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Zydus granted Fast Track Designation by the USFDA for Saroglitazar in the treatment of patients with Primary Biliary Cholangitis (PBC)

Ahmedabad, India December 9, 2020

Zydus, a leading discovery based, global pharmaceutical company today announced that United States Food and Drug Administration (USFDA) has granted "Fast Track Designation" to Saroglitazar Mg for the treatment of patients with Primary Biliary Cholangitis (PBC). Fast Track is a process of the USFDA which expedites the review of drugs to treat serious conditions and fill an unmet medical need. A drug that receives Fast Track designation is eligible for Accelerated Approval and Priority Review, if the relevant criteria are met. The purpose is to get important new drugs to the patients faster. The global market for primary biliary cholangitis 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.

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 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 primary biliary cholangitis and Saroglitazar holds immense potential based on its safety and efficacy profile so far.

Speaking on the development, Pankaj R. Patel, Chairman, Zydus Cadila said, "The awarding of Fast Track Designation to Saroglitazar, an investigational candidate for the treatment of PBC, is an important recognition by USFDA to address the serious condition and bridge an unmet medical need in the treatment of PBC patients. We are very thankful to the USFDA for their timely and useful feedback on the clinical trial designs of Saroglitazar Mg and will continue to work closely with the USFDA for Clinical Development for Saroglitazar Mg for patients with Primary Biliary Cholangitis (PBC)."

About Fast Track Designation

Fast Track Designation is an FDA process designed to facilitate the development, and expedite the review of, medicines to treat serious conditions and fill unmet medical need. The FDA created this process to help deliver important new drugs to patients earlier, and it covers a broad range of serious illnesses. Fast Track designation can lead to an Accelerated Approval and Priority Review if certain criteria are met.

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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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