Zydus receives Final Approval from the USFDA for Isosorbide Mononitrate Extended-Release, Tablets USP, 30 mg, 60 mg, and 120 mg

Ahmedabad, India, February 16, 2024

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 Isosorbide Mononitrate Extended-Release, Tablets USP, 30 mg, 60 mg, and 120 mg (USRLD: Imdur® Extended-Release Tablets).

Isosorbide mononitrate is used to prevent chest pain (angina) in patients with a certain heart condition (coronary artery disease). The product will be manufactured at the group's formulation manufacturing facility at Ahmedabad SEZ, India.

Isosorbide Mononitrate Extended-Release, Tablets USP, 30 mg, 60 mg, and 120 mg had annual sales of USD 47 mn in the United States (IQVIA Dec. Nov. 2023).

The group now has 388 approvals and has so far filed over 460* ANDAs since the commencement of the filing process in FY 2003-04.

(*as of 31st December 2023)

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PRESS RELEASE

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