Zydus receives tentative approval from USFDA for Azilsartan Medoxomil and Chlorthalidone Tablets

Ahmedabad, India, 14 June, 2024

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) to market Azilsartan Medoxomil and Chlorthalidone Tablets, 40 mg/12.5 mg and 40 mg/25 mg (USRLD: Edarbyclor® tablets).

Azilsartan and chlorthalidone is an angiotensin II receptor blocker (ARB) and a thiazide like diuretic combination product indicated for the treatment of high blood pressure (hypertension), to lower blood pressure. The drug will be manufactured at the group's formulation manufacturing facility in Ahmedabad SEZ - II, India.

Azilsartan Medoxomil and Chlorthalidone Tablets had annual sales of USD 77.9 mn in the United States (IQVIA MAT March 24).

The group now has 397 approvals and has so far filed over 460* ANDAs since the commencement of the filing process in FY 2003-04.

*(*as of 31st March 2024)*

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PRESS RELEASE

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