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Global Primary Biliary Cholangitis Treatment Market - 2025-2033

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Abstracts

Overview

The global primary biliary cholangitis treatment market reached US$ 1.33 billion in 2024 and is expected to reach US$ 2.72 billion by 2033, growing at a CAGR of 7.8 % during the forecast period of 2025-2033.

Primary biliary cholangitis (PBC), previously known as primary biliary cirrhosis (PBC), is a chronic and progressive autoimmune disease that primarily affects the bile ducts within the liver. In PBC, the body's immune system mistakenly targets and attacks the small bile ducts that are responsible for carrying bile from the liver to the small intestine. The damage to these bile ducts leads to inflammation, and over time, this inflammation destroys the ducts.

As bile accumulates in the liver, it leads to tissue damage. Eventually, scar tissue forms, replacing healthy liver tissue, which results in a loss of liver function. This process is known as cirrhosis. PBC was previously referred to as primary biliary cirrhosis.

Market Dynamics: Drivers & Restraints

Accelerated R&D in Novel Therapeutics

The rapid advancement of R&D in novel therapeutics is transforming the global primary biliary cholangitis (PBC) treatment market by filling critical gaps in care, introducing more effective and targeted therapies, and enhancing long-term patient outcomes.

Accelerated R&D efforts have led to the identification of new drug classes designed to

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target specific molecular mechanisms involved in primary biliary cholangitis (PBC). For example, drugs like obeticholic acid and fibrates have emerged, which modulate bile acid metabolism and improve liver function in PBC patients. It refers to the rapid pace at which new drug candidates and therapies are being developed, researched, and brought to market to improve the treatment outcomes for PBC patients.

Researchers are also investigating combination therapies to tackle PBC from multiple angles, including inflammation reduction, bile acid metabolism, and fibrosis inhibition. These approaches are designed to improve patient outcomes and slow disease progression more effectively than single-agent therapies.

The introduction of innovative, targeted treatments provides options that are likely more effective and tailored to individual patient needs. As these drugs undergo clinical trials and progress through regulatory approval, they generate anticipation in the market and offer the potential for growth in treatment options, attracting investment from pharmaceutical companies.

For instance, in July 2024, Parvus Therapeutics announced that the U.S. Food and Drug Administration (FDA) had granted Orphan Drug Designation to PVT201 for the treatment of primary biliary cholangitis (PBC). Additionally, PVT201 has received approval from the Australian Human Research Ethics Committee (HREC) to begin its first-in-human Phase I clinical trial.

Also, in January 2025, COUR Pharmaceuticals received Orphan Drug Designation (ODD) from the U.S. Food and Drug Administration (FDA) for CNP-104. This designation is for the treatment of Primary Biliary Cholangitis (PBC). All these factors demand the global primary biliary cholangitis treatment market.

Complications Associated with the Treatment

Treatment-related complications pose a significant challenge to the management and expansion of the global primary biliary cholangitis (PBC) treatment market. Although current therapies like Ursodeoxycholic Acid (UDCA) and Obeticholic Acid (OCA) provide some effectiveness in slowing the progression of the disease, they come with notable limitations and adverse effects.

UDCA, the first-line treatment, fails to elicit an adequate response in a substantial portion of patients and may cause gastrointestinal side effects. OCA, commonly prescribed as a second-line option, can intensify pruritus (itching), a major symptom of

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PBC, and carries a risk of liver-related complications, particularly in patients with advanced cirrhosis, leading to regulatory warnings and prescribing restrictions.

According to the American Liver Foundation data in March 2024, as PBC advances, it can lead to symptoms associated with cirrhosis, such as yellowing of the skin and eyes (jaundice), swelling in the legs and feet (edema), and fluid accumulation in the abdomen (ascites). In more severe cases, internal bleeding may occur due to enlarged veins in the upper stomach and esophagus (varices).

Bone thinning (osteoporosis) is another significant complication, increasing the risk of fractures and often emerging in the later stages, though it can appear earlier in the disease. Additionally, individuals with cirrhosis caused by PBC face an elevated risk of developing liver cancer, particularly hepatocellular carcinoma. Thus, the above factors could be limiting the global primary biliary cholangitis treatment market's potential growth.

Segment Analysis

The global primary biliary cholangitis treatment market is segmented based on drug type, age group, and region.

Drug Type:

The ursodeoxycholic acid (UDCA) segment in drug type is expected to dominate the global primary biliary cholangitis treatment market with the highest market share

Ursodeoxycholic Acid (UDCA), also known as ursodiol, is a naturally occurring hydrophilic bile acid that is used as a therapeutic agent in the treatment of various cholestatic liver diseases, most notably primary biliary cholangitis (PBC). UDCA works primarily by reducing the concentration of toxic bile acids in the liver, promoting bile flow, and protecting liver cells from damage.

UDCA achieves this by replacing hydrophobic (toxic) bile acids with more hydrophilic forms, which are less harmful to hepatocytes. This therapeutic mechanism helps reduce liver inflammation, improve biochemical markers such as alkaline phosphatase (ALP), and delay disease progression, particularly when started in the early stages of PBC.

For instance, in August 2024, Gilead Sciences, Inc. announced that the U.S. Food and Drug Administration (FDA) had granted accelerated approval for Livdelzi (seladelpar) for

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the treatment of Primary Biliary Cholangitis (PBC). This approval applies to its use in combination with ursodeoxycholic acid (UDCA) for adults who have not responded adequately to UDCA, or as a monotherapy for patients unable to tolerate UDCA. These factors have solidified the segment's position in the global primary biliary cholangitis treatment market.

Geographical Analysis

North America is expected to hold a significant position in the global primary biliary cholangitis treatment market with the highest market share

North America, particularly the United States and Canada, has a relatively higher prevalence of primary biliary cholangitis compared to many other regions. Enhanced screening practices, improved access to healthcare, and better disease awareness among clinicians and patients contribute to more frequent diagnoses. This rising detection rate directly boosts the demand for treatment options, especially first-line and emerging second-line therapies.

According to the American Liver Foundation, Data of March 2024, it is estimated that around 65 out of every 100,000 women in the United States are affected by PBC. This means that PBC is relatively rare but still a significant health concern, especially for women. PBC predominantly affects women, with approximately 90% of diagnosed cases occurring in women. This gender disparity may be linked to immune system factors, as autoimmune diseases, in general, tend to be more common in women.

PBC generally presents in middle age, with the most common age range for diagnosis being 45-65 years. This means that individuals are often diagnosed with PBC during their 40s to 60s. The disease can develop slowly, and symptoms may not be obvious in the early stages, which is why it often goes undetected until patients are middle-aged.

North America is the world’s leading pharmaceutical companies and academic research centers, which are actively engaged in clinical research and drug development for PBC. Ongoing trials for promising candidates such as Saroglitazar, CNP-104, and Pemafibrate are mostly conducted in the U.S. and Canada. This robust R&D ecosystem fosters innovation, expands treatment options, and contributes to early adoption of advanced therapies.

For instance, in June 2024, Ipsen announced that the U.S. Food and Drug Administration (FDA) had granted accelerated approval for Iqirvo (elafibranor) 80 mg

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tablets for the treatment of Primary Biliary Cholangitis (PBC). This approval applies to its use in combination with ursodeoxycholic acid (UDCA) for adults who have an inadequate response to UDCA, or as a monotherapy for patients who cannot tolerate UDCA. Thus, the above factors are consolidating the region's position as a dominant force in the global primary biliary cholangitis treatment market.

Competitive Landscape

The major global players in the primary biliary cholangitis treatment market include Intercept Pharmaceuticals, Inc., Gilead Sciences, Inc., Ipsen Biopharmaceuticals, Inc., Teva Pharmaceuticals USA, Inc., Glenmark Pharmaceuticals Inc., AbbVie Inc., Aden Healthcare., Zydus Therapeutics Inc., COUR Pharmaceuticals, Kowa Company, Ltd., Mirum Pharma, Parvus Therapeutics Inc, GSK plc., Strides Pharma Science Limited, and Calliditas Therapeutics AB. Among others.

Key Developments

In February 2025, Gilead Sciences, Inc. announced that the European Commission (EC) had granted conditional marketing authorization for seladelpar for the treatment of Primary Biliary Cholangitis (PBC). This approval allows the use of seladelpar in combination with ursodeoxycholic acid (UDCA) for adults who have had an inadequate response to UDCA alone, or as a monotherapy for those who cannot tolerate UDCA.

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The global primary biliary cholangitis treatment market report delivers a detailed analysis with 69 key tables, more than 48 visually impactful figures, and 176 pages of expert insights, providing a complete view of the market landscape.

Target Audience 2024

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

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