Zydus announces Phase IV EVIDENCES-XI trial to generate Real World Evidence of Saroglitazar Mg in Non-Alcoholic Fatty Liver Disease (NAFLD) patients with comorbidities

- Phase IV EVIDENCES- XI trial will enrol approximately 1500 NAFLD patients with comorbidities

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Zydus Lifesciences Ltd. (including its subsidiaries/affiliates, hereafter referred to as "Zydus"), a discovery-driven, global life sciences company announced the commencement of Phase of IV Real World Data Registry trial "EVIDENCES- XI" for Saroglitazar Magnesium in NAFLD patients with comorbidities [ClinicalTrials.gov Identifier: NCT05872269]

The Phase IV EVIDENCES- XI trial will enrol approximately 1500 male and female NAFLD patients with comorbidities (either obesity, type 2 diabetes mellitus, dyslipidemia or metabolic syndrome- 200 patients each). The study duration is approximately 56 weeks. The primary endpoint is to measure the change in liver stiffness measurement performed by transient elastography from Baseline to Week 52.

Rohit Loomba, MD, Professor of Medicine, Division Chief of Gastroenterology at University of California, San Diego School of Medicine and Director of Hepatology at UC San Diego Health will lead the Steering Committee of this Phase IV EVIDENCES- RWD Study.

Dr. Rohit Loomba mentioned that, "This Phase 4 EVIDENCES- study is a landmark study establishing one of the largest prospective registry of patients with Non-Alcoholic Steatohepatitis (NASH) in the world. It will help generate novel Real World Data (RWD) in NAFLD/NASH patients that is especially lacking in Asian populations. Real World Data is crucial to formulate clinical guidelines, to further support its use in clinical practice and this will add to our existing knowledge of Saroglitazar Mg and its role in the management of NAFLD/ NASH."

Mr. Pankaj R. Patel, Chairman, Zydus Lifesciences Ltd. said, "NAFLD and NASH are serious life-threatening conditions and we have now studied Saroglitazar Mg in over 10 different trials which have been completed and the ongoing EVIDENCES I to X series of clinical trials in patients with NAFLD and NASH across clinical sites in India, Mexico, USA and Europe. I'd like to thank all the patients, investigators and study sites that are now participating in our Phase 4 EVIDENCES- XI Real World Evidence trial. We hope that this will be a big leap forward in managing and treating the unmet healthcare needs of NAFLD and NASH."

Saroglitazar Mg has been studied in two well controlled Phase 3 clinical trials in patients with NAFLD and NASH in India. The first Phase 3 trial was conducted in biopsy proved NASH patients, where Saroglitazar Mg demonstrated a significant difference of 28% versus placebo in the primary end-point NAFLD Activity Score (NAS) by at least 2 points spread across at least 2 of the NAS components [steatosis, hepatocyte ballooning, and lobular inflammation] with no worsening of fibrosis in greater proportion of patients [CTRI/2015/10/006236].

The second Phase III study of Saroglitazar Mg in NAFLD patients demonstrated that treatment with Saroglitazar Mg had a beneficial effect on primary end-point of change in liver fat content as measured by non-invasive magnetic resonance imaging (MRI) as well as secondary end-points including Liver stiffness as measured by transient elastography/FibroScan® in patients with NAFLD at week 24. [CTRI/2017/11/010511].

In the USA, the 'EVIDENCES-X' Phase 2b study of Saroglitazar Mg is currently ongoing in 240 patients with NASH with a 72-week biopsy driven end-point [ClinicalTrials.gov Identifier: NCT05011305]. Earlier the Phase 2 results of Saroglitazar Mg in patients with NAFLD was published in "Oct 2021 issue of Hepatology", while the Phase 2 results of Saroglitazar Mg in patients with Post transplant NASH has been published in the prestigious "Clin Gastroenterol Hepatol".

Saroglitazar Mg has been studied in patients with Primary Biliary Cholangitis (PBC), a rare liver disease with two separate EPICS-I and EPICS-II series of trials conducted in USA and Mexico. There two Phase 2 study results have been published in the prestigious "Journal of Hepatology" and "Gastroenterol Hepatololgy". A third Phase 2b/3 adaptive trial [EPICS-III] is currently ongoing in patients with PBC, with sites in USA and Europe [ClinicalTrials.gov Identifier: NCT05133336]. The USFDA has granted Fast Track status and Orphan Drug Designation for Saroglitazar Mg in PBC. Saroglitazar Mg has also received Orphan Drug Designation in Europe for the treatment of PBC. The Orphan drug designation will lead to 10 years of market exclusivity in Europe (once approved).

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Saroglitazar Mg is a prescription drug authorised for sale in India only and can be taken only under the advice and guidance of a registered medical practitioner.

About Zydus

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