



February 6, 2026

**BSE Limited**

P J Towers,  
Dalal Street,  
Mumbai-400001

**Code: 532321**

**National Stock Exchange of India Limited**

Exchange Plaza,  
C/1, Block G,  
Bandra-Kurla Complex, Bandra (East),  
Mumbai-400051

**Code: Zyduslife**

**Re.: Press Release**

Dear Sir / Madam,

Please find enclosed a copy of press release dated February 6, 2026, titled "**Zydus receives USFDA Orphan Drug Designation (ODD) for Desidustat for the treatment of Sickle Cell Disease**".

The contents of the press release give full details.

Please bring the aforesaid news to the notice of the members of the exchange and the investors' at large.

Yours faithfully,  
For, **ZYDUS LIFESCIENCES LIMITED**

**DHAVAL N. SONI**  
**COMPANY SECRETARY AND COMPLIANCE OFFICER**  
**MEMBERSHIP NO. FCS7063**

**Encl.: As above**

**Zydus Lifesciences Limited**

Regd. Office : 'Zydus Corporate Park', Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, S. G. Highway, Ahmedabad-382 481, Gujarat, India. | Phone : +91-79-71800000, +91-79-48040000  
website : [www.zyduslife.com](http://www.zyduslife.com) | CIN : L24230GJ1995PLC025878



## **Zydus receives USFDA Orphan Drug Designation (ODD) for Desidustat for the treatment of Sickle Cell Disease**

*Zydus' NCE Desidustat is a hypoxia inducible factor (HIF)-prolyl hydroxylase inhibitor (PHI) and has the potential to increase haemoglobin and red blood cell counts*

*The ODD by the USFDA for Desidustat provides eligibility for a potential seven-year marketing exclusivity, subject to the USFDA approval*

*Ahmedabad, February 6, 2026*

Zydus, a leading, discovery-based, global pharmaceutical company today announced that the USFDA has granted Orphan Drug Designation (ODD) to Desidustat, a novel oral HIF-PHI, for the treatment of Sickle Cell Disease (SCD). The USFDA's Office of Orphan Drug Products grants orphan status to support development of medicines for the treatment of rare diseases that affect fewer than 200,000 people in the United States.

Speaking on the development, Dr. Sharvil Patel, Managing Director, Zydus Lifesciences Limited, said, "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."

Therapeutic options for management of Sickle Cell Disease are limited. Hydroxyurea, reduced frequency of painful crisis in SCD, but is not universally effective and associated with side-effects like neutropenia and thrombocytopenia. Blood transfusions are expensive, not uniformly accessible, and are accompanied by risks including alloimmunization, hemolysis, and transfusion iron overload. A Phase II, double blind, randomized, 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 medical journal.

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.

### **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 lifesciences company that discovers, develops, manufactures, and markets a broad range of healthcare therapies. The group employs over 29,000 people worldwide, including 1,500 scientists engaged in R & D, and is driven by its mission to unlock new



For further information please contact :  
**The Corporate Communications Department**

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# **PRESS RELEASE**

possibilities in lifesciences 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](http://www.zyduslife.com)

### References

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