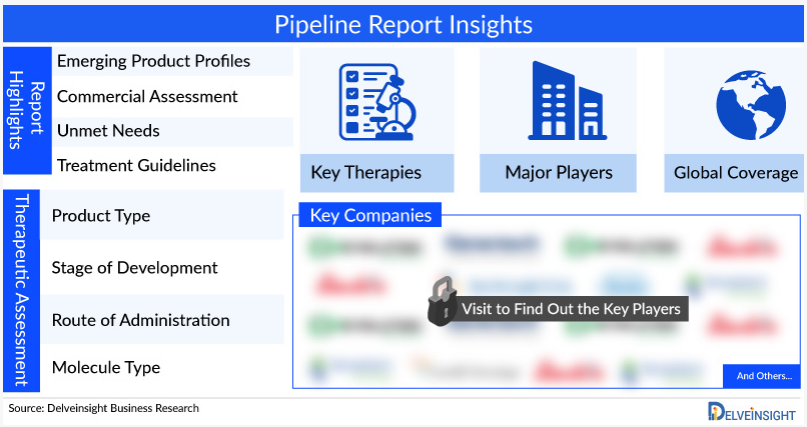
Primary Biliary Cholangitis Clinical Trial Pipeline | 20+ Companies Pioneering the Future of Treatment

Pharmaceutical companies are advancing the Primary Biliary Cholangitis treatment pipeline to unlock future growth potential.



Primary Biliary Cholangitis Clinical Trial Pipeline

LAS VEGAS, NV, UNITED STATES, February 13, 2025 /EINPresswire.com/ -- DelveInsight's 'Primary Biliary Cholangitis Pipeline Insight 2024' report provides comprehensive global coverage of pipeline Primary Biliary Cholangitis therapies in various stages of clinical development. Major pharmaceutical companies are working to advance the pipeline space and future growth potential of the Primary Biliary Cholangitis pipeline domain.

For Primary Biliary Cholangitis emerging drugs, the Primary Biliary Cholangitis pipeline analysis report provides a 360° view of the therapeutics landscape by development point, product type, route of administration, molecule type, and MOA. The pipeline research covers business opportunities, challenges, future partnerships, strong competitors, and growth strategies.

Key Takeaways from the Primary Biliary Cholangitis Pipeline Report
• DelveInsight's Primary Biliary Cholangitis Pipeline analysis depicts a robust space with 20+ active players working to develop 25+ pipeline drugs for Primary Biliary Cholangitis treatment.

• The leading Primary Biliary Cholangitis companies include CymaBay Therapeutics, Zydus Therapeutics, Genfit, GlaxoSmithKline, Calliditas Therapeutics AB, Intercept Pharmaceuticals, Mirum Pharmaceuticals, Escient Pharmaceuticals, Gannex Pharma, Nanjing Chia-tai Tianqing Pharmaceutical, and others are evaluating their lead assets to improve the Primary Biliary Cholangitis treatment landscape.

• Key Primary Biliary Cholangitis pipeline therapies in various stages of development include Seladelpar, Saroglitazar Magnesium, Elafibranor, Linerixibat, Setanaxib, Bezafibrate + Obeticholic

acid, Volixibat, EP547, ASC42, Obeticholic Acid, and others.

• In January 2025, COUR Pharmaceuticals announced that the FDA granted Orphan Drug Designation to CNP-104 for treating PBC.

• In December 2024, the FDA granted accelerated approval for Livdelzi® (seladelpar) to treat PBC, for use with UDCA or as a monotherapy.

• In December 2024, the FDA reported serious liver injury cases with Ocaliva (obeticholic acid) in PBC patients without cirrhosis.

• In October 2024, Intercept Pharmaceuticals announced the FDA is still reviewing the sNDA for OCALIVA® (obeticholic acid) for full approval.

• In September 2024, the European Commission gave conditional approval to Iqirvo® (elafibranor) for PBC in adults who cannot tolerate or respond to UDCA.

Request a sample and discover the recent breakthroughs happening in the Primary Biliary Cholangitis pipeline landscape @ Primary Biliary Cholangitis Pipeline Outlook

Primary Biliary Cholangitis Overview
Primary Biliary Cholangitis (PBC) is a chronic autoimmune disease that progressively damages the bile ducts in the liver. This inflammation leads to the destruction of small bile ducts, causing bile to accumulate in the liver (cholestasis), which can result in liver damage, fibrosis, and eventually cirrhosis. While the exact cause of PBC is unknown, it mostly affects middle-aged women and is thought to be triggered by a combination of genetic and environmental factors, including infections or exposure to toxins.

In its early stages, PBC may have no symptoms, but as it progresses, common signs include persistent fatigue, pruritus (itching), and dry eyes or mouth. In more advanced stages, symptoms can include jaundice (yellowing of the skin and eyes), dark urine, pale stools, and abdominal or leg swelling due to fluid retention. Complications can include vitamin deficiencies, osteoporosis, and an increased risk of liver failure or hepatocellular carcinoma.

The disease is believed to be caused by an autoimmune response in which the immune system mistakenly attacks the bile ducts. A genetic predisposition may play a role, as PBC is more common in those with a family history of autoimmune diseases, and environmental triggers such as infections or toxins may also contribute.

Diagnosis is made through a combination of blood tests, imaging studies, and occasionally liver biopsy. Elevated levels of alkaline phosphatase (ALP) and other liver enzymes indicate bile duct dysfunction, while the presence of antimitochondrial antibodies (AMA) in the blood is a key diagnostic marker in more than 90% of cases. Imaging tests like ultrasound or MRI can rule out

other causes of bile duct issues, and a liver biopsy may help confirm the diagnosis and assess disease severity.

Although PBC has no cure, treatments focus on slowing disease progression, managing symptoms, and addressing complications. Ursodeoxycholic acid (UDCA) is the first-line treatment, improving bile flow and liver function. For patients who don't respond to UDCA, Obeticholic acid (OCA) may be used. Symptom management includes antihistamines for itching and vitamin supplements for deficiencies. In advanced cases, liver transplantation may be necessary, which can be curative. Lifestyle changes, such as avoiding alcohol and eating a balanced diet, can also help support liver health.

Find out more about Primary Biliary Cholangitis medication @
https://www.delveinsight.com/report-store/primary-biliary-cholangitis-pbc-pipeline-insight?utm_source=einpresswire&utm_medium=pressrelease&utm_campaign=jpr

Primary Biliary Cholangitis Treatment Analysis: Drug Profile

Saroglitazar Magnesium: Zydus Therapeutics
Saroglitazar (LIPAGLYN) contains two main classes of PPAR agonists, which include PPARα (alpha) and PPARγ (gamma). The drug has lipid and glucose-lowering effects in a single molecule; it lowers high blood triglycerides and blood sugar and improves insulin resistance. The drug is available in tablet form of 4 mg dose for oral administration. Saroglitazar is indicated for treating diabetic dyslipidemia and hypertriglyceridemia with type 2 diabetes mellitus not controlled by statin therapy. In clinical studies, saroglitazar has demonstrated a reduction of triglycerides (TG), LDL cholesterol, VLDL cholesterol, and non-HDL cholesterol and an increase in HDL cholesterol, a characteristic hallmark of atherogenic diabetic dyslipidemia (ADD). The US FDA has granted ODD and FTD to saroglitazar Mg for PBC. It is currently being investigated in Phase III stage of clinical development for the treatment of Primary Biliary Cholangitis.

Setanaxib: Calliditas Therapeutics
Setanaxib (GKT831), a NOX1 and NOX4 inhibitor, has shown evidence of anti-fibrotic activity in a Phase II clinical trial in primary biliary cholangitis (PBC, an orphan liver disease). Based on its Phase II results, a phase II/III trial with Setanaxib in PBC was initiated. Setanaxib is also being evaluated in an investigator-initiated Phase II clinical trial in Type 1 Diabetes and Kidney Disease (DKD) as well as being studied in an investigator led Phase II clinical trial in idiopathic pulmonary fibrosis (IPF), a chronic lung disease that results in fibrosis of the lungs.

Key Primary Biliary Cholangitis Therapies and Companies
• Seladelpar: CymaBay Therapeutics
• Saroglitazar Magnesium: Zydus Therapeutics
• Elafibranor: Genfit
• Linerixibat: GlaxoSmithKline
• Setanaxib: Calliditas Therapeutics AB (Calliditas Therapeutics Suisse SA)

• Bezafibrate + obeticholic acid: Intercept Pharmaceuticals
• Volixibat: Mirum Pharmaceuticals
• EP547: Escient Pharmaceuticals
• ASC42: Gannex Pharma
• Obeticholic Acid: Nanjing Chia-tai Tianqing Pharmaceutical

Learn more about the novel and emerging Primary Biliary Cholangitis pipeline therapies @ https://www.delveinsight.com/report-store/primary-biliary-cholangitis-pbc-pipeline-insight?utm_source=einpresswire&utm_medium=pressrelease&utm_campaign=jpr

Primary Biliary Cholangitis Therapeutics Assessment

By Product Type
• Mono
• Combination
• Mono/Combination.

By Stage
• Late stage products (Phase III)
• Mid-stage products (Phase II)
• Early-stage product (Phase I) along with the details of
• Pre-clinical and Discovery stage candidates
• Discontinued & Inactive candidates

By Route of Administration
• Intravenous
• Subcutaneous
• Oral
• Intramuscular

By Molecule Type
• Monoclonal antibody
• Small molecule
• Peptide

Scope of the Primary Biliary Cholangitis Pipeline Report
• Coverage: Global
• Key Primary Biliary Cholangitis Companies: CymaBay Therapeutics, Zydus Therapeutics, Genfit, GlaxoSmithKline, Calliditas Therapeutics AB, Intercept Pharmaceuticals, Mirum Pharmaceuticals, Escient Pharmaceuticals, Gannex Pharma, Nanjing Chia-tai Tianqing Pharmaceutical, and others
• Key Primary Biliary Cholangitis Pipeline Therapies: Seladelpar, Saroglitazar Magnesium, Elafibranor, Linerixibat, Setanaxib, Bezafibrate + Obeticholic acid, Volixibat, EP547, ASC42, Obeticholic Acid, and others.

Dive deep into rich insights for drugs used for Primary Biliary Cholangitis treatment; visit @ Primary Biliary Cholangitis Drugs

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