

Zydus announces IND clearance of a novel Anti-PCSK9 candidate

- *Company will initiate Phase I clinical trials*
- *Aim is to treat Dyslipidemia with a potential for once-in-6-month dosing regimen*

Ahmedabad, India, September 29, 2023

Zydus, a leading discovery-based, global pharmaceutical company announced today that it has received permission from CDSCO, India to initiate the Phase I clinical study of its novel PCSK9 inhibitor. The Phase I prospective randomised, double-blind, placebo-controlled study will study the safety and tolerability of anti-PCSK9 product administered subcutaneously in healthy human volunteers.

Cardiovascular diseases (CVDs) are the leading cause of death globally and the World Health Organisation (WHO) estimates approximately 17.9 million people die each year due to cardiovascular diseases. Dyslipidaemia patients with high LDL-C are at a high risk of atherosclerotic cardiovascular disease (ASCVD) events, such as heart attack and stroke. A PCSK9 inhibitor will regulate the levels of LDL receptors, which are responsible for the uptake and clearance of cholesterol from the blood.

Mr. Pankaj R. Patel, Chairman, Zydus Lifesciences Ltd., said, “Our aim is to treat Dyslipidemia by inhibiting PCSK9 with a novel entity, which will enhance the removal of LDL-C from the bloodstream and provide patients with a potential for once-in-6-month dosing regimen. We at Zydus are committed to develop novel therapies to address unmet medical needs, and are looking forward to the clinical development of our novel anti-PCSK9 product.”

Zydus has a team of 1400 scientists engaged in R&D and five research verticals each focussed in discovery of NCE's, Biologics, Vaccines, Novel Formulations and Novel API Process at Zydus. The novel Anti-PCSK9 product was innovated through Zydus Innovation Forum, a collaborative research initiative between the five different R&D centres of excellence at Zydus.

About Zydus

The Zydus Group with an overarching purpose of empowering people with freedom to live healthier and more fulfilled lives, is an innovative, global lifesciences company that discovers, develops, manufactures, and markets a broad range of healthcare therapies. The group employs nearly 24,000 people worldwide and is driven by its mission to unlock new possibilities in lifesciences through quality healthcare solutions that impact lives. The group aspires to transform lives through path-breaking discoveries. For more details visit www.zyduslife.com



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