Zydus receives final approval from the USFDA for Minocycline Hydrochloride Extended-Release Tablets USP, 55 mg, 65 mg, and 115 mg

Ahmedabad, India, 19 June, 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 Minocycline Hydrochloride Extended-Release Tablets USP, 55 mg, 65 mg, and 115 mg (USRLD: Solodyn Tablets, 55 mg, 65 mg, and 115 mg).

Minocycline Hydrochloride Extended-Release is used to treat moderate to severe acne in people 12 years and older. Minocycline belongs to a class of drugs known as tetracycline antibiotics. The product will be manufactured at the group's formulation manufacturing facility in Moraiya, Ahmedabad (India).

Minocycline Hydrochloride Extended-Release Tablets USP, 55 mg, 65 mg, and 115 mg had annual sales of USD 0.7 mn in the United States (IQVIA MAT April 2023).

The group now has 372 approvals and has so far filed over 442* ANDAs since the commencement of the filing process in FY 2003-04.

(*as of 31st March 2023)

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PRESS RELEASE

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