

**PRESS RELEASE**

9<sup>th</sup> November, 2020, Vadodara, India

**Alembic Pharmaceuticals receives USFDA Tentative Approval for Palbociclib Capsules, 75 mg, 100 mg, and 125 mg.**

Alembic Pharmaceuticals Limited today announced that the Company has received tentative approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Palbociclib Capsules, 75 mg, 100 mg, and 125 mg. The tentatively approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Ibrance Capsules, 75 mg, 100 mg, and 125 mg, of Pfizer Inc. (Pfizer). Palbociclib Capsule is a kinase inhibitor indicated for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with an aromatase inhibitor as initial endocrine based therapy in postmenopausal women; or in combination with fulvestrant in women with disease progression following endocrine therapy.

Palbociclib Capsules, 75 mg, 100 mg, and 125 mg have an estimated market size of US\$ 624 million for twelve months ending Jun 2020 according to IQVIA. Alembic is currently in litigation with Pfizer in District Court of Delaware and launch of the product will depend on litigation outcome.

Alembic now has a total of 135 ANDA approvals (117 final approvals and 18 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 Alembic can be found at <http://www.alembicpharmaceuticals.com/>; (Reuters: ALEM.NS) (Bloomberg: ALPM) (NSE: APL LTD) (BSE: 533573)

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