Zydus receives final approval from the USFDA for Tavaborole Topical Solution, 5%

Ahmedabad, India, 11 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 Tavaborole Topical Solution, 5% (USRLD: Kerydin® Topical Solution).

Tavaborole topical solution is indicated to treat fungal toenail infections (infections that may cause nail discoloration, splitting, or pain). The drug will be manufactured at the group's topical manufacturing facility at Changodar, Ahmedabad (India).

Tavaborole Topical Solution, 5% had annual sales of USD 3.1 mn in the United States (IQVIA MAT Feb. 2023).

The group now has 361 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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