PRESS RELEASE

27th January, 2026 Vadodara, India

Alembic Pharmaceuticals Limited announces USFDA Final Approval for Difluprednate Ophthalmic Emulsion, 0.05%.

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) Difluprednate Ophthalmic Emulsion, 0.05%. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Durezol Ophthalmic Emulsion, 0.05%, of Sandoz Inc. (Sandoz). Difluprednate ophthalmic emulsion is indicated for the treatment of inflammation and pain associated with ocular surgery and also indicated for the treatment of endogenous anterior uveitis. Refer label for a detailed indication.

Alembic has a cumulative total of 233 ANDA approvals (213 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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