Zydus receives final approval from the USFDA for Azithromycin Tablets USP, 500 mg

Ahmedabad, India, 10 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 Azithromycin Tablets USP, 500 mg (USRLD: Zithromax Tablets).

Azithromycin is indicated to treat certain bacterial infections such as bronchitis, pneumonia, sexually transmitted diseases (STD), infections of the ears, lungs, sinuses, skin, throat, and reproductive organs. The drug will be manufactured at the group's formulation manufacturing facility in Moraiya, Ahmedabad (India).

Azithromycin Tablets USP, 500 mg had annual sales of USD 20 mn in the United States (IQVIA MAT Feb. 2023).

The group now has 360 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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