Zydus receives Final Approval from the USFDA for Lubiprostone Capsules, 8 mcg and 24 mcg

Ahmedabad, India, 24 March, 2023

Zydus Lifesciences Limited (including its subsidiaries/affiliates, hereinafter referred to as "Zydus") has received final approval for Lubiprostone Capsules, 8 mcg and 24 mcg (USRLD: Amitiza® Capsules) from the United States Food and Drug Administration (USFDA).

Lubiprostone capsule is indicated to treat certain types of constipation (chronic idiopathic constipation and irritable bowel syndrome with constipation). The drug will be manufactured at the group's formulation manufacturing facility in Moraiya, Ahmedabad (India).

Lubiprostone Capsules, 8 mcg and 24 mcg had annual sales of USD 196.5 mn in the United States (IQVIA MAT, January 2023).

The group now has 354 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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