Zydus receives final approval from the USFDA for Acetazolamide Tablets USP, 125 mg and 250 mg

Ahmedabad, India, 6 April, 2023

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) to manufacture and market Acetazolamide Tablets USP, 125 mg and 250 mg (USRLD: Diamox Tablets, 125 mg and 250 mg).

Acetazolamide is used to treat glaucoma, a condition in which increased pressure in the eye can lead to gradual loss of vision. Acetazolamide decreases the pressure in the eye. Acetazolamide is also used to reduce the severity and duration of symptoms (upset stomach, headache, shortness of breath, dizziness, drowsiness, and fatigue) of altitude (mountain) sickness. The drug is used with other medicines to reduce edema (excess fluid retention) and to help control seizures in certain types of epilepsy. The product will be manufactured at the group's formulation manufacturing facility in Baddi, Himachal Pradesh (India).

Acetazolamide Tablets USP, 125 mg and 250 mg had annual sales of USD 16 mn in the United States (IQVIA MAT Dec. 2022).

The group now has 358 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)

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PRESS RELEASE

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