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® 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)*

PRESS RELEASE

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