Zydus receives approval for Phase III trial of Desidustat in patients with Sickle Cell Disease, to be conducted in collaboration with ICMR

- *Zydus and ICMR successfully completed the Phase II Proof-of-concept (PoC) trial to evaluate the efficacy and safety of Desidustat oral tablet for treatment of sickle cell disease. The study met its primary endpoint, demonstrating positive outcomes in line with the trial objectives.*
- *The Phase III trial will be a double blind, randomised, placebo controlled, parallel, multicentre, study to evaluate the efficacy and safety of Desidustat oral tablets for treatment of anaemia in sickle cell disease patients.*
- *The US FDA has granted Orphan Drug Designation (ODD) to Zydus' Desidustat for treating two rare blood disorders: Sickle Cell Disease (SCD) and beta-thalassemia.*
- *Desidustat represents a potential first-in-class therapeutic opportunity for the treatment of sickle cell disease which will be studied further in Phase III clinical trial.*

Ahmedabad, India, 23 July 2026

Zydus Lifesciences Limited (Zydus), an innovation-led global lifesciences company, has received permission to conduct a Phase III clinical trial of Desidustat for patients with sickle cell disease. Conducted in collaboration with the Indian Council of Medical Research (ICMR), the 203-day study will evaluate the efficacy and safety of Desidustat oral tablets in treating anemia. The trial will enrol 164 patients diagnosed with the disease.

Sickle Cell Disease is a significant public health concern in India, especially among tribal populations where prevalence is higher. According to National Health Mission estimates, nearly 20 million people live with the condition, and roughly 50,000 children are born with sickle cell anaemia annually. While treatments like hydroxyurea and blood transfusions exist, their limited accessibility, inconsistent effectiveness, and associated risks remain significant challenges.

Dr. Rajiv Bahl, Secretary, Department of Health Research & Director General, ICMR, said, “We have successfully completed the Phase II study of Desidustat in Sickle Cell Disease in collaboration

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with Zydus Lifesciences. This truly marks a significant leap forward for patients who have limited options beyond hydroxyurea. As we move towards Phase III trials, we see a huge potential of this Indian innovation in addressing severe health challenge. This collaboration reflects our commitment to clinical research through strong public–private partnerships."
Speaking on this development, Dr. Sharvil Patel, Managing Director, Zydus Lifesciences Ltd., said, "Sickle cell disease severely impacts the lives of millions of people and represents a high unmet medical need. We are happy to collaborate with ICMR to develop new and effective therapeutic options for patients living with Sickle Cell Disease. Desidustat, discovered and developed at the Zydus Research Centre, reflects our commitment to advancing novel innovations and improve quality of life for patients."

About the Phase II Proof-of-concept (PoC) trial
Zydus and ICMR had earlier completed a Phase II, double blind, randomised, placebo controlled, parallel, multi-centre, proof-of-concept study, co-funded and co-monitored by ICMR-INTENT (Indian National Clinical Trial and Education Network, Clinical Studies and Trial Unit) to evaluate the efficacy and safety of Desidustat oral tablet for treatment of sickle cell disease. The study found that Desidustat was well tolerated up to 150 mg dose, with only minimal adverse events reported. The trial demonstrated a promising trend toward improvement in Hb levels and higher responder rates compared to placebo in patients with SCD. Across the three dose (50 mg, 100 mg and 150 mg), the drug exhibited a favourable safety and tolerability profile. The incidence of treatment-emergent adverse events (TEAEs) was low and comparable across cohorts.

The reported TEAEs included nasopharyngitis, polyarthritis, and headache, all of which were mild in severity. No SAEs were reported during the study period. Additionally, no significant differences were observed between treatment arms in laboratory parameters, vital signs, physical examinations, or 12-lead ECG findings. [CTRI Registration: CTRI/2024/06/068363].

About Desidustat
Desidustat is a hypoxia-inducible factor (HIF) prolyl hydroxylase inhibitor (PHI) that stimulates endogenous erythropoietin (EPO) production through a mechanism similar to the physiological response to hypoxia. Discovered and developed at Zydus' research and development laboratories, Desidustat received approval from the Drug Controller General of India (DCGI) in March 2022 for the treatment of anaemia in patients with chronic kidney disease (CKD), including patients not on dialysis as well as patients on dialysis. In March 2026, Desidustat was also approved by the National

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Medical Products Administration (NMPA) of China for the treatment of renal anaemia in CKD patients.

About Zydus Lifesciences Limited

Zydus Lifesciences Ltd., with an overarching purpose of empowering people with freedom to live healthier and more fulfilled lives, is an innovative, global life sciences company that discovers, develops, manufactures, and markets a broad range of healthcare therapies. The group employs over 30,000 people worldwide, including 1,500 scientists engaged in R & D, and is driven by its mission to unlock new possibilities in life sciences through quality healthcare solutions that impact lives. The group aspires to transform lives through pathbreaking discoveries. Over the last decade, Zydus has introduced several innovative, first-in class products in the market for treating unmet healthcare needs with vaccines, therapeutics, biologicals, and New Chemical Entities. For more details visit www.zyduslife.com

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