PRESS RELEASE

30th March, 2023, Vadodara, India

Alembic Pharmaceuticals announces USFDA Final Approval for Brimonidine Tartrate Ophthalmic Solution, 0.15%.

Alembic Pharmaceuticals Limited (Alembic) today announced that it has received final approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Brimonidine Tartrate Ophthalmic Solution, 0.15%. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Alphagan P Ophthalmic Solution, 0.15%, of AbbVie Inc. Brimonidine Tartrate Ophthalmic Solution is an alpha adrenergic receptor agonist indicated for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.

Brimonidine Tartrate Ophthalmic Solution, 0.15% has an estimated market size of US$ 97 million for twelve months ending Dec 2022 according to IQVIA.

Alembic has a cumulative total of 180 ANDA approvals (156 final approvals and 24 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 https://www.alembicpharmaceuticals.com/; (Reuters: ALEM.NS) (Bloomberg: ALPM) (NSE: APLLTD) (BSE: 533573)

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