Zydus receives final approval from the USFDA for Apixaban Tablets, 2.5 mg and 5 mg

Ahmedabad, India, 28 February, 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 Apixaban Tablets, 2.5 mg and 5 mg (USRLD: Eliquis® Tablets).

Apixaban blocks the activity of certain clotting substances in the blood. It is used to lower the risk of stroke or a blood clot in people with a heart rhythm disorder called atrial fibrillation. It is also used to reduce the risk of forming a blood clot in the legs and lungs of people who have just had hip or knee replacement surgery. It is also used for treatment of blood clots in the veins of legs or lungs, and reduces the risk of them occurring again. The drug will be manufactured at the group's formulation manufacturing facility at Moraiya, Ahmedabad (India).

Apixaban Tablets, 2.5 mg and 5 mg had annual sales of USD 18,876 mn in the United States (IQVIA MAT Dec. 2022).

The group now has 347 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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