# Zydus receives approval from USFDA to initiate Phase 2 clinical trials of Saroglitazar in patients with Non-Alcoholic Steatohepatitis (NASH) of the liver in USA.

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***Ahmedabad, India, June 4, 2016***

Zydus Cadila, a research-driven, global healthcare provider, today announced that USFDA has approved the company's plan to initiate a Phase 2 clinical trial of Saroglitazar in patients with Non-Alcoholic Steatohepatitis (NASH) of the liver. This randomized, double-blind Phase 2 trial will evaluate Saroglitazar 1 mg, 2mg and 4 mg Vs. Placebo.

NASH is the area of significant unmet medical need in the USA with an estimated 6.5 million adults in the United States and five major European countries having advanced NASH. NASH is a liver disease in which fat accumulates in the liver. Obesity, insulin resistance, diabetes and lipid disorders lead to NAFLD which progresses to a lethal NASH situation. The diagnosis of NASH is most commonly carried out using liver biopsy and this condition can progress to cirrhosis and liver failure. Liver transplantation is the only treatment for advanced cirrhosis with liver failure. NASH ranks as one of the major causes of cirrhosis in America, behind hepatitis C and alcoholic liver disease. Biotech Analysts estimate the worldwide market for NASH medicines to reach USD 35-40 billion by 2025.

Speaking on the development, Mr. Pankaj Patel, Chairman and Managing Director of Zydus Cadila said, "NASH is an area of unmet healthcare need as there are currently no drugs approved for the treatment of NASH. Saroglitazar has significant and differentiated effect on hepatic steatosis, while it shows all other beneficial effects on reducing inflammation and fibrosis in the liver in NASH models. With a Phase III trial in biopsy proven NASH patients ongoing in India and a Phase II trial in NASH patients planned in USA, we are committed towards developing this drug for millions of patients suffering from NASH".

Dr. Naga Chalasani, MD, FACG, David W. Crabb Professor & Director, Division of Gastroenterology and Hepatology, Indiana University School of Medicine will be the Principal investigator on this planned trial. This trial will be conducted across several medical sites in the USA., which will measure several parameters including the reduction in liver enzymes (serum ALT levels), liver stiffness (FibroScan®), liver fat content via MRI-PDFF, cytokeratin-18 (CK-18), enhanced liver fibrosis (ELF), aspartate aminotransferase-to-platelet ratio index (APRI), lipids, insulin resistance as well as glycemic control.

Zydus had earlier initiated a 52 week Phase III clinical trial of Lipaglyn™ in India to treat patients with biopsy proven NASH. Saroglitazar has demonstrated good efficacy in animal models of NASH, along with associated biomarkers. It has reduced hepatic steatosis, ballooning, inflammation and fibrosis in liver. The recently concluded phase 2 studies of Saroglitazar in patients with biopsy proven NASH has shown improvement in liver enzymes along with favorable effects on lipid and glycemic indices.

**About Lipaglyn™ (Saroglitazar)**

Lipaglyn™ (Saroglitazar) is currently approved in India as a prescription medicine for the treatment of Hypertriglyceridemia and Diabetic Dyslipidemia in Patients with Type 2 Diabetes not controlled by statins. The recommended dose of Lipaglyn™ is 4 mg once-a-day. Lipaglyn™ (Saroglitazar) was launched in India during September 2013. Since then more than 300,000 patients have been treated with Lipaglyn™ in India to date and data has been presented at several scientific and medical conferences. Additional Phase III trials are ongoing in non-alcoholic steatohepatitis (NASH), lipodystrophy, severe hypertriglyceridemia and few additional indications. A post-marketing Phase-IV study is currently underway in patients suffering from hypertriglyceridemia in India.

**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 19,000 people worldwide, including 1200 scientists engaged in R & D, and is dedicated to creating healthier communities globally. For more information, please visit www.zyduscadila.com