PRESS RELEASE

11th December, 2025 Vadodara, India

Alembic Pharmaceuticals Limited announces USFDA Final Approval for Loteprednol Etabonate and Tobramycin Ophthalmic Suspension, 0.5%/0.3%

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) Loteprednol Etabonate and Tobramycin Ophthalmic Suspension, 0.5%/0.3% (5 mL and 10 mL). The approved ANDA is therapeutically equivalent to the reference listed drug (RLD), Zylet Ophthalmic Suspension, 0.5%/0.3%, of Bausch & Lomb Incorporated. Loteprednol etabonate and tobramycin ophthalmic suspension, 0.5%/0.3%, is indicated for steroid-responsive inflammatory ocular conditions for which a corticosteroid is indicated and where superficial bacterial ocular infection or a risk of bacterial ocular infection exists. Refer label for a detailed indication.

Alembic was granted a Competitive Generic Therapy (CGT) designation for this application. With this approval, Alembic is eligible for 180 days of CGT exclusivity upon commercialization.

Alembic has a cumulative total of 231 ANDA approvals (211 final approvals and 20 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 field force of over 5500 are well recognized by doctors and patients.

Information about the Company can be found at www.alembicpharmaceuticals.com; (Reuters:ALEM.NS) (Bloomberg:ALPM) (NSE:APLLTD) (BSE:533573)

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