

PRESS RELEASE

26th November, 2018, Vadodara, India

Alembic Pharmaceuticals announces its joint venture Aleor Dermaceuticals receives USFDA Approval for Lidocaine Ointment USP, 5%.

Alembic Pharmaceuticals Limited (Alembic) today announced that its joint venture Aleor Dermaceuticals Limited (Aleor) has received approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Lidocaine Ointment USP, 5%. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Xylocaine Ointment, 5%, of AstraZeneca Pharmaceuticals LP (AstraZeneca). Lidocaine Ointment USP, 5% are indicated for production of anesthesia of accessible mucous membranes of the oropharynx. It is also useful as an anesthetic lubricant for intubation and for the temporary relief of pain associated with minor burns, including sunburn, abrasions of the skin and insect bites.

Lidocaine Ointment USP, 5%, has an estimated market size of US\$ 97 million for twelve months ending December 2017 according to IQVIA.

Alembic has a cumulative total of 79 ANDA approvals (66 final approvals and 13 tentative approvals) from USFDA, including this first ANDA approval for Aleor.

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: APLD) (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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