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Alembic Pharma gets US FDA approval for cancer drug

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Erlotinib tablets are available in 25 mg, 100 mg, and 150 mg strengths



Alembic Pharmaceuticals has received final approval from the US Food & Drug Administration (US FDA) 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 tumours 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 $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 US FDA.