

Zydus Cadila receives tentative approval from USFDA for Palbociclib Capsules

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Zydus Cadila has received tentative approval from the USFDA to market Palbociclib Capsules, (US RLD: Ibrance Capsules) in the strengths of 75 mg, 100 mg, and 125 mg.

Palbociclib is an anti-cancer medicine that interferes with the growth and spread of cancer cells in the body. It is used in adults to treat hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer that has spread to other parts of the body (metastatic) in combination with an aromatase inhibitor as the first hormonal based therapy in postmenopausal women or in men, or fulvestrant with disease progression following hormonal therapy. The drug will be manufactured at the group's formulation manufacturing facility at the SEZ, Ahmedabad.

The group now has 302 approvals and has so far filed over 390 ANDAs since the commencement of the filing process in FY 2003-04.

About Zydus Cadila

Zydus Cadila is an innovative, global pharmaceutical company that discovers, develops, manufactures and markets a broad range of healthcare therapies. The group employs nearly 25000 people worldwide and is dedicated to creating healthier communities globally.

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