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Zydus receives Ph I approval for RA drug from DCGI

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Approval received from the Drug Controller General of India (DCGI) to initiate Phase I clinical trials for its Investigational New Drug (IND) ZYBK2, a New Chemical Entity (NCE) intended to treat Rheumatoid Arthritis (RA).

Zydus Cadila, an innovation-driven, global pharmaceutical company, announced that it has received approval from the Drug Controller General of India (DCGI) to initiate Phase I clinical trials for its Investigational New Drug (IND) ZYBK2, a New Chemical Entity (NCE) intended to treat Rheumatoid Arthritis (RA).

RA is a progressive, systemic autoimmune disease that affects at least 1 in every 100 people worldwide. Autoimmune diseases cause the body's immune system to mistakenly attack one's own healthy normal tissues. In the case of RA, the body's own immune system attacks the lining of joints and can affect other body organs as well. While its most visible hallmarks are pain, stiffness, inflammation and eventual deterioration of joints, patients also are at heightened risk for cardiovascular disease and other inflammatory complications. Nearly 13 million are estimated to suffer from the disease in India

ZYBK2 has been specifically designed to inhibit HLA-DRB1 Shared Epitope (SE) that determines the susceptibility of a person to develop rheumatoid arthritis. The vast majority of RA patients carry this genetic sequence. Several studies have pointed out that the SE binds to cell-surface calreticulin and causes an inflammatory response and bone erosion, a characteristic feature present in millions of patients with RA. ZYBK2 inhibits this SE and calreticulin interaction. The molecule addresses a high unmet medical need and has a large market potential for the treatment of RA.

Speaking on the development, Mr Pankaj Patel, Chairman, Zydus Group said, "There are significant unmet medical needs among patients with Rheumatoid Arthritis (RA). Unlike other therapeutic strategies for managing RA, targeting upstream molecular interactions with ZYBK2 is less likely to cause adverse events. This clinical trial will seek to find answers if inhibiting HLA-DRB1- mediated effects could provide a safe remedy for treating this debilitating disease".

The pioneering work on the SE concept that led to the identification of the discovery of the ZYBK2 molecule was conducted at the University of Michigan, in the laboratories of Dr Joseph Holoshitz, Professor of Internal Medicine, Division of Rheumatology and Dr Henry Mosberg, Tom D Rowe Collegiate Professor of Pharmacy of Medicinal Chemistry, College of

Pharmacy. Zydus acquired the rights for this molecule and conducted all the development work including IND enabling nonclinical studies at Zydus Research Centre, the R&D hub of the Zydus Group