Zydus receives final approval from USFDA for Niacin Extended-Release Tablets USP, 500 mg, 750 mg, and 1,000 mg

Ahmedabad, India, 30 April, 2025

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 Niacin Extended-Release Tablets USP, 500 mg, 750 mg, and 1,000 mg (Niaspan® Extended-Release Tablets, 500 mg, 750 mg, and 1,000 mg).

Niacin is indicated to reduce elevated total cholesterol (TC), LDL cholesterol (LDL-C), apolipoprotein B (Apo B), and triglycerides (TG), and to increase HDL cholesterol (HDL-C) in patients with primary hyperlipidaemia and mixed dyslipidaemia. It is also indicated to reduce the risk of recurrent myocardial infarction in patients with a history of myocardial infarction and hyperlipidaemia and to reduce TG in adult patients with severe hypertriglyceridemia. Niacin-Extended-Release tablets will be produced at the Group's manufacturing site at Moraiya, Ahmedabad.

Niacin-Extended-Release tablets had annual sales of USD 5.5 mn in the United States (IQVIA MAT February 2025).

The group now has 425 approvals and has so far filed 492* ANDAs since the commencement of the filing process in FY 2003-04.

*(*As on 31st March, 2025.)*

PRESS RELEASE

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