Zydus' novel orally administered GLP-1 agonist – 'ZYOG1' to treat Diabetes and Obesity enters Phase I clinical trial

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Zydus Cadila, a global healthcare provider and one of India's leading healthcare companies has received Phase I clinical trial permission from the DCGI for ZYOG1 - a novel GLP-1 agonist. Designed and developed at the Zydus Research Centre using a unique platform technology, ZYOG1 is a novel, oral, antidiabetic molecule.

The new class of anti-diabetic drugs called Glucagon Like Peptide-1 (GLP -1) agonists came to the fore in May 2005 when the first molecule of this class was approved by the USFDA. Glucagon Like Peptide-1 agonists are being used to treat people with type 2 diabetes who have not been able to control their blood sugar levels with oral medicines. It is an injectible which acts like the natural hormones in the body that lowers blood sugar.

ZYOG1 would represent a next generation GLP-1 agents, as it would not have to be injected but can be taken orally. ZYOG1, when administered by oral route demonstrated beneficial effects in preclinical models on glucose reduction, HbA1c reduction and showed an added benefit of weight loss. Additionally, ZYOG1 has displayed a differentiated preclinical safety profile with no nausea-like symptoms in the preclinical studies.

Speaking on the new development, Mr. Pankaj R. Patel, Chairman and Managing Director, Zydus Cadila, said, "The discovery of the novel oral GLP-1 agonist, ZYOG1, using our own unique, discovery platform technology, is a significant achievement for us. This novel molecule would address unmet medical needs in treating diabetes and holds promising potential in the anti-diabetic and anti-obesity market."

The number of diabetics in the world, now estimated to be 246 million, is expected to increase rapidly to 380 million in 2025. Currently, 41 million (16.6%) of the diabetic population live in India and the number of diabetics are expected to touch 70 million (18.4%) in 2025. In 2025 nearly half of the world's diabetic population will be from India, China, Brazil, Russia and Turkey. Research in the field of anti-diabetic therapy seeks to address the problems of hypoglycemia, GI side effects, lactic acidosis, weight gain, CV risks, edema, potential immunogenicity etc., which pose a major challenge in the treatment of diabetes. The global anti-diabetic market was estimated at \$24 bn in 2008.

ZYOG1 is the latest addition to the group's strong research pipeline of NMEs in clinical development. The NME - ZYH1, for treating dyslipidemia is undergoing Phase III clinical trials. ZYI1, the anti-inflammatory and pain management compound is currently in Phase II clinical trials. ZYO1, a novel drug candidate for treating obesity and related disorders has completed Phase I clinical trials. ZYH7, a novel drug candidate for treating dyslipidemia and metabolic disorders, ZYH2, the novel agent for treating diabetes, ZYT1, a novel TR-beta agonist for treating dyslipidemia are in Phase 1 clinical trials.

The Zydus Research Centre has over 20 discovery programmes on with several candidates in the preclinical development stage focused on metabolic, cardiovascular, pain and inflammation therapeutic areas. With over 375 research professionals spearheading its research programme, Zydus has in-house capabilities to conduct discovery research from concept to IND enabling pre-clinical development and human proof-ofconcept clinical trials.