

Zydus' Desidustat gets USFDA orphan drug status for sickle cell disease

Synopsis

Zydus Lifesciences announced a significant development today. The US Food and Drugs Administration has granted Orphan Drug Designation to Desidustat. This novel oral medication is intended for the treatment of Sickle Cell Disease. This designation supports the development of therapies for rare diseases. Zydus believes Desidustat can address an urgent medical need for patients.

New Delhi: [Zydus Lifesciences](#) on Friday said the US health regulator has granted [Orphan Drug Designation](#) to Desidustat, a novel oral product medication for the treatment of Sickle Cell Disease.

The US Food and Drugs Administration's ([USFDA](#)) grants orphan status to support development of medicines for the treatment of rare diseases that affect fewer than 2 lakh people in the US.

"This Orphan Drug Designation from the USFDA underlines the urgent medical need to develop a therapy for sickle cell disease. We believe that Desidustat can address this unmet need," [Zydus Lifesciences](#) MD Sharvil Patel said in a statement.

Therapeutic options for management of Sickle Cell Disease are currently limited.

A Phase II, double blind, randomised, placebo controlled, parallel, multi-centre, proof-of-concept study to evaluate the efficacy and safety of Desidustat oral tablet for treatment of SCD has been completed, and data will be published in a medical journal, the drug firm said.

Orphan drug designation by the USFDA for Desidustat, provides eligibility for certain development incentives, including tax credits for qualified clinical testing, prescription drug user fee exemptions and a potential seven-year marketing exclusivity upon the USFDA approval.

Zydus shares were trading 1.81 per cent down at Rs 888.70 apiece on BSE.

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