Date: 18th June, 2024

To,
The Manager,
Department of Corporate Services,
BSE Limited
P. J. Towers, Dalal Street,
Fort, Mumbai – 400 001
BSE Scrip Code: 533573

To,
The Manager,
Listing Department,
National Stock Exchange of India Ltd.
'Exchange Plaza', Bandra Kurla
Complex, Bandra (E), Mumbai – 400 051
NSE Symbol: APLLTD

Dear Sir/Madam,

Sub: Alembic Pharmaceuticals receives USFDA Final Approval for Dabigatran Etexilate Capsules, 75 mg and 150 mg and Tentative approval for Dabigatran Etexilate Capsules, 110 mg.

With reference to the captioned subject, this is to inform the exchange that the Company has received US Food & Drug Administration (USFDA) Final Approval for Dabigatran Etexilate Capsules, 75 mg and 150 mg and Tentative approval for Dabigatran Etexilate Capsules, 110 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

Manisha Saraf
Digitally signed by Manisha Saraf
Date: 2024.06.18 13:48:06 +05'30'

Manisha Saraf
Company Secretary

Encl.: A/a.

PRESS RELEASE

18th June, 2024, Vadodara, India

Alembic Pharmaceuticals announces USFDA Final Approval for Dabigatran Etexilate Capsules, 75 mg and 150 mg and Tentative approval for Dabigatran Etexilate Capsules, 110 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) for Dabigatran Etexilate Capsules, 75 mg and 150 mg and Tentative approval for Dabigatran Etexilate Capsules, 110 mg. The 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 and reduction in the risk of recurrence of deep venous thrombosis and pulmonary embolism in adult patients. Refer label for a detailed indication.

Dabigatran Etexilate Capsules 75 mg and 150 mg have an estimated market size of US$ 179 million for twelve months ending Mar 2024 according to IQVIA. Dabigatran Etexilate Capsules 110 mg have an estimated market size of US$ 5 million for twelve months ending Mar 2024 according to IQVIA.

Alembic has a cumulative total of 205 ANDA approvals (178 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)

For more information contact:
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