

Zydus' IND application of ZYGK1 for treating diabetes receives USFDA approval

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Zydus Cadila, a global healthcare provider and one of India's leading healthcare companies announced that it has received an approval from the USFDA for its IND application of ZYGK1. Designed and developed at the Zydus Research Centre, the NME is a potent and orally administered small molecule glucokinase activator. The company will now initiate Phase I clinical trials for ZYGK1.

Glucokinase (GK) is the enzyme that acts as a glucose sensor in the pancreas and regulates glucose metabolism in the liver. When, circulating glucose levels rise above a certain threshold, the glucokinase enzyme enhances insulin release from pancreas and decreases glucose production in liver. In normal individuals, the pancreas secrete insulin in response to increased levels of glucose in the blood. In patients with Type 2 diabetes, there is a reduction of GK activity in the pancreas and the liver.

Speaking on the new development, Mr. Pankaj R. Patel, Chairman and Managing Director, Zydus Cadila, said, "We have been building a promising pipeline of new molecular entities at the Zydus Research Centre and with each step forward, we are moving closer to our goal of becoming a research driven pharma major. We believe that these sustained efforts will help us address unmet healthcare needs in the focus areas of metabolic disorders and cardiovascular diseases."

In multiple preclinical models of Type 2 diabetes, ZYGK1 was found to be effective in controlling both fasting and non-fasting blood glucose. ZYGK1 showed very good safety profile in preclinical studies. Activating GK with small molecules such as ZYGK1 lower blood glucose levels by enhancing the ability of the pancreas to sense glucose, which leads to increased insulin production. Simultaneously, glucokinase activators increase the net uptake of blood glucose by the liver. Glucokinase activators, such as ZYGK1, represent a promising new class of drugs for the treatment of Type 2 diabetes.

Starting with its first IND filing in 2005, Zydus today has several NMEs in various stages of clinical trials. The NME - ZYH1, for treating dyslipidemia is undergoing Phase III clinical trials and ZYI1, the anti-inflammatory and pain management compound is currently in Phase II clinical trials. ZYOG1, a oral GLP-1 agonist for treating diabetes, ZYH7, a novel drug candidate for treating dyslipidemia and ZYH2, the novel agent for treating diabetes have completed Phase I clinical trials. ZYO1, a novel drug candidate for treating obesity and related disorders, ZYD1, a GLP-1 agonist to treat diabetes and 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 pre-clinical development stage focused on metabolic, cardiovascular, pain and inflammation therapeutic areas. With over 400 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-of-concept clinical trials.

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