PRESS RELEASE

14th November, 2026 Vadodara, India

Alembic Pharmaceuticals Limited receives USFDA Final Approval for Binimetinib Tablets, 15 mg and 45 mg.

Alembic Pharmaceuticals Limited (Alembic) today announced that it has received final approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) for Binimetinib Tablets, 15 mg and 45 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Mektovi Tablets, 15 mg, of Array BioPharma Inc. (Array). Binimetinib is a kinase inhibitor indicated, in combination with encorafenib, for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation. It is also indicated, in combination with encorafenib, for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) with a BRAF V600E mutation. Refer label for a detailed indication.

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

Binimetinib tablets have an estimated market size of US$ 282 million for twelve months ending September 2026 according to IQVIA.

Alembic has a cumulative total of 248 ANDA approvals (230 final approvals and 18 tentative approvals) from the USFDA.

About Alembic Pharmaceuticals Limited

Alembic Pharmaceuticals Limited, a vertically integrated research and development pharmaceutical company, has been at the forefront of healthcare since 1907. Headquartered in India, Alembic is a publicly listed company that manufactures and markets generic pharmaceutical products all over the world. Alembic's state of the art research and manufacturing facilities are approved by regulatory authorities of many developed countries including the USFDA. Alembic is one of the leaders in branded generics in India. Alembic's brands, marketed through a field force of over 5,800 are well recognized by doctors and patients.

Information about the Company can be found at www.alembicpharmaceuticals.com; (Reuters:ALEM.NS) (Bloomberg:ALPM) (NSE:APLLTD) (BSE:533573)

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