

Date: 11th December, 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 Final Approval for Asenapine Sublingual Tablets, 5 mg and 10 mg.

With reference to the captioned subject, this is to inform the exchange that the Company has received US Food & Drug Administration (USFDA) Final Approval for Asenapine Sublingual Tablets, 5 mg and 10 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

11th December, 2020, Vadodara, India

Alembic Pharmaceuticals announces USFDA Final Approval for Asenapine Sublingual Tablets, 5 mg and 10 mg.

Alembic Pharmaceuticals Limited (Alembic) today announced it has received approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Asenapine Sublingual Tablets, 5 mg and 10 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Saphris Sublingual Tablets, 5 mg and 10 mg, of Allergan Sales, LLC (Allergan). Asenapine is an atypical antipsychotic indicated for bipolar I disorder as adjunctive treatment to lithium or valproate in adults. **Alembic had previously received tentative approval for this ANDA. Alembic was one of the first ANDA applicants to submit a substantially complete ANDA with a paragraph IV certification and hence is eligible for 180 days of shared exclusivity.**

Asenapine Sublingual Tablets, 5 mg and 10 mg have an estimated market size of US\$ 217 million for twelve months ending September 2020 according to IQVIA.

Alembic has a cumulative total of 137 ANDA approvals (119 final approvals and 18 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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