Alembic
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PRESS RELEASE

17th September, 2018, Vadodara, India

Alembic Pharmaceuticals receives USFDA Approval for Desvenlafaxine Extended-Release Tablets, 25 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) Desvenlafaxine Extended-Release Tablets, 25 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), PRISTIQ® Extended-Release Tablets, 25 mg of Wyeth Pharma Inc. Desvenlafaxine Extended-Release Tablets, 25 mg are indicated for the treatment of major depressive disorder (MDD).

Desvenlafaxine Extended-Release Tablets, 25 mg has an estimated market size of US$ 13.3 million for twelve months ending December 2017 according to IQVIA

Alembic now has a total of 77 ANDA approvals (64 final approvals and 13 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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