



November 6, 2025

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 November 6, 2025, titled **“Zydus receives USFDA Orphan Drug Designation (ODD) for Desidustat for the treatment of beta-thalassemia”**.

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,
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Zydus receives USFDA Orphan Drug Designation (ODD) for Desidustat for the treatment of beta-thalassemia

- Desidustat is a hypoxia inducible factor (HIF)-prolyl hydroxylase inhibitor (PHI) and has the potential to increase haemoglobin and red blood cell counts
- Orphan drug designation by the USFDA for Desidustat, provides eligibility for a potential seven-year marketing exclusivity subject to the USFDA approval

Ahmedabad, 6 November, 2025

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 beta-thalassemia. 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 Desidustat to address beta-thalassemia."

Beta thalassaemia patients have low levels of haemoglobin, which results in a lack of oxygen in many parts of the body, leading to weakness, fatigue and more serious complications. Treatment for people with beta thalassaemia often requires lifelong regimens of chronic blood transfusions for survival and treatment for iron overload due to the transfusions.

Desidustat is a hypoxia inducible factor (HIF)-prolyl hydroxylase inhibitor (PHI) and has the potential to increase haemoglobin and red blood cell counts. Research in beta-thalassaemic mice showed that desidustat treatment led to an increase in haemoglobin and red blood cell (RBC) levels¹. 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

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 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



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The Corporate Communications Department

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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

References

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