PRESS RELEASE

24th November, 2026 Vadodara, India

Alembic Pharmaceuticals Limited receives USFDA Final Approval for Bosutinib Tablets, 400 mg.

Alembic Pharmaceuticals Limited (Alembic) today announced that it has received final approval from the U.S. Food and Drug Administration (USFDA) for its Supplemental Abbreviated New Drug Application (sANDA) for Bosutinib Tablets, 400 mg.

The approved ANDA is therapeutically equivalent to the Reference Listed Drug (RLD), Bosulif® Tablets, 400 mg, of PF Prism C.V. Bosutinib is a kinase inhibitor indicated for the treatment of:

(i) adult patients with chronic phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML), either newly diagnosed or resistant/intolerant to prior therapy; and

(ii) adult patients with accelerated phase or blast phase Ph+ CML who are resistant or intolerant to prior therapy.

Alembic had previously received USFDA final approval for its ANDA for Bosutinib Tablets, 100 mg and 500 mg, and has since launched both strengths. Refer to the label for a detailed indication.

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

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

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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