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14 May 2013 | News | By BioSpectrum Bureau

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Piramal Enterprises Limited (PEL) has announced that it has received approval from the USFDA 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 percent 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 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."