

PRESS RELEASE

9th July, 2021, Vadodara, India

Alembic Pharmaceuticals announces USFDA Final Approval for Erlotinib Tablets, 25 mg, 100 mg, and 150 mg.

Alembic Pharmaceuticals Limited (Alembic) today announced that it has received final approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) for Erlotinib Tablets, 25 mg, 100 mg, and 150 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Tarceva Tablets, 25 mg, 100 mg, and 150 mg, of OSI Pharmaceuticals, LLC. Erlotinib Tablets are indicated for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test receiving first-line, maintenance, or second or greater line treatment after progression following at least one prior chemotherapy regimen. Erlotinib Tablet in combination with gemcitabine is indicated for the first-line treatment of patients with locally advanced, unresectable or metastatic pancreatic cancer.

Erlotinib Tablets, 25 mg, 100 mg, and 150 mg, have an estimated market size of US\$ 37 million for twelve months ending March 2021 according to IQVIA.

Alembic has a cumulative total of 148 ANDA approvals (130 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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