Aurobindo Pharma arm gets USFDA nod for generic blood cancer drug

The approval by the US Food & Drug Administration (USFDA) is for manufacturing and marketing of Dasatinib tablets of strengths 20 mg, 50 mg, 70 mg, 80 mg, 100 mg, and 140 mg, Aurobindo Pharma said in a regulatory filing.

New Delhi: Aurobindo Pharma on Wednesday said its wholly- owned arm Eugia Pharma Specialities Ltd has received final approval from the USFDA to manufacture and market its generic version of Dasatinib tablets indicated in certain types of cancer of bone marrow and blood.

The approval by the US Food & Drug Administration (USFDA) is for manufacturing and marketing of Dasatinib tablets of strengths 20 mg, 50 mg, 70 mg, 80 mg, 100 mg, and 140 mg, Aurobindo Pharma said in a regulatory filing.

These are bioequivalent and therapeutically equivalent to the reference listed drug Sprycel Tablets in the same strengths, of Bristol-Myers Squibb Company (BMS), it added.

The product is expected to be launched in Q1FY26, Aurobindo Pharma said.

The approved product has an estimated market size of USD 1.8 billion for the 12 months ended February 2025, it said citing IQVIA MAT data.

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