Zydus receives final approval from the USFDA for Varenicline 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 Varenicline Tablets, 0.5 mg and 1 mg (USRLD: Chantix® Tablets). The product will be launched shortly.

Varenicline tablets is indicated to treat smoking addiction. The drug will be manufactured at the group's formulation manufacturing facility at Ahmedabad SEZ, India.

Commenting on the approval, Dr. Sharvil Patel, Managing Director, Zydus Lifeciences Limited said, "We are pleased with the approval and imminent launch of generic Verinicline which validates the agility of our supply chain as well as the focused efforts by our R&D team which will improve access and availability of the generic product for patients in the US market. This an important product which will support our growth plans in US market in the current fiscal."

Varenicline Tablets, 0.5 mg and 1 mg had annual sales of USD 501 mn in the United States (IQVIA MAT Mar. 2023).

The group now has 374 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

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