Zydus receives USFDA approval for Estradiol and Levonorgestrel Transdermal System, eligible for 180-day CGT exclusivity

Ahmedabad, India, 21 October 2026

Zydus Lifesciences Limited (Zydus) today announced that the United States Food and Drug Administration (USFDA) has granted final approval for its Abbreviated New Drug Application (ANDA) for Estradiol and Levonorgestrel Transdermal System, 0.045 mg/0.015 mg per day. (URLD: Climara Pro® Transdermal System 0.045 mg/0.015 mg per day).

The ANDA has been designated by the USFDA as a Competitive Generic Therapy (CGT). The product is eligible for the 180-day exclusivity period available to certain first approved applicants under the CGT pathway, subject to the provisions of the U.S. Federal Food, Drug, and Cosmetic Act. Any exclusivity period, where applicable, would commence upon first commercial marketing of the product.

Estradiol and Levonorgestrel Transdermal System is primarily used treat moderate to severe symptoms of menopause. It is also used in postmenopausal women for prevention of osteoporosis. The product will be manufactured at the group's manufacturing plant at Moraiya, near Ahmedabad, Gujarat.

Estradiol and Levonorgestrel Transdermal System had annual sales of approximately USD 45.7 mn in the United States. (IQVIA MAT Aug-2026). The Group now has 458 approvals and has so far filed 516* ANDA with the USFDA.

*(*As on 30-Sept-2026)*

PRESS RELEASE

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