Zydus receives tentative approval from USFDA for Dapagliflozin Tablets, 5 mg and 10 mg

Ahmedabad, India, 4 February, 2026

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 Dapagliflozin Tablets, 5 mg and 10 mg (USRLD: Farxiga® Tablets, 5 mg and 10 mg).

Dapagliflozin is a sodium-glucose cotransporter 2 (SGLT2) inhibitor indicated as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes mellitus.

Dapagliflozin tablets will be manufactured at the group's formulation manufacturing facility at SEZ, Ahmedabad.

Dapagliflozin tablets had annual sales of USD 10,486.9 mn in the United States (IQVIA MAT December 2025).

The group now has 430 approvals and has so far filed 505* ANDAs since the commencement of the filing process in FY 2003-04.

*(*As on 31-Dec-2025)*

PRESS RELEASE

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