Zydus receives tentative approval from the USFDA for Palbociclib Tablets, 75 mg, 100 mg, and 125 mg

Ahmedabad, India, 28 June, 2023

Zydus Lifesciences Limited (including its subsidiaries/affiliates, hereafter referred to as "Zydus") has received tentative approval from the United States Food and Drug Administration (USFDA) for Palbociclib Tablets, 75 mg, 100 mg, and 125 mg (USRLD: Ibrance Tablets, 75 mg, 100 mg, and 125 mg).

Palbociclib is used to treat a certain type of breast cancer. It works by slowing or stopping the growth of cancer cells. The product will be manufactured at the group's formulation manufacturing facility in SEZ, Ahmedabad (India).

Palbociclib Tablets, 75 mg, 100 mg, and 125 mg had annual sales of USD 3.3 bn in the United States (IQVIA MAT April 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

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