PRESS RELEASE

12th January, 2026 Vadodara, India

Alembic Pharmaceuticals Limited announces USFDA Tentative Approval for Bosutinib Tablets, 400 mg

Alembic Pharmaceuticals Limited (Alembic) today announced that it has received tentative approval from the US Food & Drug Administration (USFDA) for its supplemental Abbreviated New Drug Application (sANDA) Bosutinib Tablets, 400 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Bosulif Tablets, 400 mg, of PF Prism C.V. (PF Prism C.V.). Bosutinib is a kinase inhibitor indicated for the treatment of i) adult patients with chronic phase Ph+ chronic myelogenous leukemia (CML), newly-diagnosed or resistant or intolerant to prior therapy, and ii) adult patients with accelerated, or blast phase Ph+ CML with resistance or intolerance to prior therapy.

Alembic had previously received final approval for its ANDA Bosutinib Tablets, 100 mg and 500mg. Refer label for a detailed indication.

Bosutinib Tablets, 400 mg, have an estimated market size of US$ 251 million for twelve months ending September 2025 according to IQVIA.

Alembic has a cumulative total of 232 ANDA approvals (212 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; (Reuters:ALEM.NS) (Bloomberg:ALPM) (NSE:APLLTD) (BSE:533573)

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