

Zydus pioneers a breakthrough with LIPAGLYN, India's first NCE to reach the market

The world's first drug for treating diabetic dyslipidemia combines lipid and glucose lowering effects in one single molecule

Editor's synopsis:

- Lipaglyn™ is the first Glitazar to be approved in the world and is the first NCE discovered and developed indigenously by an Indian Pharma Company
- The drug has been approved for launch in India by the Drug Controller General of India (DCGI)
- Over 80% of all diabetic patients are estimated to be suffering from diabetic dyslipidemia. There are more than 350 million diabetics globally – so the people suffering from diabetic dyslipidemia could be around 300 million
- With 20 discovery research programmes under various stages of clinical development, the group invests over 7% of its turnover in research
- At group's state-of-the-art research arm, the Zydus Research Centre, over 400 research scientists are engaged in NCE research alone

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The Zydus Group announced a breakthrough in its research efforts with Lipaglyn™ (Saroglitazar), a novel drug targeted at bridging an unmet healthcare need for treating Diabetic Dyslipidemia or Hypertriglyceridemia in Type II diabetes, not controlled by statins alone. The drug has been approved for launch in India by the Drug Controller General of India (DCGI). With a novel action that offers lipid and glucose lowering effects in one molecule, Lipaglyn™ is the first Glitazar to be approved anywhere in the world.

"Lipaglyn™ provides patients suffering from diabetic dyslipidemia the option of a once-daily oral therapy that has a beneficial effect on both lipid parameters as well as glycemic control," said Mr. **Pankaj R. Patel, Chairman and Managing Director, Zydus Cadila**. "It has always been our dream to take a molecule right from the concept stage up to its launch. Today, we have

realized this dream. It is an important breakthrough and I would like to dedicate this to all the Indian research scientists in the field of drug discovery," Mr. Patel added.

Diabetic Dyslipidemia is a condition where a person is diabetic and has elevated levels of the total cholesterol, the "bad" low-density lipoprotein (LDL) cholesterol and the triglycerides and a decrease in the "good" high-density lipoprotein (HDL) cholesterol concentration in the blood. Optimal LDL cholesterol levels for adults with diabetes are less than 100 mg/dL, optimal HDL cholesterol levels are equal to or greater than 40 mg/dL, and desirable triglycerides levels are less than 150 mg/dL. LipaglynTM, a non-thiazolidinedione, is the first therapy to be approved for this condition.

World over, it is estimated that 30% of all deaths occur due to cardiovascular diseases (CVD). In India, one out of every five persons is at serious risk of developing CVD. Research has shown that diabetes is one of the major risk factors of CVD. India has a population of nearly 65 million diabetics and 77 million pre-diabetics. 85 - 97% of the diabetes patients suffer from dyslipidemia or lipid abnormalities. Hence, addressing the problem of diabetes and dyslipidemia is crucial in tackling the health risk posed by CVD.

Discovered by the Zydus Research Centre, the dedicated NCE research arm of the Zydus group, LipaglynTM is a best-in-class innovation, designed to have a unique cellular mechanism of action following an extensive structure-activity relationship study initiated in the year 2000. LipaglynTM has a predominant affinity to PPAR alpha isoform and moderate affinity to PPAR gamma isoform of PPAR nuclear receptor subfamily. The molecule has shown beneficial effects on lipids and glycemic control without side effects. This molecule underwent extensive pre-clinical characterisation and the IND was submitted in the year 2004.

As a part of the clinical development programme, extensive Phase-I, Phase-II and Phase-III clinical trials were conducted to evaluate the pharmacokinetics, pharmacodynamics, efficacy and safety of LipaglynTM. The new drug application for LipaglynTM was based on a comprehensive clinical development programme spanning eight years.

Results from the first Phase III programme with Pioglitazone as a comparator drug in diabetes patients showed that the 4 mg dose of LipaglynTM led to a reduction of triglycerides and LDL (bad) cholesterol, and an increase in HDL (good) cholesterol and also showed a reduction in Fasting Plasma Glucose and glycosylated haemoglobin (HbA1c) thereby confirming its beneficial effects of both lipid and glycemic control in diabetic patients.

In the second Phase III study, LipaglynTM was studied in diabetic dyslipidemic patients insufficiently controlled with statin therapy. The results from this study confirmed that LipaglynTM had a pronounced beneficial effect on both the lipid and glycemic parameters in these subjects.

In both the studies, LipaglynTM was well tolerated and had a better safety profile than the comparators. Importantly LipaglynTM has a non-renal route of elimination, and did not show adverse events like edema, weight gain, myopathies or derangement of liver and/or kidney

functions, thus making it safe and efficacious. Lipaglyn™ is recommended for once daily administration as 4 mg tablets.

Zydus will offer a dedicated Lipaglyn™ support programme to patients and caregivers. The programme shall provide important support and information regarding access, adherence, education and thereby help patients to start and appropriately manage their disease and therapy over time.

About Zydus Cadila

Zydus Cadila is an innovative, global pharmaceutical company that discovers, develops, manufactures and markets a broad range of healthcare therapies. From a turnover of Rs. 250 crore in 1995, the group posted revenues of over Rs. 6300 crore in FY2013. With 20 discovery research programmes under various stages of clinical development, the group invests over 7% of its turnover in research. At the group's state-of-the-art research arm, the Zydus Research Centre, over 400 research scientists are engaged in NCE research alone. The group employs over 15,000 people worldwide and is dedicated to creating healthier communities globally. It aims to be a leading global healthcare provider with a robust product pipeline; achieve sales of over \$3 billion by 2015 and be a research-based pharmaceutical company by 2020.

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