December 10, 2021

BSE Limited **Code: 532321**
1st Floor,
P J Towers,
Dalal Street,
Mumbai-400001

National Stock Exchange of India Limited **Code: Cadilahc**
Exchange Plaza, 5th Floor,
Plot No. C/1, G Block,
Bandra-Kurla Complex, Bandra (East),
Mumbai-400051

Re.: Press Release

Dear Sir / Madam,

Please find enclosed a copy of press release dated December 10, 2021 titled "**Zydus announces EPICS-IIITM Phase 2(b)/3 adaptive pivotal clinical trial of Saroglitazar Mg in PBC**".

The contents of the press release give full details.

Please bring the aforesaid news to the notice of the members of the exchange and the investors' at large.

Thanking you,

Yours faithfully,
For, **CADILA HEALTHCARE LIMITED**

DHAVAL NARENDRA SONI
Digitally signed by DHAVAL NARENDRA SONI
Date: 2021.12.10 09:27:29 +05'30'

DHAVAL N. SONI
COMPANY SECRETARY

Encl.: As above

Zydus announces EPICS-III™ Phase 2(b)/3 adaptive pivotal clinical trial of Saroglitazar Mg in PBC

- Zydus has initiated a global pivotal Phase 2(b)/3 clinical trial in patients with Primary Biliary Cholangitis (PBC) - EPICS-III™
- Positive Results from the Phase 2(a) Clinical Trial Evaluating Saroglitazar Mg in patients with NASH were published in the Journal of Hepatology

Ahmedabad, India, December 10, 2021

Zydus, a leading discovery based, global pharmaceutical company today announced that it has received permission from the USFDA to initiate the Phase 2(b)/3 Prospective, Multi-centre, Randomized, Double-blind, Placebo-controlled adaptive clinical trial to evaluate Efficacy and Safety of Saroglitazar Magnesium in Subjects With Primary Biliary Cholangitis (PBC).

The EPICS-III™ trial will randomise 192 subjects in a 1:1:1 ratio to Saroglitazar 1 mg, Saroglitazar 2 mg or Placebo and will study the Saroglitazar Magnesium (1 or 2 mg) relative to Placebo based on the composite endpoints of Alkaline Phosphatase (ALP),total bilirubin, liver stiffness measurement (LSM) by FibroScan®, liver enzyme parameters (ALT, AST, GGT, total bilirubin, and albumin), lipid parameters (TG, LDL-C, HDL-C, VLDL-C, total cholesterol, and non-HDL-C), health related quality of life using PBC 40 questionnaire (a patient-derived, disease specific quality of life measure developed and validated for use in PBC) and other outcome measures over a period of 52 weeks [NCT05133336].The change in Pruritus (60- 70 % of Patients with PBC liver disease develop systemic itch of the skin that significantly impairs activity and sleep) will be studied using 5-Domains (5-D) itch scale, Patient Global Impression of Change scale, Patient Global Therapeutic Benefit scale and Patient Global Impression of Worst Itch Severity scale. The EPICS-III™ Phase 2(b)/3 trial will be led by Prof. Naga Chalasani, M.D., Interim Chair, Department of Medicine, Indiana University School of Medicine as Principal Investigator.

Speaking on the new development, Chairman of Cadila Healthcare Ltd., Pankaj R. Patel said, “Primary Biliary Cholangitis (PBC) is a severe liver disease leading to cirrhosis of the liver, liver failure, and possibly death. PBC patients have limited treatment options and approximately 50% of the PBC patients are not able to benefit from the existing therapy due to lack of response or intolerable side effects. Based on the positive results from our earlier Phase 2 study, we have now initiated the pivotal EPICS III trial in both cirrhotic and non-cirrhotic PBC patients.”

The Phase 2(a) EPICS trials results published in Journal of Hepatology has demonstrated that Saroglitazar holds immense potential based on its safety and efficacy profile. 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.

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

SaroglitazarMg for PBC. 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 eventually is 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 Hepatol*. 2021 Sep 3:S0168-8278(21)02023-7. doi: 10.1016/j.jhep.2021.08.025. Epub ahead of print. PMID: 34487750.
- 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.PMID: 3376935

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 over 23,000 people worldwide, including 1400 scientists engaged in R & D, and is dedicated to creating healthier communities globally. www.zyduscadila.com

For further information please contact :
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