**PRESS RELEASE**

30th May, 2025 Vadodara, India

**Alembic Pharmaceuticals Limited announces USFDA Final Approval for Bosutinib Tablets, 100 mg and 500 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) Bosutinib Tablets, 100 mg and 500 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Bosulif Tablets, 100 mg and 500 mg, of PF Prism C.V. (PF Prism).

Bosutinib tablets are indicated for the treatment of adult patients with chronic, accelerated, or blast phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML) with resistance or intolerance to prior therapy. Refer label for a detailed indication.

Bosutinib Tablets, 100 mg and 500 mg have an estimated market size of US$ 291 million for twelve months ending March 2025 according to IQVIA.

Alembic has a cumulative total of 223 ANDA approvals (200 final approvals and 23 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 5200 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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