

PRESS RELEASE

12th February, 2021, Vadodara, India

Alembic Pharmaceuticals announces its wholly-owned subsidiary, Alembic Global Holding SA receives USFDA Final Approval for Treprostinil Injection, 20 mg/20 mL (1 mg/mL), 50 mg/20 mL (2.5 mg/mL), 100 mg/20 mL (5 mg/mL), and 200 mg/20 mL (10 mg/mL), Multiple-Dose Vials.

Alembic Pharmaceuticals Limited today announced that its wholly-owned subsidiary Alembic Global Holding SA has received final approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Treprostinil Injection, 20 mg/20 mL (1 mg/mL), 50 mg/20 mL (2.5 mg/mL), 100 mg/20 mL (5 mg/mL), and 200 mg/20 mL (10 mg/mL), Multiple-Dose Vials. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Remodulin Injection, 20 mg/20 mL (1mg/mL), 50 mg/20 mL (2.5 mg/mL), 100 mg/20 mL (5 mg/mL), and 200 mg/20 mL (10mg/mL), of United Therapeutics Corp. (United). Treprostinil Injection is indicated for the treatment of pulmonary arterial hypertension (PAH;WHO Group 1) to diminish symptoms associated with exercise. In patients with PAH requiring transition from epoprostenol, Treprostinil Injection is indicated to diminish the rate of clinical deterioration. Alembic had previously received tentative approval for this ANDA.

Treprostinil Injection has an estimated market size of US\$ 17 million for twelve months ending December 2020 according to IQVIA.

Alembic now has a total of 138 ANDA approvals (121 final approvals and 17 tentative approvals) from USFDA, including this first injectable ANDA approval.

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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