Zydus Announces Completion of Enrolment for EPICS III™ Phase 2b/3 trial evaluating Saroglitazar Mg in treatment of Primary Biliary Cholangitis

- *EPICS III™ is a Phase 2b/3 trial evaluating Saroglitazar Mg in patients with Primary Biliary Cholangitis (PBC)*
- *Earlier Phase 2 trial results published in 'Journal of Hepatology', had demonstrated a Best-in-Disease Profile for a Second-Line Therapy for PBC*
- *Saroglitazar Mg has received Orphan Drug Designation and Fast Track Designation from USFDA for PBC*
- *Saroglitazar Mg has received Orphan Status from EMA for PBC*

Ahmedabad, May 09, 2024

Zydus Lifesciences Limited (including its subsidiaries/affiliates hereafter referred to as "Zydus") a discovery-driven, global lifesciences company announced that it has completed enrolment of Phase 2b/3 EPICS III™ trial of Saroglitazar Mg in patients with Primary Biliary Cholangitis (PBC).

PBC is a rare, progressive autoimmune disease which gradually destroys the bile ducts, resulting in an accumulation of bile in the liver which can result in fibrosis, cirrhosis, the need for liver transplantation or death. PBC disproportionately affects women, with 1 in 1,000 women over the age of 40 being afflicted, 9 times the rate for men. PBC is characterized by increases in biochemical markers, especially alkaline phosphatase (ALP), bilirubin and liver transaminases. Clinical symptoms include pruritus (itching) and fatigue, both of which can be severe. PBC is a life-long condition and only medications can be used to manage and slow its progression.

PRESS RELEASE

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CIN : L24230GJ1995PLC025878

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], and has been published in the 'Journal of Hepatology'.

Overall Principal Investigator for Saroglitazar Mg global development programme, Professor Naga Chalasani, David W. Crabb Chair in Gastroenterology and Hepatology, Indiana University School of Medicine, Indianapolis, USA lauded the Zydus team and investigators across 3 countries for achieving this milestone in a record time. The results from this pivotal trial holds potential to greatly improve the treatment choices available for this difficult to treat and rare liver disorder.

The EPICS-III™ Phase 2(b)/3 trial is led by Lead Principal Investigator Prof Raj Vuppalanchi. The late-stage clinical program with Saroglitazar Mg EPICS III™ trial is now fully enrolled and will assess the efficacy and safety in patients with PBC who are uncontrolled on the usual first line PBC treatment [ClinicalTrials.gov ID NCT05133336].

Prof Raj mentioned that "Patients with PBC often look for treatments that not only improve liver health but also alleviate associated symptoms like itching and fatigue ultimately enhancing overall quality of life. There is growing optimism that Saroglitazar Mg at optimal dosage will address these needs with better efficacy, safety and tolerability compared to existing options. Both patients and medical community are eagerly awaiting the outcomes of this trial. I have strong hope that Saroglitazar Mg will establish itself as a primary therapy, significantly improving the daily lives of individuals suffering with PBC."

Speaking on the development, Chairman, Zydus Lifesciences Ltd., Mr. Pankaj Patel, said that, "The conclusion of enrolment marks an important milestone for the for EPICS III™ Phase 2b/3 trial and we would like to thank all our clinical collaborators and patients. There is a high need for new treatment options to reduce the risk of disease progression in patients living with PBC and we are looking forward to working with patient advocacy groups."

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Saroglitazar Mg is an investigational compound in the USA, and is yet to be approved by the U.S. Food & Drug Administration (USFDA) or European Medicines Agency (EMA). The USFDA has granted 'Orphan Drug Designation' and '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 European Medicines Agency (EMA) has designated 'Saroglitazar Magnesium' with Orphan status for Treatment of Primary Biliary Cholangitis. Orphan drug designation provides eligibility for certain development incentives, regulatory fee exemptions, seven-year marketing exclusivity upon USFDA approval and a 10-year period of market exclusivity if the treatment is eventually approved by EMA.

Primary Biliary Cholangitis (PBC) Publications

- Vuppalanchi R, Caldwell SH, Pyrsopoulos N, deLemos AS, Rossi S, Levy C, Goldberg DS, Mena EA, Sheikh A, Ravinuthala R, Shaikh F, Bainbridge JD, Parmar DV, Chalasani NP. Proof-of-concept study to evaluate the safety and efficacy of saroglitazar in patients with primary biliary cholangitis. J Hepatology. 2022 Jan;76(1):75-85. doi: 10.1016/j.jhep.2021.08.025. Epub 2021 Sep 4.
- Vuppalanchi R, González-Huezo MS, Payan-Olivas R, Muñoz-Espinosa LE, Shaikh F, Pio Cruz-Lopez JL, Parmar D. A Multicenter, Open-Label, Single-Arm Study to Evaluate the Efficacy and Safety of Saroglitazar in Patients With Primary Biliary Cholangitis. Clin Transl Gastroenterol. 2021 Mar 26;12(4):e00327. doi: 10.14309/ctg.0000000000000327.

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 Lifesciences Ltd. with an overarching purpose of empowering people with freedom to live healthier and more fulfilled lives, is an innovative, global lifesciences company that discovers, develops, manufactures, and markets a broad range of healthcare therapies. The

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group employs over 26,000 people worldwide, including 1,400 scientists engaged in R & D, and is driven by its mission to unlock new possibilities in lifesciences through quality healthcare solutions that impact lives. The group aspires to transform lives through path-breaking discoveries. Over the last decade, Zydus has introduced several innovative, first-in-class products in the market for treating unmet healthcare needs with vaccines, therapeutics, biologicals and New Chemical Entities. For more details visit www.zyduslife.com

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