# NASH market accelerates with new FDA-approved therapies and robust pipeline through 2034



The market for nonalcoholic steatohepatitis (NASH), recently redefined as metabolic dysfunction-associated steatohepatitis (MASH) by leading liver disease authorities in 2023, is anticipated to undergo substantial growth in the coming decade. This projection follows the introduction of FDA-approved therapies and a strong pipeline of emerging treatment options, according to a comprehensive report by DelveInsight.

NASH is a progressive liver disease characterised by inflammation and damage due to fat accumulation in the liver, linked to metabolic dysfunction. The renaming of the disease to MASH by the American Association for the Study of Liver Diseases (AASLD) and the European Association for the Study of the Liver (EASL) aims to better represent its metabolic origins and improve diagnostic clarity.

DelveInsight’s report, “Nonalcoholic Steatohepatitis Market Insight, Epidemiology And Market Forecast - 2034,” reveals that approximately 42 million prevalent cases of the disease existed across the seven major markets (7MM)—comprising the United States, Germany, France, Italy, Spain, the United Kingdom, and Japan—in 2023. Of these, around 15 million cases were diagnosed, with a steady increase expected through to 2034. The US represented the largest market segment, with an estimated value of USD 1.5 billion in 2023. Among European nations, Germany held the largest share at USD 89 million.

The epidemiology data highlight that among diagnosed patients in the US, approximately 38% were at the early F1 stage of liver fibrosis in 2023, a concern given the potential for progression without treatment. Gender disparities exist as well, with male patients accounting for roughly 56% of diagnosed cases in the 7MM, a trend expected to continue.

A significant milestone in the treatment of NASH occurred in March 2024 with the FDA approval of REZDIFFRA by Madrigal Pharmaceuticals. REZDIFFRA is currently the only FDA-approved therapy for adults with non-cirrhotic NASH accompanied by moderate to advanced liver fibrosis. DelveInsight reports that the two Phase III MAESTRO clinical trials demonstrated a robust efficacy and safety profile, positioning REZDIFFRA as a cornerstone therapy in NASH management.

Adding to this momentum, Novo Nordisk announced promising Phase III trial results for Semaglutide in November 2024. This glucagon-like peptide-1 receptor agonist targets the metabolic dysfunction central to NASH and is considered a significant advancement in therapy options.

In April 2025, 89bio advanced pegozafermin, a fibroblast growth factor 21 (FGF21) analog currently in Phase III trials, which has received both Breakthrough Therapy designation from the FDA and PRIME status from the European Medicines Agency (EMA). The drug is anticipated to launch in the US by 2026, promising notable impact on liver and cardiometabolic disease management.

Other notable treatments under clinical evaluation include GLP-1/glucagon receptor agonists—such as Tirzepatide by Eli Lilly and Survodutide by Boehringer Ingelheim—as well as FGF21 analogues like Efruxifermin from Akero Therapeutics. Thyroid hormone receptor agonists, including VK2809 from Viking Therapeutics and ALG-055009 from Aligos Therapeutics, are also in development.

Galectin Therapeutics reported on belapectin, an investigational therapy for NASH cirrhosis with portal hypertension, during the Phase IIb/III NAVIGATE trial in February 2025. The drug demonstrated a more than 68% reduction in new varices among US patients, with further follow-up data expected in Q2 2025 as the company plans to engage regulatory bodies.

DelveInsight identifies a highly competitive and rapidly evolving therapeutic landscape, with key players such as Inventiva Pharma, Zydus Therapeutics, Novo Nordisk, Eli Lilly and Company, Madrigal Pharmaceuticals, Terns, Inc., Intercept Pharmaceuticals, Enyo Pharma, 89bio, Akero Therapeutics, and Galectin Therapeutics driving innovation.

The NASH market was valued at around USD 2 billion in 2023 in the 7MM and is expected to grow significantly through 2034, propelled by increasing disease prevalence, innovation in drug development, and unmet medical needs. Advanced understanding of NASH pathogenesis and novel therapies targeting various cellular and molecular pathways promise an expanding range of treatment options aimed at improving patient outcomes.

DelveInsight’s report provides detailed insights into epidemiology, therapeutic approaches, competitive intelligence, and market dynamics that collectively underline the transformation underway in the management of this complex liver disease.

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