

Zydus files IND application with the DCGI for 'ZYD1' – a novel candidate to treat Diabetes and Obesity

Ahmedabad, June 04, 2009

Zydus Cadila, a global healthcare provider and one of India's leading healthcare companies, announced the filing of the IND application for ZYD1 - a novel GLP-1 agonist molecule with the DCGI. Designed and developed at the Zydus Research Centre, ZYD1 is a novel candidate in the class of antidiabetic agents known as incretin mimetics and has displayed a better efficacy and safety profile.

Incretin mimetics are poised to dominate the future of anti-diabetic therapy and presents a huge opportunity in bridging unmet medical needs that still continues to dodge the treatment and care of diabetes. The new class of drugs called incretins came to the fore in May 2005 when the world's first GLP-1 agonist was approved by the USFDA.

ZYD1 has demonstrated beneficial effects in preclinical animal models on glucose reduction, HbA1c reduction and added benefits of weight loss. ZYD1 displayed a differentiated preclinical safety profile with no nausea-like symptoms and absence of antibody generation 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 GLP-1 agonist, ZYD1, using our discovery platform technology is an important achievement for us. We believe that it holds promising commercial potential as a best-in-class candidate due to unmet medical needs in the treatment of diabetes."

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 lives in India and it is expected to rise to 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.

ZYD1 is the latest addition to the group's strong research pipeline of 6 NMEs which are in various stages of clinical trials. 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 and ZYT1, a novel drug candidate for treating dyslipidemia are in Phase 1 clinical trials.

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

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