



November 14, 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 14, 2025, titled **“Zydus receives final approval from USFDA for Leuprolide Acetate injection, 14 mg/2.8 mL (1 mg/0.2 mL) multiple-dose vial”**.

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 final approval from USFDA for Leuprolide Acetate injection, 14 mg/2.8 mL (1 mg/0.2 mL) multiple-dose vial**

*Ahmedabad, India, 14 November, 2025*

Zydus Lifesciences Limited (including its subsidiaries/ affiliates, hereafter referred to as “Zydus”) has received final approval from the United States Food and Drug Administration (USFDA) for Leuprolide Acetate injection, 14 mg/2.8 mL (1 mg/0.2 mL) multiple-dose vial (USRLD: Lupron Injection<sup>®</sup>, 1 mg/0.2 mL).

Leuprolide Acetate injection is indicated in the palliative treatment of advanced prostatic cancer. Leuprolide Acetate injections will be manufactured at the Company’s oncology injectable manufacturing facility at SEZ1, Ahmedabad (‘ALIDAC’).

Leuprolide Acetate injection had annual sales of USD 69 mn in the United States (IQVIA MAT Sept-2025).

The group now has 427 approvals and has so far filed 487\* ANDAs since the commencement of the filing process in FY 2003-04.

*(\*As on 30-Sept-25)*



**PRESS  
RELEASE**

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

**Zydus Lifesciences Limited**

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