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PRESS RELEASE

5th August, 2020, Vadodara, India

Alembic Pharmaceuticals receives USFDA Final Approval for Vardenafil Hydrochloride Tablets, 2.5 mg (base), 5 mg (base), 10 mg (base), and 20 mg (base).

Alembic Pharmaceuticals Limited today announced that the Company has received final approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Vardenafil Hydrochloride Tablets, 2.5 mg (base), 5 mg (base), 10 mg (base), and 20 mg (base). The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Levitra Tablets, 2.5 mg, 5 mg, 10 mg, and 20 mg, of Bayer Healthcare Pharmaceuticals Inc. (Bayer). Vardenafil Hydrochloride Tablets are indicated for the treatment of erectile dysfunction.

Vardenafil Hydrochloride Tablets have an estimated market size of US$ 35 million for twelve months ending June 2020 according to IQVIA.

Alembic now has a total of 127 ANDA approvals (112 final approvals and 15 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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