Date: 3rd January, 2019

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 Approval for Pramipexole Dihydrochloride Extended-Release Tablets, 0.375 mg, 0.75 mg, 1.5 mg, 2.25 mg, 3 mg, 3.75 mg, and 4.5 mg.

With reference to the captioned subject, this is to inform the exchange that the Company has received US Food & Drug Administration (USFDA) Approval Pramipexole Dihydrochloride Extended-Release Tablets, 0.375 mg, 0.75 mg, 1.5 mg, 2.25 mg, 3 mg, 3.75 mg, and 4.5 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

3rd Jan, 2019, Vadodara, India

Alembic Pharmaceuticals receives USFDA Approval for Pramipexole Dihydrochloride Extended-Release Tablets, 0.375 mg, 0.75 mg, 1.5 mg, 2.25 mg, 3 mg, 3.75 mg, and 4.5 mg.

Alembic Pharmaceuticals Limited today announced that the Company has received approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Pramipexole Dihydrochloride Extended-Release Tablets, 0.375 mg, 0.75 mg, 1.5 mg, 2.25 mg, 3 mg, 3.75 mg, and 4.5 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD) Mirapex ER Tablets, 0.375 mg, 0.75 mg, 1.5 mg, 2.25 mg, 3 mg, 3.75 mg, and 4.5 mg, of Boehringer Ingelheim Pharmaceuticals, Inc. (Boehringer). Pramipexole dihydrochloride extended-release tablets are indicated for the treatment of Parkinson's disease.

Pramipexole Dihydrochloride Extended-Release Tablets, 0.375 mg, 0.75 mg, 1.5 mg, 2.25 mg, 3 mg, 3.75 mg, and 4.5 mg have an estimated market size of US$ 38.6 million for twelve months ending December 2017 according to IQVIA.

Alembic has a cumulative total of 84 ANDA approvals (71 final approvals and 13 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 the company 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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