

## PRESS RELEASE

6<sup>th</sup> September, 2021, Vadodara, India

### **Alembic Pharmaceuticals announces its joint venture Aleor Dermaceuticals receives USFDA Final Approval for Metronidazole Gel USP, 1%.**

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 Metronidazole Gel USP, 1%. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Metrogel Gel, 1%, of Galderma Laboratories LP (Galderma). Metronidazole Gel USP, 1% is indicated for the topical treatment of inflammatory lesions of rosacea. Aleor had previously received tentative approval for this ANDA.

Metronidazole Gel USP, 1% has an estimated market size of US\$ 29 million for twelve months ending June 2021 according to IQVIA.

Alembic has a cumulative total of 149 ANDA approvals (132 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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