Alembic
Touching Lives over 100 years

PRESS RELEASE

15th April, 2019, Vadodara, India

Alembic Pharmaceuticals receives USFDA Approval for Bimatoprost Ophthalmic Solution, 0.03%.

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) Bimatoprost Ophthalmic Solution, 0.03%. The approved ANDA is therapeutically equivalent to the reference listed drug (RLD), Lumigan, 0.03% of Allergan Sales, LLC (Allergan). Bimatoprost Ophthalmic Solution, 0.03% is indicated for the reduction of elevated intraocular pressure in patients with open angle glaucoma or ocular hypertension.

Bimatoprost Ophthalmic Solution, 0.03% have an estimated market size of US$ 10 million for twelve months ending December 2018 according to IQVIA.

Alembic now has a total of 90 ANDA approvals (78 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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