

**PRESS RELEASE**

19<sup>th</sup> June, 2026 Vadodara, India

**Alembic Pharmaceuticals Limited announces USFDA Tentative Approval for Binimetinib Tablets, 45 mg.**

Alembic Pharmaceuticals Limited (Alembic) today announced that it has received tentative approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Binimetinib Tablets, 45 mg. Alembic had previously received tentative approval for Binimetinib Tablets, 15mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Mektovi Tablets, 15 mg of 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.

Based on FDA's Paragraph IV Certifications List, Alembic is the sole first applicant to have filed its ANDA for Binimetinib Tablets, 45mg, containing a Paragraph IV certification under the provisions of the Hatch-Waxman Act. Upon final approval of this ANDA by the USFDA, Alembic may be eligible for 180 days of generic marketing exclusivity in the US.

Binimetinib Tablets have an estimated market size of US\$ 259 million for twelve months ending March 2026 according to IQVIA.

Alembic has a cumulative total of 242 ANDA approvals (222 final approvals and 20 tentative approvals) from 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 5500 are well recognized by doctors and patients.

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

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