Zydus receives final approval from the USFDA for Ivabradine Tablets, 5 mg and 7.5 mg

Ahmedabad, India, December 1, 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) for Ivabradine Tablets, 5 mg and 7.5 mg (USRLD: Corlanor® Tablets, 5 mg and 7.5 mg).

Ivabradine is indicated to reduce the risk of hospitalization for worsening heart failure in adult patients with stable, symptomatic chronic heart failure with reduced left ventricular ejection fraction. It is also used in children aged 6 months and older for the treatment of stable symptomatic heart failure due to cardiomyopathy. The drug will be manufactured at the group's formulation manufacturing facility at Ahmedabad SEZ, India.

Zydus was one of the first ANDA applicants to submit a substantially complete ANDA with a paragraph IV certification for Ivabradine Tablets, 5 mg and 7.5 mg and therefore may be eligible for 180 days of shared generic exclusivity for Ivabradine Tablets, 5 mg and 7.5 mg.

Ivabradine Tablets, 5 mg and 7.5 mg had annual sales of USD 136.5 mn in the United States (IQVIA MAT October,2023).

The group now has 382 approvals and has so far filed over 448* ANDAs since the commencement of the filing process in FY 2003-04.

(*as of 30th September 2023)

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PRESS RELEASE

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