

Zydus receives tentative approval from the USFDA for Canagliflozin and Metformin Hydrochloride Tablets

Ahmedabad, India, 20 February, 2023

Zydus Lifesciences Limited's (including its subsidiaries/affiliates hereafter referred to as "Zydus") subsidiary Zydus Pharmaceuticals (USA) Inc. has received tentative approval from the United States Food and Drug Administration (USFDA) for Canagliflozin and Metformin Hydrochloride Tablets, 50 mg/500 mg, 50 mg/1,000 mg, 150 mg/500 mg, and 150 mg/1,000 mg_ (USRLD: Invokamet® Tablets).

Canagliflozin and metformin combination product is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus who are not adequately controlled on a regimen containing metformin or canagliflozin or in patients already being treated with both canagliflozin and metformin. The drug will be manufactured at the group's formulation manufacturing facility at Moraiya.

Canagliflozin and Metformin Hydrochloride Tablets had annual sales of USD 49.4 mn in the United States (IQVIA MAT Dec. 2022).

The group now has 344 approvals and has so far filed over 440* ANDAs since the commencement of the filing process in FY 2003-04.

(*as of 31st December 2022)



**PRESS
RELEASE**

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