Date: 7th April, 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 Dabigatran Etexilate Capsules, 75 mg, 110 mg, and 150 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 Dabigatran Etexilate Capsules, 75 mg, 110 mg, and 150 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

7th April, 2022, Vadodara, India

Alembic Pharmaceuticals announces USFDA Tentative Approval for Dabigatran Etexilate Capsules, 75 mg, 110 mg, and 150 mg.

Alembic Pharmaceuticals Limited today announced that it has received tentative approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) for Dabigatran Etexilate Capsules, 75 mg, 110 mg, and 150 mg. The tentatively approved ANDA is therapeutically equivalent to the reference listed drug product (RLD) Pradaxa® Capsules, 75 mg, 110 mg, and 150 mg, of Boehringer Ingelheim Pharmaceuticals, Inc. (Boehringer). Dabigatran Etexilate Capsules, are indicated for reduction of risk of stroke and systemic embolism in non-valvular atrial fibrillation in adult patients, treatment of deep venous thrombosis and pulmonary embolism in adult patients, reduction in the risk of recurrence of deep venous thrombosis and pulmonary embolism in adult patients, prophylaxis of deep vein thrombosis and pulmonary embolism in adult patients following hip replacement surgery. It may not be indicated for certain other uses due to unexpired exclusivities for the RLD for such uses.

Dabigatran Etexilate Capsules, 75 mg, 110 mg, and 150 mg have an estimated market size of US$ 465 million for twelve months ending December 2021 according to IQVIA.

Alembic has received a cumulative total of 162 ANDA approvals (139 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 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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