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®, 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
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
CIN : L24230GJ1995PLC025878