Alembic
Touching Lives over 100 years

Date: 20th July, 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 Empagliflozin and Metformin Hydrochloride Tablets, 5 mg/500 mg, 5 mg/1000 mg, 12.5 mg/500 mg, and 12.5 mg/1000 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 Empagliflozin and Metformin Hydrochloride Tablets, 5 mg/500 mg, 5 mg/1000 mg, 12.5 mg/500 mg, and 12.5 mg/1000 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

20th July, 2020, Vadodara, India

Alembic Pharmaceuticals receives USFDA Tentative Approval for Empagliflozin and Metformin Hydrochloride Tablets, 5 mg/500 mg, 5 mg/1000 mg, 12.5 mg/500 mg, and 12.5 mg/1000 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) Empagliflozin and Metformin Hydrochloride Tablets, 5 mg/500 mg, 5 mg/1000 mg, 12.5 mg/500 mg, and 12.5 mg/1000 mg. The tentatively approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Synjardy Tablets, 5 mg/500 mg, 5 mg/1000 mg, 12.5 mg/500 mg, and 12.5 mg/1000 mg, of Boehringer Ingelheim Pharmaceuticals, Inc. (Boehringer Ingelheim). Empagliflozin and Metformin Hydrochloride Tablets are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both empagliflozin and metformin hydrochloride is appropriate.

Empagliflozin and Metformin Hydrochloride Tablets, 5 mg/500 mg, 5 mg/1000 mg, 12.5 mg/500 mg, and 12.5 mg/1000 mg have an estimated market size of US$ 172 million for twelve months ending March 2020 according to IQVIA. Alembic is currently in litigation with Boehringer Ingelheim in District Court of Delaware and launch of the product will depend on litigation outcome.

Alembic now has a total of 126 ANDA approvals (111 final approvals and 15 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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