Date: 7th January, 2022

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 Tentative Approval for Vortioxetine Tablets 5 mg, 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 Vortioxetine Tablets 5 mg, 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.

**PRESS RELEASE**

7th January, 2022, Vadodara, India

## Alembic Pharmaceuticals receives USFDA Tentative Approval for Vortioxetine Tablets 5 mg, 10 mg, 15 mg, and 20 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) for Vortioxetine Tablets 5 mg, 10 mg, 15 mg, and 20 mg. The tentatively approved ANDA is therapeutically equivalent to the reference listed drug product (RLD) Trintellix Tablets 5 mg, 10 mg, 15 mg, and 20 mg, of Takeda Pharmaceuticals, USA, Inc. (Takeda). Vortioxetine Tablets are indicated for the treatment of major depressive disorder (MDD).

Vortioxetine Tablets 5 mg, 10 mg, 15 mg, and 20 mg have an estimated market size of US$ 1249 million for twelve months ending September 2021 according to IQVIA. Alembic is currently in litigation with H.Lundbeck in Court of Appeals for the Federal Circuit and launch of the product will depend on litigation outcome. Please refer to detailed prescribing information on our label. It is possible that our ANDA may not be indicated for certain uses due to unexpired exclusivities for the RLD for such uses.

Alembic has received year to date (YTD) 18 approvals (13 final approvals and 5 tentative approvals) and a cumulative total of 157 ANDA approvals (136 final approvals and 21 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 VADODARA 390 003