PRESS RELEASE

1st July, 2024, Vadodara, India

Alembic Pharmaceuticals announces USFDA Tentative Approval for Bosutinib Tablets, 100 mg and 500 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) for Alembic Pharmaceuticals Limited (Alembic) today announced that it has received tentative approval for 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 a certain type of leukemia called Philadelphia chromosome-positive chronic myelogenous leukemia. Refer label for a detailed indication.

Bosutinib Tablets, 100 mg and 500 mg have an estimated market size of US$ 275 million for twelve months ending March 2024 according to IQVIA.

Alembic has a cumulative total of 206 ANDA approvals (179 final approvals and 27 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 marketing team of over 5000 are well recognized by doctors and patients.

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

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