Zydus receives tentative approval from USFDA for Azilsartan Medoxomil Tablets, 40 mg and 80 mg

Ahmedabad, India, 04 July, 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 Tablets, 40 mg and 80 mg (USRLD: Edarbi® tablets).

Azilsartan is an angiotensin II receptor blocker (ARB) indicated for the treatment of hypertension to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. Azilsartan medoxomil tablets may be used either alone or in combination with other antihypertensive agents. The drug will be manufactured at the group's formulation manufacturing facility in Ahmedabad SEZ - II, India.

Azilsartan Medoxomil Tablets had annual sales of USD 89 mn in the United States (IQVIA MAT March 24).

The group now has 398 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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