

## **Zydus receives approval from DCGI for Saroglitazar Magnesium for treatment of Type II Diabetes**

*Zydus' Saroglitazar Magnesium has been approved for the treatment of diabetes mellitus type 2 by the Drug Controller General of India*

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Ahmedabad, India, 03 February 2020

Zydus Cadila, an innovation-driven, global pharmaceutical company, announced that it has received the approval from the Drug Controller General of India for use of Saroglitazar Mg in the treatment of Type II Diabetes Mellitus as an add on therapy with Metformin. The drug was previously approved in the year 2013 for the treatment of Hypertriglyceridemia and Diabetic Dyslipidemia in India. More than 1 Million patients are being treated with Lipaglyn™.

The Diabetes Phase 3 clinical trial was a Multi-centric, Prospective, Randomized, Double-blind Study to Evaluate the Safety and Efficacy of Saroglitazar Mg 2 mg and 4 mg as compared to Pioglitazone 30 mg in patients with type 2 diabetes. The Phase 3 trial conducted in 1140 type 2 diabetes patients for a total of 56 weeks met the primary end-points (CTRI/2015/09/006203). The primary outcome measure was the change from baseline in glycosylated hemoglobin (HbA1c) for Saroglitazar 4 mg, 2 mg and Pioglitazone 30 mg at 24 weeks. The secondary outcome measures included the change from baseline in fasting plasma glucose, 2 hour postprandial plasma glucose, lipid profile, Triglyceride (TG) cholesterol, Low density lipoprotein (LDL) cholesterol, Very low density lipoprotein (VLDL) cholesterol, High density lipoprotein (LDL) cholesterol, Total cholesterol (TC) cholesterol, Non HDL cholesterol, Apolipoprotein (Apo) A1 and Apo B between Saroglitazar (4 mg, 2 mg) and Pioglitazone (30 mg) treatment at Week 12, 24 and 56.

In Phase III diabetes trial, at 24 weeks, HbA1c was reduced by 1.38 g/dL with Saroglitazar 2 mg, 1.47 g/dL with Saroglitazar 4 mg and 1.41 g/dL with Pioglitazone 30 mg. At 56 weeks, HbA1c reduced by 1.34 g/dL with Saroglitazar 2 mg, 1.49 g/dL with Saroglitazar 4 mg and 1.47 g/dL with Pioglitazone 30 mg. Saroglitazar did not cause hypoglycemia or weight gain in this trial.

“Insulin resistance is one of the primary causes of diabetes and there is a huge unmet medical need for a safe and effective insulin sensitizer. Saroglitazar is an important scientific and medical breakthrough in our effort to develop medicines for patients suffering from Type 2 diabetes mellitus. With the increasing cases of diabetes in India, the need to strengthen diabetes management and help patients control their blood sugar levels is of critical importance.” mentioned Pankaj Patel, Chairman, Zydus Group.

Saroglitazar (Lipaglyn™), is a novel PPAR $\alpha/\gamma$  agonist having predominant PPAR alpha activity. The recommended dose of Lipaglyn™ is 4 mg once-a-day. Lipaglyn™ is a prescription drug and should be taken under guidance of a registered medical practitioner. Lipaglyn™ was first launched in India during September 2013. Over the last several years, more than 1 Million patients have been treated with Lipaglyn™ in India for management of Hypertriglyceridemia and Diabetic Dyslipidemia, and data has been presented at several scientific and medical conferences.

### **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](http://www.zyduscadila.com)