Zydus begins Phase - III study of Saroglitazar in NASH, a liver disease caused by obesity, diabetes and lipid disorders

The Zydus group announced the initiation of Phase III clinical trials to study its effect in adult nonalcoholic steatohepatitis (NASH) patients. 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 lethal NASH situation. The diagnosis of NASH is most commonly carried out using liver biopsy and this condition can lead to cirrhosis and liver failure. This is currently an unmet healthcare need as there are currently no drugs approved for the treatment of NASH and patients often have to undergo liver transplant to survive.

The Phase III trial will be of 52 week duration and will study the efficacy and safety of once daily 4 mg oral dose of Saroglitazar. The drug 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 completed phase 2 studies of Saroglitazar have shown improvement in both liver enzymes along with favorable effects on lipid and glycemic indices in patients with nonalcoholic fatty liver disease.

Mr. Pankaj Patel, Chairman & Managing Director of Zydus said that "NASH has grown to epidemic proportions worldwide, having become a leading cause of cirrhosis and liver failure. NASH is an area of significant unmet medical need with no drug on the market, and this phase III trial will give us useful insights into the efficacy and safety of the drug in NASH patients."

The trial will randomize NASH patients to receive Saroglitazar or placebo. The primary endpoint will be evaluated by histological improvement of NASH by liver biopsy. Multiple secondary objectives will also be evaluated including lipid profile and relevant biomarkers for inflammation and liver function.

Lipaglyn (Saroglitazar) was launched in September 2013 in India, for treating Hypertriglyceridemia and Diabetic Dyslipidemia in Patients with Type 2 Diabetes not controlled by statins. Since then, more than 60000 patients are availing this drug with a prescriber base over 3000 diabetologists, cardiologists and physicians. Since its launch several thousand patients have been treated with Saroglitazar. Lipaglyn™ helps in a reduction of triglycerides and LDL (bad) cholesterol, and an increase in HDL (good) cholesterol and has also shown a reduction in Fasting Plasma Glucose and glycosylated haemoglobin (HbA1c), thereby confirming its beneficial effects of both lipid and glycemic control in diabetic patients. With a non-renal route of elimination, Lipaglyn™ has no adverse events like edema, weight gain, myopathies or derangement of liver and/or kidney functions, thus making it safe and efficacious. Lipaglyn ™ can be taken only under the advice and 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. With 20 discovery research programmes under various stages of clinical development, the group invests over 7% of its turnover in research. The group employs over 16,000 people worldwide, including over 1200 scientist engaged in R & D, and is dedicated to creating healthier communities globally. It aims to be a leading global healthcare provider with a robust product pipeline; and be a research-based pharmaceutical company by 2020.