Zydus receives final approval from the USFDA for Darunavir Tablets 600 mg and 800 mg, and tentative approval for 75 mg and 150 mg tablets

Ahmedabad, India, 15 December, 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 Darunavir Tablets 600 mg and 800 mg, and tentative approval for 75 mg and 150 mg tablets (USRLD: Prezista® Tablets, 75 mg, 150 mg, 600 mg, and 800 mg).

Darunavir is a protease inhibitor antiviral medicine that prevents Human Immunodeficiency Virus (HIV-1) from multiplying in the body. It is indicated for the treatment of HIV-1 infection in adult patients. It is also indicated for the treatment of HIV-1 infection in pediatric patients 3 years of age and older. It must be –co-administered with Ritonavir and with other antiretroviral agents. The product will be manufactured at the group's formulation manufacturing facility in SEZ, Ahmedabad (India).

Darunavir Tablets, 75 mg, 150 mg, 600 mg, and 800 mg had annual sales of USD 275 mn in the United States (IQVIA MAT Oct. 2023).

The group now has 383 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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