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# Zydus granted Orphan Drug Designation by the USFDA for Saroglitazar in the treatment of patients with Primary Biliary Cholangitis (PBC)

*Ahmedabad, India January 28, 2021*

Zydus, a leading discovery based, global pharmaceutical company today announced that United States Food and Drug Administration (USFDA) has granted 'Orphan Drug Designation' (ODD) to Saroglitazar Mg for the treatment of patients with Primary Biliary Cholangitis (PBC). Orphan drug designation provides eligibility for certain development incentives, including tax credits for qualified clinical testing, prescription drug user fee exemptions and seven-year marketing exclusivity upon FDA approval. This follows the grant of 'Fast Track Designation' by the USFDA to Saroglitazar Mg for PBC in December 2020.

Saroglitazar Mg is a potent and selective peroxisome proliferator-activated receptor alpha and gamma dual agonist. Results of PHASE 2, prospective multicentre randomized double-blind, placebo controlled study to evaluate the safety, tolerability and efficacy of Saroglitazar Mg in patients with PRIMARY BILIARY CHOLANGITIS (EPICS) was presented earlier at the Liver Meeting® 2020, the Annual Meeting of the American Association for the Study of Liver Diseases (AASLD) [ClinicalTrials.gov Identifier: NCT03112681]. The treatment options are still evolving for PBC and Saroglitazar holds immense potential based on its safety and efficacy profile so far. The global market for PBC treatment is expected to grow at a CAGR of 36.3% from 2018 – 2026 and is expected to reach USD 10.8 bn by 2026 as per Coherent market insights.

Speaking on the development, Pankaj R. Patel, Chairman, Zydus Group said, "We are pleased that the USFDA has granted an Orphan Drug Designation apart from the earlier Fast Track Designation to Saroglitazar Mg for the treatment of Primary Biliary Cholangitis (PBC). This underlines the urgent need to address this serious health condition which is an unmet medical need. We are committed in our clinical development efforts to improve the quality of life of patients suffering from PBC with a safe and efficacious treatment."

For further information please contact :
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**About Primary Biliary Cholangitis (PBC)**

PBC is a liver disease, caused due to progressive destruction of the bile ducts in the liver which leads to reduction of bile flow – a condition referred to as cholestasis. With an increasing number of people being affected by PBC which can lead to progressive cholestasis and even turn fatal, there is a pressing need to develop therapies which help to achieve an adequate reduction in Alkaline Phosphotase (ALP) or bilirubin, reduce strong side effects of existing drugs such as pruritus or increase in LDL-c and bring in better tolerance and efficacy.

**About Zydus**

Zydus Cadila is an innovative, global pharmaceutical company that discovers, develops, manufactures and markets a broad range of healthcare therapies, including small molecule drugs, biologic therapeutics and vaccines. The group employs nearly 25,000 people worldwide, including 1,400 scientists engaged in R & D, and is dedicated to creating healthier communities globally. www.zyduscadila.com

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