

Date: 22<sup>nd</sup> June, 2020

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

Dear Sir/Madam,

**Sub: Alembic Pharmaceuticals receives USFDA Tentative Approval for Rivaroxaban Tablets, 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) Tentative Approval for Rivaroxaban Tablets, 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**



**Charandeep Singh Saluja**  
**Company Secretary**

Encl.: A/a.

**ALEMBIC PHARMACEUTICALS LIMITED**

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**PRESS RELEASE**

22<sup>nd</sup> June, 2020, Vadodara, India

**Alembic Pharmaceuticals receives USFDA Tentative Approval for Rivaroxaban Tablets, 10 mg, 15 mg, and 20 mg.**

Alembic Pharmaceuticals Limited today announced that the Company has received tentative approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Rivaroxaban Tablets, 10 mg, 15 mg, and 20 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Xarelto Tablets, 10 mg, 15 mg, and 20 mg, of Janssen Pharmaceuticals, Inc. (Janssen). Rivaroxaban Tablets are indicated for i) the reduction of the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation. ii) the treatment of deep vein thrombosis (DVT). iii) the treatment of pulmonary embolism (PE). iv) the reduction in the risk of recurrence of deep vein thrombosis and of pulmonary embolism following initial 6 months treatment for DVT and/or PE. and v) the prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip replacement surgery.

Rivaroxaban Tablets, 10 mg, 15 mg, and 20 mg have an estimated market size of US\$ 6.1 billion for twelve months ending March 2020 according to IQVIA.

Alembic now has a total of 124 ANDA approvals (110 final approvals and 14 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 <http://www.alembicpharmaceuticals.com/>; (Reuters: ALEM.NS) (Bloomberg: ALPM) (NSE: APLLTD) (BSE: 533573)

For more information contact:

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