH/MASH. Currently, several treatments are in late-stage clinical trials, targeting different disease mechanisms such as fibrosis, liver inflammation, and insulin resistance. Drugs like Semaglutide, Survodutide, Pegozafermin, Lanifibranor, Denifanstat, and Efruxifermin are emerging as potential solutions to address the growing MASH prevalence.

Limited availability of approved drugs is hampering market growth

The limited availability of approved drugs is one of the major challenges hampering the

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growth of the market. Despite growing awareness, increasing diagnosis, and rising demand for effective treatments, the market is constrained by the fact that only one drug is currently approved, which is Rezdiffra (resmetirom) for the treatment of NASH/MASH, and many promising drugs are still in clinical trials or facing regulatory hurdles. This has created a significant gap between the need for effective treatments and their availability, impacting patient care and limiting market growth.

The lack of approved drugs means that patients with NASH/MASH have limited therapeutic options, and the growth of the market is slower than it could be. With only one approved drug, healthcare providers may be limited in the treatment options they can offer. Another challenge contributing to the limited availability of drugs is the lack of long-term data on the efficacy and safety of existing and trialed drugs. Most of the NASH/MASH drugs currently being tested are still undergoing long-term clinical trials, and many do not have substantial data on how they affect the disease in the long run.

Segment Analysis

The North American metabolic dysfunction-associated steatohepatitis (MASH) treatment market is segmented based on stage, age group and gender.

Stage:

Stage 4 segment are expected to dominate the North America metabolic dysfunction-associated steatohepatitis (MASH) treatment market with the highest market share.

Cirrhosis (fibrosis stage 4), the liver exhibits extensive scarring that changes its shape. Despite this severe damage, the liver can still function and may have the capacity to repair some of the injuries. However, if excessive scarring occurs, the liver's ability to carry out its essential functions may be impaired. This stage represents a critical condition that requires continuous management to prevent further deterioration and related complications.

At this stage, the individuals diagnosed with cirrhosis are indicating severe liver damage and scarring. This group includes those with compensated cirrhosis, where the liver still functions adequately despite significant scarring, and decompensated cirrhosis, where the liver can no longer maintain its functions, leading to serious complications such as fluid accumulation (ascites), jaundice, or hepatic encephalopathy. This statistic highlights a major public health concern, as it points to a substantial population at risk for severe health complications and emphasizes the urgent need for effective

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management and treatment strategies.

Competitive Landscape

Top companies in the North America metabolic dysfunction-associated steatohepatitis (MASH) treatment market include Madrigal Pharmaceuticals. And the emerging players includes Novo Nordisk A/S, Boehringer Ingelheim International GmbH, 89bio, Inc., Inventiva, Sagimet Biosciences, and Akero Therapeutics, Inc., among others

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The North America metabolic dysfunction-associated steatohepatitis (MASH) treatment market report delivers a detailed analysis with 30 key tables, more than 22 visually impactful figures, and 188 pages of expert insights, providing a complete view of the market landscape.

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Manufacturers: Pharmaceutical, Medical Device, Biotech Companies, Contract Manufacturers, Distributors, Hospitals.

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