Zydus explores newer treatment options with its breakthrough drug, Lipaglyn™

Commences Phase III trials of Lipaglyn™ (Saroglitazar) in patients suffering from Lipodystrophy

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Exploring newer therapeutic usage of its breakthrough drug Lipaglyn™ (Saroglitazar), the Zydus Group has now initiated Phase III trials of the molecule for patients suffering from lipodystrophy. The drug is already approved in India for treating diabetic dyslipidemia and hypertriglyceridemia. The goal of this trial is to evaluate the safety and efficacy of Lipaglyn 4 mg versus standard-of-care with placebo in the treatment of lipodystrophy.

Lipodystrophy is a problem with the way the body produces, uses, and stores fat. Inherited lipodystrophies are caused by mutations in a gene. Acquired lipodystrophies are caused by medications, autoimmune mechanisms or unknown mechanisms. Patients with lipodystrophy suffer from metabolic disorders including lipid disorder and insulin resistance that leads to diabetes. These disorders can also increase the risk for other problems such as heart or liver disease.

Speaking on the new development Chairman and Managing Director, Zydus Group, Mr. Pankaj R. Patel said, "Following the launch of Lipaglyn™ in India we continue to pursue additional clinical development in indications having significant unmet needs such as lipodystrophy. The results from the previously conducted Phase II studies in patients with lipodystrophy have been encouraging and we are hopeful of extending the development of Lipaglyn™ for the treatment of lipodystrophy."

Launched in September 2013, Lipaglyn™ (Saroglitazar) is a breakthrough therapy in the treatment of diabetic dyslipidemia and India's first NCE to reach the market. Since then, thousands of patients have been treated with Lipaglyn™ in this country. It is a prescription drug available across India and prescribed by cardiologists, diabetologists and general physicians. A dual PPAR agonist, Lipaglyn™ has a predominant affinity to PPAR alpha and moderate affinity to PPAR gamma. This dual action helps reduce triglycerides and LDL (bad) cholesterol and increase HDL (good) cholesterol. It has also showed a reduction in Fasting Plasma Glucose and glycosylated haemoglobin (HbA1c), confirming its beneficial effects of both lipid and glycemic control. 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.

About Zydus

Zydus Cadila is an innovative, global pharmaceutical company that discovers, manufactures and markets a broad range of healthcare therapies. The group employs over 16,000 people worldwide including over 1100 scientists engaged in R & D and is dedicated to creating healthier communities globally. As a leading healthcare provider, it aims to become a global research-based pharmaceutical company by 2020. The group has a strong research pipeline of NCEs, biologics and vaccines which are in various stages of clinical trials including late stage.

About Zydus Research Centre

The Zydus Research Centre has over 20 discovery programmes in the areas of cardio-metabolic disorders, pain, inflammation and oncology. Zydus has inhouse capabilities to conduct discovery research from concept to IND-enabling pre-clinical development and human proof-of-concept clinical trials.