Zydus receives final approval from USFDA and 180 days shared exclusivity for Mirabegron Extended-Release Tablets

Ahmedabad, India, 03 October, 2022

Zydus Lifesciences Limited's (formerly known as Cadila Healthcare Limited) U.S. subsidiary Zydus Pharmaceuticals (USA) Inc. has received final approval from the United States Food and Drug Administration (USFDA) to market Mirabegron Extended-Release Tablets USP 25 mg and 50 mg (USRLD: Myrbetriq®).

Zydus was one of the first ANDA applicants to submit a substantially complete ANDA with a paragraph IV certification for Mirabegron Extended-Release Tablets, 25 mg and 50 mg and therefore is eligible for 180 days of shared generic drug exclusivity for Mirabegron Extended-Release Tablets, 25 mg and 50 mg.

Mirabegron is indicated for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency and urinary frequency. The drug will be manufactured at the group's formulation manufacturing facility at Ahmedabad SEZ, India.

Mirabegron Extended-Release Tablets USP 25mg and 50mg had annual sales of USD 2.42 bn in the United States according to IQVIA data (IQVIA MAT August 2022).

The group now has 324 approvals and has so far filed over 428* ANDAs since the commencement of the filing process in FY 2003-04.

*(*as of 30th June 2022)*

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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