

Zydus completes phase III trial of diabetes drug in India

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Saroglitazar Magnesium was launched for the treatment of type 2 diabetes



Zydus Cadila, an innovation-driven, global pharmaceutical company, announced that it has completed Phase 3 Clinical Trial in India of Saroglitazar Mg for treating Type 2 Diabetes.

The trial was a multi-centric, randomized, double blind study to evaluate the safety and efficacy of 2mg and 4mg of Saroglitazar compared to Pioglitazone 45mg in patients with Type 2 Diabetes Mellitus. The Phase 3 trial enrolled 1140 subjects and studied the patients over a period of 56 weeks.

The primary outcome of the trial was a change from baseline in glycosylated haemoglobin (HbA1c) for Saroglitazar 4 mg, 2 mg and Pioglitazone 30 mg at 24 weeks. The study also measured glycosylated haemoglobin (HbA1c) and other secondary outcome measures including fasting plasma glucose, Triglyceride (TG) cholesterol, Low Density Lipoprotein (LDL) cholesterol, Very Low Density Lipoprotein (VLDL) cholesterol, High Density Lipoprotein (HDL) cholesterol, Total Cholesterol (TC) cholesterol, Non HDL cholesterol, Apolipoprotein (Apo) A1, Apo B between Saroglitazar 4 mg, 2 mg and Pioglitazone 30 mg at Week 12, Week 24, and Week 56.

The Phase 3 trial has demonstrated efficacy and achieved statistical significance for its primary endpoint which was the change in mean HbA1c as compared to the baseline. No severe hypoglycaemia events were reported. There was no weight gain or edema observed with Saroglitazar Mg.

“Insulin resistance is the root cause of Type 2 Diabetes Mellitus and the data from this trial reveals that Saroglitazar Mg, a next-generation Insulin Sensitizer without the edema and weight gain sideeffects, could emerge as a potent anti-diabetic agent for millions of patients suffering from Type-2 Diabetes.” said Pankaj R. Patel, Chairman, Zydus group.

Saroglitazar Magnesium was launched in India during September 2013 under the brand name ‘Lipaglyn’, for the treatment of hypertriglyceridemia and diabetic dyslipidemia in patients with Type-2 diabetes not controlled by statins.