

Zydus announces regulatory filing of Saroglitazar Magnesium for treatment of NASH with DCGI

Ahmedabad, India, 05 December 2019

- *Zydus' Saroglitazar Magnesium could become the first medicine indicated for the treatment of Non-alcoholic Steatohepatitis, if approved.*

Zydus Cadila, an innovation-driven, global pharmaceutical company, announced that it has filed the NDA of Saroglitazar Mg in Non-alcoholic Steatohepatitis (NASH) with the Drug Controller General of India (DCGI).

NASH is a progressive disease of the liver and a significant unmet medical need. There are currently no treatments available for the treatment of NASH. Starting with fat accumulation in liver, this condition can progress to cirrhosis and liver failure. 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.

“There is a significant need for new therapies for patients with NASH, who have no treatment options as their liver disease progresses, other than opting for eventual liver transplants to survive” said Pankaj R. Patel, Chairman, Zydus group said, “We are very pleased that our NDA filing has been accepted for review which we believe represents an important step towards providing an innovative treatment option for millions of patients suffering from this devastating liver disease.”

Saroglitazar Magnesium was launched in India during September 2013, for the treatment of hypertriglyceridemia and diabetic dyslipidemia in patients with type-2 diabetes not controlled by statins. Saroglitazar Mg has demonstrated beneficial effects in NASH animal models. Saroglitazar Mg favorably affects all components of NASH including steatosis, ballooning, inflammation and fibrosis in NASH models. Saroglitazar Mg has previously demonstrated improvement in both liver enzymes along with favorable effects on lipid and glycemic indices in patients with nonalcoholic fatty liver disease in Phase II clinical trials.

Zydus had also achieved positive results in **EVIDENCES II** Phase 3 biopsy-driven trial of Saroglitazar 4 mg versus Placebo in patients with Non-Alcoholic SteatoHepatitis. The primary endpoint evaluated the histological improvement of NASH using liver biopsy at the end of 52 weeks. Separately, the results of **EVIDENCES IV** trial of Saroglitazar Mg in patients with NASH were presented as a Late Breaker at The Liver Meeting® 2019, the annual meeting of the American Association for the Study of Liver Diseases.

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 25000 people worldwide, including 1400 scientists engaged in R & D, and is dedicated to creating healthier communities globally. www.zyduscadila.com