Zydus Announces Positive Topline Results from Completed EVIDENCES-X Phase II(b) Clinical Trial of Saroglitazar Mg in MASH

- *EVIDENCES-X™ global Phase II(b) clinical trial of Saroglitazar Mg in MASH has been successfully completed.*
- *The trial achieved its primary endpoint of resolution of steatohepatitis with no worsening of fibrosis.*
- *Results add to the body of evidence being generated for Saroglitazar Mg in the ongoing development programme for MASH.*
- *MASH remains a significant global health burden affecting millions worldwide with limited approved treatment options.*

Ahmedabad, India, 31st August 2026

Zydus, a leading innovation-led global lifesciences company, today announced positive topline results from its completed EVIDENCES-X™ Phase II(b), prospective, multicentre, randomized, double-blind, placebo-controlled clinical trial evaluating the efficacy and safety of Saroglitazar Magnesium in patients with Metabolic dysfunction Associated Steatohepatitis (MASH) and fibrosis.

The liver biopsy-driven EVIDENCES-X™ study enrolled 189 subjects who were randomized in a 1:1:1 ratio to receive Saroglitazar 2 mg, Saroglitazar 4 mg or placebo over a treatment period of 52 weeks. The study successfully met its primary endpoint of resolution of steatohepatitis with no worsening of fibrosis at week 52 with the treatment difference of 26.5%. In addition to achieving the primary endpoint, the study demonstrated encouraging findings across key secondary and exploratory endpoints, including improvements in liver histology parameters, steatosis, inflammation and ballooning assessments. Further details would be presented in the upcoming Liver Congress.

The EVIDENCES-X™ trial was led by Prof. Naga Chalasani, M.D., Interim Chair, Department of Medicine, Indiana University School of Medicine, and Prof. Arun J. Sanyal, M.D., Division of Gastroenterology, Virginia Commonwealth University, as co-Principal Investigators.

Metabolic dysfunction Associated Steatotic Liver Disease (MASLD) and MASH, continue to represent significant unmet medical needs globally. Experts estimate that approximately 25% of adults worldwide are affected by MASLD, while MASH affects an estimated 5% to 20% of the adult population. MASH is characterized by hepatic steatosis, inflammation, and hepatocellular injury and can progress to advanced fibrosis, cirrhosis, liver failure, liver cancer, and death.

PRESS RELEASE

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Commenting on the positive outcome, Managing Director, Zydus Lifesciences Limited, Dr. Sharvil Patel said, "The successful completion of the EVIDENCES-X™ Phase II(b) trial and achievement of the primary endpoint marks an important milestone in our MASH development programme. These results reinforce the therapeutic potential of Saroglitazar Mg and our commitment to developing innovative treatment options for patients suffering from chronic liver diseases."

The positive results build upon previously published findings from earlier Phase II studies of Saroglitazar in MASH and MASLD patients. Data from the EVIDENCES-X™ trial will be presented at upcoming scientific meetings and submitted for publication in a peer-reviewed medical journal. Saroglitazar Mg was approved by the Drug Controller General of India (DCGI), for the treatment of MASH and MASLD in India in 2020. Saroglitazar Mg is an investigational compound in the United States and has not yet been approved by the U.S. Food & Drug Administration (FDA) or the European Medicines Agency (EMA) for the treatment of MASH and MASLD.

About EVIDENCES-X™

EVIDENCES-X™ was a global, multicentre, randomized, double-blind, placebo-controlled Phase II(b) clinical trial designed to evaluate the efficacy and safety of Saroglitazar Magnesium in patients with MASH and fibrosis. The study enrolled 189 patients across USA, Turkey and Argentina randomized to Saroglitazar 2 mg, Saroglitazar 4 mg, or placebo. The primary endpoint was resolution of steatohepatitis with no worsening of fibrosis as assessed by liver biopsy after 52 weeks of treatment.

About MASH

Metabolic dysfunction Associated Steatohepatitis (MASH) is a progressive form of Metabolic dysfunction Associated Steatotic Liver Disease (MASLD) characterized by fat accumulation, inflammation, and liver cell injury. MASH can progress to fibrosis, cirrhosis, hepatocellular carcinoma, liver transplantation, and death, creating a substantial clinical and economic burden worldwide.

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 life sciences company that discovers, develops, manufactures, and markets a broad range of healthcare therapies. The group employs over 30,000 people worldwide, including 1,500 scientists engaged in R & D, and is driven by its mission to unlock new possibilities in life sciences through quality healthcare solutions that impact lives. The group aspires to transform lives through pathbreaking 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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