Alembic Pharma Gets USFDA Final Nod for 400 mg Generic Cancer Drug Bosutinib

New Delhi: Alembic Pharmaceuticals Ltd on Tuesday said it has received final approval from the US health regulator for an additional strength of its generic leukaemia drug Bosutinib.

The US Food and Drug Administration (USFDA) approved the company's Supplemental Abbreviated New Drug Application (sANDA) for Bosutinib Tablets in the 400 mg strength, Alembic Pharmaceuticals said in a regulatory filing. The approved product is a generic equivalent of Pfizer's brand-name drug Bosulif tablets (400 mg), used to treat a type of blood cancer.

Alembic had previously received USFDA final approval for Bosutinib Tablets in 100 mg and 500 mg strengths, and has since launched both, the filing noted.

According to IQVIA, Bosutinib Tablets, 400 mg, have an estimated market size of $246 million for the 12-month period ended September 2026.

With this, Alembic has received a cumulative total of 248 ANDA approvals from the USFDA, comprising 230 final approvals and 18 tentative ones, the filing added.

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