

PRESS RELEASE

22nd October, 2020, Vadodara, India

Alembic Pharmaceuticals announces its joint venture Aleor Dermaceuticals receives USFDA Final Approval for Tavaborole Topical Solution, 5%.

Alembic Pharmaceuticals Limited (Alembic) today announced that its joint venture Aleor Dermaceuticals Limited (Aleor) has received final approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) for Tavaborole Topical Solution, 5%. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Topical Solution, 5%, of Anacor Pharmaceuticals, Inc. (Anacor). Tavaborole Topical solution, 5% is an oxaborole antifungal indicated for the treatment of onychomycosis of the toenails due to *Trichophyton rubrum* or *Trichophyton mentagrophytes*. **Aleor had previously received tentative approval for this ANDA.** Aleor was one of the first ANDA applicants to submit a substantially complete ANDA with a paragraph IV certification and hence is eligible for 180 days of shared exclusivity.

Tavaborole Topical Solution, 5% has an estimated market size of US\$ 82 million for twelve months ending June 2020 according to IQVIA.

Alembic has a cumulative total of 133 ANDA approvals (116 final approvals and 17 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 the company can be found at <http://www.alembicpharmaceuticals.com/>; (Reuters: ALEM.NS) (Bloomberg: ALPM) (NSE: APL LTD) (BSE: 533573).

About Aleor Dermaceuticals Limited

Aleor is a 60:40 joint venture between Alembic and Orbicular Pharmaceutical Technologies Pvt Ltd (Orbicular) formed in Apr'16 focusing on commercialising dermatology products globally.

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