Zydus announces US FDA approval for initiating Phase I clinical trials of 'ZYDPLA1' – a novel next generation orally active, small molecule DPP-4 inhibitor to treat Type 2 Diabetes

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- Zydus strengthens its cardiometabolic pipeline with the addition of ZYDPLA1
- Novel next generation New Chemical Entity (NCE) would offer once-a-week oral treatment option, a significant benefit to Type-2 diabetic patients

Close on the heels of launching Lipaglyn, the breakthrough therapy to treat diabetic dyslipidemia and India's first NCE to reach the market, the Zydus group announced the Phase I clinical trial approval from the USFDA for ZYDPLA1 - a Next Generation, long-acting DPP-4 Inhibitor.

ZYDPLA1 is an orally active, small molecule NCE, discovered and developed by the Zydus Research Centre, the NCE research wing of Zydus. ZYDPLA1 is a novel compound in the Gliptin class of antidiabetic agents. It works by blocking the enzyme Dipeptidyl Peptidase-4 (DPP-4), which inactivates the Incretin hormone GLP-1. By increasing the GLP-1 levels, ZYDPLA1 glucose-dependently increases insulin secretion and lowers glucagon secretion. This results in an overall improvement in the glucose homoeostasis, including reduction in HbA1c and blood sugar levels.

Currently, all available DPP-4 inhibitors are dosed once-daily. ZYDPLA1 with a once-a-week dosing regimen, would provide diabetic patients with a more convenient treatment alternative. ZYDPLA1 will offer sustained action, which will result in an improved efficacy profile.

Speaking on the new development, Mr. Pankaj R. Patel, Chairman and Managing Director, Zydus Group, said, "After a promising start with Lipaglyn, we take another big leap forward in the area of diabetic research and long term management of Type 2 diabetes. The IND approval by USFDA is another major regulatory milestone for us. We believe that ZYDPLA1 holds promise and would take us closer to our mission of reducing the burden of chronic diseases and addressing unmet medical needs in the treatment of diabetes."

The number of diabetics in the world is estimated to be over 360 million. In 2025 nearly half of the world's diabetic population will be from India, China, Brazil, Russia and Turkey. The sales of the DPP-IV inhibitors is expected to peak at almost $14 billion by 2022. 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.

About Zydus

Zydus Cadila is an innovative, global pharmaceutical company that discovers, develops, manufactures and markets a broad range of healthcare therapies. The group employs over 15,000 people worldwide and is dedicated to creating healthier communities globally. Zydus is the only Indian pharma company to launch its own patented NCE – Lipaglyn™, the world's first drug to be approved for the treatment of diabetic dyslipidemia. It aims to be a leading global healthcare provider with a robust product pipeline, achieve sales of over $3 billion by 2015 and be a research-based pharmaceutical company by 2020.

About Zydus Research Centre

The Zydus Research Centre has over 20 discovery programmes ongoing with several candidates in the pre-clinical development stage focused on metabolic, cardiovascular, pain, inflammation and oncology therapeutic areas. With over 400 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. ZYDPLA1 is the latest addition to the group's strong research pipeline of 6 NCEs which are in various stages of clinical trials. For more information, please visit: www.zyduscadila.com

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