Zydus receives final approval from the USFDA for Isotretinoin Capsules USP, 10 mg, 20 mg 30 mg and 40 mg

Ahmedabad, India, 31 August, 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 Isotretinoin Capsules USP, 10 mg, 20 mg 30 mg and 40 mg (RLD: Accutane® Capsules, 10 mg, 20 mg and 40 mg: RS: Claravis 10 mg, 20 mg, 30 mg and 40 mg).

Isotretinoin Capsules is used to treat severe cystic acne (also known as nodular acne) that has not responded to other treatment (such as benzoyl peroxide or clindamycin applied to the skin or tetracycline or minocycline taken by mouth). The drug will be manufactured at the group's formulation manufacturing facility in Moraiya, Ahmedabad (India).

Section 505-1 of the FD&C Act authorizes FDA to require the submission of a Risk Evaluation and Mitigation Strategy (REMS) for this product. Zydus' proposed REMS has also been approved by FDA. The Isotretinoin iPLEDGE REMS consists of Elements to Assure Safe Use (ETASU) and an implementation system.

Isotretinoin Capsules USP, 10 mg, 20 mg 30 mg and 40 mg had annual sales of USD 165 mn in the United States (IQVIA MAT July 2023).

The group now has 378 approvals and has so far filed over 444* ANDAs since the commencement of the filing process in FY 2003-04.

(*as of 30th June 2023)

###

PRESS RELEASE

For further information please contact :
The Corporate Communications Department

Zydus Lifesciences Limited
(formerly known as Cadila Healthcare Limited)
Regd. Office : 'Zydus Corporate Park', Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, S. G. Highway, Ahmedabad 382 481, Gujarat, India. | Phone : +91-79-71800000, +91-79-48040000 | website : www.zyduslife.com
CIN : L24230GJ1995PLC025878