Date: 10th June, 2022

To,
The Manager,
Department of Corporate Services,
BSE Limited
P. J. Tower, Dalal Street,
Fort, Mumbai – 400 001

Dear Sir/Madam,

Sub: Alembic Pharmaceuticals Limited receives USFDA Tentative Approval for Dasatinib Tablets, 20 mg, 50 mg, 70 mg, 80 mg, 100 mg, and 140 mg.

With reference to the captioned subject, this is to inform the exchange that the Company has received US Food & Drug Administration (USFDA) Tentative Approval for Dasatinib Tablets, 20 mg, 50 mg, 70 mg, 80 mg, 100 mg, and 140 mg.

Please find enclosed herewith our press release.

We request you to kindly take the same on record.

Thanking you,

Yours faithfully,
For Alembic Pharmaceuticals Limited

Charandeep Singh Saluja
Company Secretary

Encl.: A/a.

PRESS RELEASE

10th June, 2022, Vadodara, India

Alembic Pharmaceuticals receives USFDA Tentative Approval for Dasatinib Tablets, 20 mg, 50 mg, 70 mg, 80 mg, 100 mg, and 140 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 Dasatinib Tablets, 20 mg, 50 mg, 70 mg, 80 mg, 100 mg, and 140 mg. The tentatively approved ANDA is therapeutically equivalent to the reference listed drug product (RLD) Sprycel Tablets, 20 mg, 50 mg, 70 mg, 80 mg, 100 mg, and 140 mg, of Bristol Myers Squibb Company (BMS). Dasatinib Tablet is indicated for the treatment of adult patients with i) newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase. ii) chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML with resistance or intolerance to prior therapy including imatinib. iii) Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) with resistance or intolerance to prior therapy.

Dasatinib Tablets have an estimated market size of US$ 1465 million for twelve months ending Dec 2021 according to IQVIA.

Alembic has a cumulative total of 168 ANDA approvals (144 final approvals and 24 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)

For more information contact:

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