Zydus receives final approval from the USFDA for Diclofenac Sodium and Misoprostol Delayed Release Tablets

Ahmedabad, India, 13 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) to manufacture and market Diclofenac Sodium and Misoprostol Delayed Release Tablets USP, 50mg/200 mcg and 75mg/200 mcg (USRLD: Arthrotec® Delayed-Release Tablets).

Diclofenac belongs to nonsteroidal anti-inflammatory drug (NSAID) group of medicines. It works by reducing substances in the body that cause pain and inflammation. Misoprostol reduces stomach acid and replaces protective substances in the stomach that are reduced by NSAIDs. Misoprostol protects the lining of the esophagus, stomach and intestines while taking diclofenac. Diclofenac Sodium and Misoprostol Delayed Release Tablets are used to treat osteoarthritis and rheumatoid arthritis in people at high risk for developing stomach or intestinal ulcers. The drug will be manufactured at the group's formulation manufacturing facility in Moraiya, Ahmedabad (India).

Diclofenac Sodium and Misoprostol Delayed Release Tablets USP, 50mg/200 mcg and 75mg/200 mcg had annual sales of USD 13 mn in the United States (IQVIA MAT Mar. 2023).

The group now has 373 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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