Zydus receives final approval from the USFDA for Icosapent Ethyl Capsules, 0.5 g and 1 g

Ahmedabad, India, 24 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) for Icosapent Ethyl Capsules, 0.5 g and 1 g (USRLD: Vascepa® Capsules, 0.5 g and 1 g).

Icosapent Ethyl Capsules are indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia.

Zydus's Icosapent Ethyl Capsules are not approved for the indication as an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) levels (≥150 mg/dL) and established cardiovascular disease or diabetes mellitus and 2 or more additional risk factors for cardiovascular disease.

Limitations of Use: The effect of Icosapent Ethyl Capsules on the risk for pancreatitis in patients with severe hypertriglyceridemia has not been determined.

Icosapent Ethyl Capsules, 0.5 g and 1 g had annual sales of USD 1,316 mn in the United States (IQVIA MAT Feb. 2023).

The group now has 365 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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