PRESS RELEASE

20th April, 2020, Vadodara, India

Alembic Pharmaceuticals announces USFDA Tentative Approval for Alcaftadine Ophthalmic Solution, 0.25%.

Alembic Pharmaceuticals Limited (Alembic) today announced it has received tentative approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Alcaftadine Ophthalmic Solution, 0.25%. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD) Lastacaft Ophthalmic Solution, 0.25%, of Allergan, Inc. (Allergan). Alcaftadine Ophthalmic Solution is an H1 histamine receptor antagonist indicated for the prevention of itching associated with allergic conjunctivitis.

Alcaftadine Ophthalmic Solution, 0.25% has an estimated market size of US$ 7 million for twelve months ending December 2019 according to IQVIA.

Alembic has a cumulative total of 120 ANDA approvals (107 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 Alembic can be found at http://www.alembicpharmaceuticals.com/; (Reuters: ALEM.NS) (Bloomberg: ALPM) (NSE: APLLTD) (BSE: 533573)

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