

Date: 15th January, 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 Tablets, 10 mg and 25 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 Tablets, 10 mg and 25 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



Authorised Signatory

Encl.: A/a.

ALEMBIC PHARMACEUTICALS LIMITED

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PRESS RELEASE

15th January, 2020, Vadodara, India

Alembic Pharmaceuticals receives USFDA Tentative Approval for Empagliflozin Tablets, 10 mg and 25 mg.

Alembic Pharmaceuticals Limited (Alembic) today announced that the Company has received tentative approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Empagliflozin Tablets, 10 mg and 25 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD) Jardiance Tablets, 10 mg and 25 mg, of Boehringer Ingelheim Pharmaceuticals, Inc. (Boehringer). Empagliflozin Tablets are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Empagliflozin Tablets have an estimated market size of US\$ 3.4 billion for twelve months ending September 2019 according to IQVIA.

Alembic has a cumulative total of 112 ANDA approvals (99 final approvals and 13 tentative approvals) from USFDA.

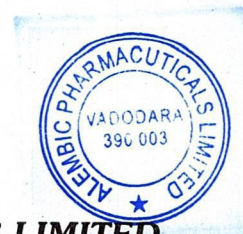
About Alembic Pharmaceuticals Limited

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 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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