

PRESS RELEASE

24th January, 2020, Vadodara, India

Alembic Pharmaceuticals announces USFDA Final Approval for Bosentan Tablets, 62.5 mg and 125 mg.

Alembic Pharmaceuticals Limited (Alembic) today announced it has received final approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Bosentan Tablets, 62.5 mg and 125 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD) Tracleer Tablets, 62.5 mg and 125 mg, of Actelion Pharmaceuticals Limited. Bosentan Tablets indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1).

Bosentan Tablets, 62.5 mg and 125 mg have an estimated market size of US\$ 68 million for twelve months ending September 2019 according to IQVIA.

Alembic has a cumulative total of 114 ANDA approvals (102 final approvals and 12 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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