

PRESS RELEASE

25th November, 2020, Vadodara, India

Alembic Pharmaceuticals announces its joint venture Aleor Dermaceuticals receives USFDA Tentative Approval for Testosterone Gel, 1.62% (20.25 mg/1.25 gm actuation).

Alembic Pharmaceuticals Limited (Alembic) today announced that its joint venture Aleor Dermaceuticals Limited (Aleor) has received tentative approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) for Testosterone Gel, 1.62% (20.25 mg/1.25 gm actuation). The tentatively approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), AndroGel 1.62%, of AbbVie Inc. (AbbVie). Testosterone Gel, 1.62% (20.25 mg/1.25 gm actuation) is indicated for replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone: Primary hypogonadism (congenital or acquired) and Hypogonadotropic hypogonadism (congenital or acquired).

Testosterone Gel, 1.62% (20.25 mg/1.25 gm actuation) has an estimated market size of US\$ 107 million for twelve months ending September 2020 according to IQVIA.

Alembic has a cumulative total of 136 ANDA approvals (117 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 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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