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Zydus, ICMR proceed with Ph III trial of Desidustat in patients with Sickle Cell Disease

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Desidustat represents a potential first-in-class therapeutic opportunity for the treatment of sickle cell disease



Ahmedabad-based Zydus Lifesciences 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.

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.