Zydus receives final approval from the USFDA for Norelgestromin and Ethinyl Estradiol Transdermal System, 150 mcg/35 mcg per day

Ahmedabad, India, 15 September, 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 Norelgestromin and Ethinyl Estradiol Transdermal System, 150 mcg/35 mcg per day (USRLD: Ortho Evra Transdermal System, 150 mcg/35 mcg per day).

Norelgestromin and Ethinyl Estradiol Transdermal System contains combination hormone medication and is used to prevent pregnancy. This is the third hormonal transdermal patch to be approved from Zydus' generics portfolio. The transdermal patch will be manufactured at the group's formulation manufacturing facility at Moraiya, Ahmedabad.

Norelgestromin and Ethinyl Estradiol Transdermal System, 150 mcg/35 mcg per day had annual sales of USD 330 mn in the United States (IQVIA MAT July 2023).

The group now has 380 approvals and has so far filed over 444* ANDAs since the commencement of the filing process in FY 2003-04.

(*as of 30th June 2023)

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PRESS RELEASE

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