

## PRESS RELEASE

11<sup>th</sup> 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)

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