Zydus receives final approval from the USFDA for Estradiol Transdermal System

Ahmedabad, India, 18 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 Estradiol Transdermal System USP, 0.014 mg/day (weekly) (USRLD: Menostar ® Transdermal System).

Estradiol transdermal system is indicated for prevention of postmenopausal osteoporosis. The drug will be manufactured at the group's formulation manufacturing facility in Moraiya, Ahmedabad (India).

Estradiol Transdermal System USP, 0.014 mg/day (weekly) had annual sales of USD 1.9 mn in the United States (IQVIA MAT Feb. 2023).

The group now has 363 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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