PRESS RELEASE

24th February, 2026 Vadodara, India

Alembic Pharmaceuticals Limited announces USFDA Final Approval for Efinaconazole Topical Solution, 10%.

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) Efinaconazole Topical Solution, 10%. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Jublia Topical Solution, 10%, of Bausch Health Americas, Inc. (Bausch). Efinaconazole Topical Solution is indicated for the topical treatment of onychomycosis of the toenail(s) due to Trichophyton rubrum and Trichophyton mentagrophytes. Refer label for a detailed indication.

Alembic was one of the first ANDA applicants to submit a substantially complete ANDA with a paragraph IV certification. Efinaconazole Topical Solution, 10%, has an estimated market size of US$ 500 million for twelve months ending December 2025 according to IQVIA.

Alembic has a cumulative total of 234 ANDA approvals (215 final approvals and 19 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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