Date: 15th May, 2025

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 Rivaroxaban Tablets USP, 2.5 mg, 10 mg, 15 mg, and 20 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 Rivaroxaban Tablets USP, 2.5 mg, 10 mg, 15 mg, and 20 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: 2025.05.15 13:25:40 +05'30'

Manisha Saraf
Company Secretary
Encl.: A/a.

PRESS RELEASE

15th May, 2025 Vadodara, India

Alembic Pharmaceuticals Limited announces USFDA Final Approval for Rivaroxaban Tablets USP, 2.5 mg, 10 mg, 15 mg, and 20 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) Rivaroxaban Tablets USP, 2.5 mg, 10 mg, 15 mg, and 20 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Xarelto Tablets, 2.5 mg, 10 mg, 15 mg, and 20 mg, of Janssen Pharmaceuticals, Inc. (Janssen).

Rivaroxaban tablets, 2.5mg, are indicated: i) to reduce the risk of major cardiovascular events in patients with coronary artery disease (CAD), ii) to reduce the risk of major thrombotic vascular events in patients with peripheral artery disease (PAD), including patients after recent lower extremity revascularization due to symptomatic PAD. Refer label for a detailed indication.

According to IQVIA, Rivaroxaban Tablets USP, 2.5 mg, has an estimated market size of US$ 445 million for twelve months ending March 2025 and Alembic will be launching this strength in Q1FY26.

The estimated market size for remaining strengths of Rivaroxaban Tablets USP, 10 mg, 15 mg, and 20 mg, is US$ 8,052 million for twelve months ending March 2025 according to IQVIA.

Alembic has a cumulative total of 222 ANDA approvals (198 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 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)

For more information, contact:
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