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'It was always our dream to discover a new entity'

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Last week, the Zydus Group announced a breakthrough in its research efforts with Lipaglyn (Saroglitazar), a novel drug for the treatment diabetic dyslipidemia or hypertriglyceridemia in Type II diabetes. 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.The drug has been approved for launch in India by the Drug Controller General of India (DCGI, with Zydus introducing the drug into the market in the next few months. Also, Lipaglyn is the first Glitazar to be approved anywhere in the world.

The journey towards India's first indigenously developed NCE started in 2000, at Zydus Research Centre, with the molecule being identified in 2001. The IND for the molecule was subsequently submitted in 2004. The clinical trials for the same took place in 50 centers across India including KEM and Hinduja hospital, Mumbai, St Johns Hospital, Bangalore, PGIMER, Chandigarh. Zydus spent approximately $250 million for the development of this drug. It has plans to spend a further $150 million for getting global approvals.

About the journey Mr. Pankaj R. Patel, chairman and managing director, Zydus Cadila says," It was always our dream to discover new entities. We had an option of outlicensing it a few years ago, but our team was decided against it. We hope that this will set a positive trend for research in India and I would like to dedicate this to all the Indian research scientists in the field of drug discover"

About Lipaglyn, he added, "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."

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. Lipaglyn is a non-thiazolidinedione and is the first therapy to be approved for this condition.Â Hence, addressing the problem of diabetes and dyslipidemia is crucial in tackling the health risk posed by CVD.

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Lipaglyn 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.

Mr.Patel added that they envision Lipaglyn to become one of the Top 50 products in the Indian pharma business with revenues exceeding Rs 100crore in the next three to five years. Additionally, Cadila currently has 8 INDs in different stages of development and is working towards an aim to achieve sales of $300 billion by 2015 and become a research based pharma company by 2020.

Zydus also announced that it would 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.

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