

Zydus announces the approval of Saroglitazar Mg for the treatment of Non-Alcoholic Fatty Liver Disease in India

Ahmedabad, India, December 30, 2020

- *Saroglitazar Mg, approved by DCGI becomes the first medicine for the treatment of Non-Alcoholic Fatty Liver Disease (NAFLD).*
- *Non-alcoholic liver disease (NAFLD) is a spectrum ranging from non-alcoholic fatty liver (NAFL) to non-alcoholic steatohepatitis (NASH), which has the propensity to progress to liver cirrhosis and hepatocellular carcinoma (HCC) a leading cause of liver transplant.*
- *Nearly 25-30 % of the population in India is estimated to be suffering from NAFLD.*

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 Mg for the treatment of Non-alcoholic Fatty Liver Disease (NAFLD) in India. The prevalence of NAFLD in India is estimated to be nearly 25-30% of the general population. This approval for NAFLD alongwith either of the comorbidities (Obesity, Type 2 Diabetes Mellitus, Dyslipidemia or Metabolic Syndrome) provides the physicians with a viable treatment option. With a once daily, 4mg dose regimen, Saroglitazar Mg will enable better compliance, reduces the pill burden and offers the patient more convenience.

Non-Alcoholic Fatty Liver Disease (NAFLD) is a progressive disease of the liver, which starts with fat accumulation in the liver in patients who do not consume alcohol or take it in insignificant amounts, but have risk factors such as overweight or obesity, diabetes mellitus (high blood sugar), hypertension (high blood pressure) or dyslipidemia (abnormal blood lipids). This NAFLD condition could progress to NASH, cirrhosis and liver failure. It is a large unmet medical need as there is currently no approved drug for the treatment of NAFLD and NASH anywhere in the world.

Speaking about the development, Mr. Pankaj Patel, Chairman, Zydus Group said, “Zydus is committed to discovering novel medicines that can improve the quality of life of people. With Saroglitazar Mg, we have been able to successfully offer an innovative medicine for dealing with chronic liver diseases like NAFLD and NASH and helping patients in leading healthier lives.”

Saroglitazar Mg 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 Mg received an approval for the treatment of Type 2 Diabetes Mellitus. In March 2020, Saroglitazar Mg had received approval for the treatment of NASH.

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In the last seven years, over one and half million patients have benefitted from this drug. Saroglitazar Mg is uniquely poised with its dual PPAR alpha and gamma properties – reducing the comorbidities (dyslipidemia, hypertriglyceridemia, and diabetes mellitus) and bringing about a NASH resolution.

Zydus achieved positive results in the EVIDENCES III trial (CTRI/2015/10/006236), a Phase 3 liver biopsy trial of Saroglitazar Mg 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 Mg 4 mg demonstrated a significant reduction in liver fat, liver enzymes and disease activity. In the EVIDENCES VIII study (CTRI/2017/11/010511), which was a Phase 3 clinical trial in patients with NAFLD, Saroglitazar 4mg led to an improvement in the liver fat content, as measured by MRI PDFF and an improvement in the liver enzymes and liver stiffness measured by Fibroscan®. In EVIDENCES I, which was a Phase 2 clinical trial, Saroglitazar Mg 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 Mg have been presented and published in leading scientific journals and conferences. Saroglitazar Mg is a prescription drug approved in India, and should be taken under guidance of a registered medical practitioner.

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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