

November 27, 2025

BSE Limited Code: 532321

P J Towers, Dalal Street, <u>Mumbai-400001</u>

National Stock Exchange of India Limited Code: Zyduslife

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

Re.: <u>Press Release</u>

Dear Sir / Madam,

Please find enclosed a copy of press release dated November 27, 2025, titled "Zydus receives tentative approval from USFDA for Empagliflozin and Linagliptin Tablets, 10 mg/5 mg and 25 mg/5 mg".

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 receives tentative approval from USFDA for Empagliflozin and Linagliptin Tablets, 10 mg/5 mg and 25 mg/5 mg

Ahmedabad, India, 27 November, 2025

Zydus Lifesciences Limited (including its subsidiaries/ affiliates, hereafter referred to as "Zydus") has received tentative approval from the United States Food and Drug Administration (USFDA) for Empagliflozin and Linagliptin Tablets, 10 mg/5 mg and 25 mg/5 mg (USRLD: Glyxambi<sup>®</sup> Tablets, 10 mg/5 mg and 25 mg/5 mg).

Empagliflozin and Linagliptin Tablets (10 mg/5 mg and 25 mg/5 mg) in a combination are indicated as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes mellitus when treatment with both empagliflozin and linagliptin is appropriate.

Empagliflozin and Linagliptin Tablets will be produced at the group's formulation manufacturing facility at SEZ, Ahmedabad.

Empagliflozin and Linagliptin Tablets had annual sales of USD 215.8 mn in the United States (IQVIA MAT Sept-2025).

The group now has 428 approvals and has so far filed 487\* ANDAs since the commencement of the filing process in FY 2003-04.

(\*As on 30-Sept-25)



For further information please contact: The Corporate Communications Department

## Zydus Lifesciences Limited

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