Alembic
Touching Lives over 100 years

PRESS RELEASE

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Alembic Pharmaceuticals receives USFDA Approval for Tadalafil Tablets USP, 2.5 mg, 5 mg, 10 mg and 20 mg.

Alembic Pharmaceuticals Limited today announced that the Company has received approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Tadalafil Tablets USP, 2.5 mg, 5 mg, 10 mg and 20 mg. The approved ANDA is therapeutically equivalent to the reference listed drug (RLD), Cialis Tablets, 2.5 mg, 5 mg, 10 mg, and 20 mg, of Eli Lilly and Company (Lilly). All strengths of Tadalafil Tablets are indicated for the treatment of erectile dysfunction (ED). Tadalafil Tablet 5mg strength is additionally indicated for treatment of signs and symptoms of benign prostatic hyperplasia (BPH). Alembic had previously received tentative approval for this ANDA.

Tadalafil Tablets have an estimated market size of US$ 1.8 billion for twelve months ending December 2018 according to IQVIA.

Alembic now has a total of 89 ANDA approvals (77 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 the company can be found at http://www.alembicpharmaceuticals.com/; (Reuters: ALEM.NS) (Bloomberg: ALPM) (NSE: APLLTD) (BSE: 533573)

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