Alembic Pharma receives USFDA approval for lung cancer drug

Alembic Pharmaceuticals has received final approval from the US FDA for its Binimetinib tablets, intended for lung cancer treatment. These tablets are therapeutically equivalent to Array BioPharma Inc.'s Mektovi. As a first ANDA applicant, Alembic will benefit from 180 days of exclusivity for both the 15 mg and 45 mg dosages.



New Delhi: Alembic Pharmaceuticals has received final approval from the US Food and Drug Administration for its Abbreviated New Drug Application for Binimetinib tablets for treatment of lung cancer.

The approved Abbreviated New Drug Application (ANDA) is therapeutically equivalent to the reference listed drug product, Mektovi Tablets (15 mg), of Array BioPharma Inc, the company said in a regulatory filing on Saturday.

Alembic is eligible for 180 days of generic drug exclusivity for Binimetinib Tablets, 15 mg and 45 mg, as it was one of the first ANDA applicants for the 15 mg strength and the sole first applicant for the 45 mg strength to submit a substantially complete ANDA with a paragraph IV certification, the filing said.

Binimetinib is a kinase inhibitor indicated, in combination with encorafenib, for the treatment of patients with unresectable or metastatic melanoma and non-small cell lung cancer with a BRAF V600E mutation, it said.

According to IQVIA, Binimetinib tablets have an estimated market size of USD 282 million for the 12 months ending September 2026, the filing noted.

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

News Source:

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