



## Press Release

### **Piramal Enterprises Limited receives IND approval from the US FDA for its GPR40 agonist P11187; an anti-diabetic molecule**

- P11187 Investigational New Drug (IND) dossier receives US FDA regulatory approval
- Piramal's first US FDA approved Diabetes Phase I clinical trial; trials in the US to be initiated shortly
- P11187's anti-diabetic action is in a glucose-dependent manner, thus decreasing the potential risks of hypoglycemia

**Mumbai, May 14, 2013:** Piramal Enterprises Limited "PEL" (NSE: PEL, BSE: 500302) announced today that it has received approval from the US FDA for its Investigational New Drug (IND) P11187. This approval will enable PEL to initiate a Phase I clinical trial of P11187 in healthy volunteers in the US.

P11187 is an orally active, small molecule New Chemical Entity (NCE), discovered and developed by the NCE Research Division of PEL. P11187 selectively acts on GPR40; a potential therapeutic target for Type 2 Diabetes Mellitus (T2DM). T2DM is an emerging worldwide health crisis with an incidence rate of 300 million by 2025 as predicted by the WHO and accounts for about 90% of the diabetic population.

P11187 will be tested for safety and its glucose-lowering properties for the first time in humans; both properties having been well-established in our preclinical studies. Currently, the T2DM treatment space has limitations in terms of efficacy and adverse side-effect profiles. **The advantage of P11187; as a GPR40 agonist, is the stimulation of insulin secretion in a glucose-dependent manner, thus reducing the potential risk of excess insulin production.**

**Dr. Swati Piramal, Vice Chairperson, Piramal Enterprises Limited** said, "The NCE Research division of PEL is dedicated to finding new cures for metabolic disorders. It focuses upon nurturing innovation and break-through thinking to impact the lives of millions of people. P11187's IND approval by the US FDA; recognizes our untiring efforts to identify candidates that would translate into more efficacious drugs for the effective management of diabetes."

## **About NCE Research**

The NCE Research Division of Piramal Enterprises Limited focuses on the discovery and development of innovative small molecule medicines to improve the lives of patients suffering from cancer, metabolic disorders and inflammatory conditions. The key elements of our strategy include capitalizing on Piramal's strengths, in particular the India advantage, and leveraging external partnerships to achieve high levels of R&D productivity. Piramal's state-of-the-art Research Centre in Mumbai has comprehensive capabilities spanning target identification all the way through clinical development. Our robust pipeline, including 9 compounds in clinical development, bears testimony to our innovative and rigorous drug discovery process.

For further information please visit our website: [www.piramalenterprises.com/NCE](http://www.piramalenterprises.com/NCE)

## **About Piramal Enterprises Limited**

Piramal Enterprises is one of India's largest diversified companies, with a presence in pharmaceutical, financial services and information management sectors. Piramal Enterprises had consolidated revenues of over \$ 650 million in FY2013. In the pharmaceutical space, PEL is one of leading custom manufacturing player globally, has presence in the global critical care segment with a portfolio of inhalation and injectable anesthetics and its OTC business is ranked no. 7 in India. PEL is also engaged in drug discovery & research and has strong pipeline of development products. In the financial services space, PEL has a real estate focused PE fund – Indiareit and a NBFC that is focused on lending to real estate and education sector. PEL's information management business, Decision Resources Group is a leading provider of information based services to the healthcare industry.

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