

**PRESS RELEASE**

7<sup>th</sup> September, 2020, Vadodara, India

**Alembic Pharmaceuticals receives USFDA Tentative 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 Holdings SA has received tentative 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 tentatively 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.

Treprostinil Injection has an estimated market size of US\$ 466.1 million for twelve months ending Dec. 2019 according to United Therapeutics Corporation's 2019 financial results.

Alembic now has a total of 131 ANDA approvals (113 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: APL LTD) (BSE: 533573)

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