

Date: 27<sup>th</sup> August, 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 Linagliptin Tablets, 10 mg/5 mg and 25 mg/5 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 Linagliptin Tablets, 10 mg/5 mg and 25 mg/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.

**ALEMBIC PHARMACEUTICALS LIMITED**

## PRESS RELEASE

27<sup>th</sup> August, 2020, Vadodara, India

### **Alembic Pharmaceuticals receives USFDA Tentative Approval for Empagliflozin and Linagliptin Tablets, 10 mg/5 mg and 25 mg/5 mg.**

Alembic Pharmaceuticals Limited (Alembic) today announced that it has received tentative approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Empagliflozin and Linagliptin Tablets, 10 mg/5 mg and 25 mg/5 mg. The tentatively approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Glyxambi Tablets, 10 mg/5 mg and 25 mg/5 mg, of Boehringer Ingelheim Pharmaceuticals, Inc. (Boehringer). Empagliflozin and Linagliptin Tablet is 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 Linagliptin is appropriate. Empagliflozin is indicated to reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease. However, the effectiveness of Empagliflozin and Linagliptin Tablets on reducing the risk of cardiovascular death in adults with type 2 diabetes mellitus and cardiovascular disease has not been established.

Empagliflozin and Linagliptin Tablets, 10 mg/5 mg and 25 mg/5 mg have an estimated market size of US\$ 244 million for twelve months ending June 2020 according to IQVIA. Alembic is currently in litigation with Boehringer in District Court of Delaware and launch of the product will depend on litigation outcome.

Alembic now has a total of 130 ANDA approvals (113 final approvals and 17 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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## **ALEMBIC PHARMACEUTICALS LIMITED**

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