Bristol Myers cancer blockbuster generic from Zydus gets FDA nod

The drug is a generic version of Bristol Myers Squibb's blockbuster drug indicated for the treatment of chronic myeloid leukaemia that in the last 12-month period till January 2025, had generated $1.8 billion in net sales.

New Delhi: Zydus Lifesciences announced that the United States Food and Drug Administration (USFDA) has given its final approval to manufacture Dasatinib Tablets, a generic medication indicated to treat chronic myeloid leukaemia.

In a stock exchange filing the drug maker informed that," it has received final approval from the US FDA to manufacture Dasatinib Tablets in the dosage strength of 20 mg, 50 mg, 70 mg, 80 mg, 100 mg, and 140 mg.

The drug is a reference version of Bristol Myers Squibb Sprycel tablets and is indicated for the treatment of newly diagnosed adults with Philadelphia chromosome-positive (Ph+) chronic myeloid leukaemia (CML) in chronic phase.

It is also used to treat adults with chronic, accelerated or myeloid or lymphoid blast phase Ph+ CML with resistance or intolerance to prior therapy including imatinib and adults with Philadelphia chromosome-positive acute lymphoblastic leukaemia (Ph+ ALL) with resistance or intolerance to prior therapy.

As per IQVIA estimates in the last 12-month period ending January 2025, in the US drug market dasatinib tablets had reported net sales of $1807.7 million ($1.8 billion)

The Indian drug maker will manufacture these tablets at its Ahmedabad facility.

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