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European Medicines Agency grants Orphan Drug Designation to Saroglitazar Mg for the treatment of patients with Primary Biliary Cholangitis (PBC)

Ahmedabad, India July 21, 2021

Zydus, a leading discovery-based, global pharmaceutical company, today announced that European Medicines Agency (EMA) has granted 'Orphan Drug Designation' (ODD) to Saroglitazar Mg for the treatment of patients with Primary Biliary Cholangitis (PBC).

Orphan drug status in Europe is given to medicines with the potential to be safe and effective treatments for rare, life-threatening, or chronically debilitating conditions affecting no more than 5 people in 10,000 people. It provides companies with a range of incentives, including assistance with trial protocols, reduced regulatory fees, differentiated evaluation procedures for Health Technology Assessments in certain countries, access to a centralized marketing authorization procedure valid in all EU Member States, and a 10-year period of market exclusivity if the treatment eventually is approved.

Earlier, the USFDA has granted 'Orphan Drug Designation' and 'Fast Track Designation' to Saroglitazar Mg for PBC.

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 EMA has granted an Orphan Drug Designation to Saroglitazar Mg for the treatment of Primary Biliary Cholangitis (PBC). This is a serious health condition and 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."

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

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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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