Zydus announces world's first drug for the treatment of Non-Cirrhotic NASH

Ahmedabad, India, March 05, 2020

- *Saroglitazar, approved by DCGI becomes the first ever drug anywhere in the world for treatment of Non-Cirrhotic Non-Alcoholic SteatoHepatitis (NASH)*
- *NASH ranks as one of the major causes of cirrhosis, behind hepatitis C and alcoholic liver disease and is a leading cause of liver transplant*

Zydus Cadila, an innovation-driven global pharmaceutical company today announced that the Drug Controller General of India (DCGI) has approved its New Drug Application (NDA) for Saroglitazar for the treatment of Non-Cirrhotic Non-Alcoholic SteatoHepatitis (NASH) in India.

NASH is a progressive disease of the liver, which starts with fat accumulation in the liver known as Non-Alcoholic Fatty Liver Disease (NAFLD). This condition could progress to cirrhosis and liver failure. It is a large unmet medical need as there is currently no approved drug for the treatment of NASH anywhere in the world, a disease that is highly prevalent with 10% to 30% of the global population being affected by it. The prevalence of NASH in India is estimated to be nearly 25% of the population. NASH ranks as one of the major causes of cirrhosis, behind hepatitis C and alcoholic liver disease. Liver transplantation is the only option for managing advanced cirrhosis with liver failure.

Speaking about the development, Pankaj Patel, Chairman, Zydus Group mentioned, "We are happy that our efforts to discover and develop a novel drug for patients living with NASH, an unmet healthcare need globally have been successful. Saroglitazar will provide hope and new lease of life for millions of patients in India suffering from NASH."

Saroglitazar was launched in India in September 2013, for the treatment of diabetic dyslipidemia and hypertriglyceridemia in patients with type-2 diabetes not controlled by statins alone. In January this year, Saroglitazar received an approval for the treatment of Type 2 Diabetes Mellitus. In the last seven years, over a million patients have benefitted from this drug.

Saroglitazar is uniquely poised with its dual PPAR alpha and gamma properties – reducing the comorbidities (dyslipidemia, hypertriglyceridemia, diabetes mellitus) and causing NASH resolution. Zydus achieved positive results in EVIDENCES II trial, a Phase 3 liver biopsy trial of Saroglitazar 4 mg versus Placebo in Indian patients with NASH. The trial evaluated histological improvement of NASH using liver biopsy at the end of 52 weeks and successfully met primary and secondary endpoints. Saroglitazar 4 mg demonstrated a significant reduction in liver fat, liver enzymes and disease activity.

In EVIDENCES I, which was a Phase 2 clinical trial, Saroglitazar demonstrated improvement in liver enzymes and lipids in patients with Non-Alcoholic Fatty Liver Disease (NAFLD). On the global front, a Phase 2 trial (EVIDENCES IV) of Saroglitazar Mg in patients with NASH in the US met primary and secondary endpoints. The results were presented at The Liver

Meeting® 2019, the annual meeting of the American Association for the Study of Liver Diseases (AASLD) held at Boston.

Additionally, 15 investigator initiated clinical studies of Saroglitazar have been presented and published in leading scientific journals and conferences.

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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