Generic Name:
Osimertinib
Trade Name:
Tagrisso
Company:
AstraZeneca
Notes:

FDA granted accelerated approval to osimertinib once-daily tablets for the treatment of patients with metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non?small cell lung cancer (NSCLC), as detected by an FDA-approved test, who have progressed on or after EGFR tyrosine kinase inhibitor (TKI) therapy.

Approval was based on two multicenter, single-arm, open-label clinical trials in patients with metastatic EGFR T790M mutation-positive NSCLC who had progressed on prior systemic therapy, including an EGFR TKI (Study 1 and 2). All patients were required to have EGFR T790M mutation-positive NSCLC as detected by the cobas EGFR mutation test and received osimertinib 80 mg once daily. The major efficacy outcome measure was objective response rate (ORR). Duration of response (DOR) was an additional outcome measure. Safety data were evaluated in 411 patients who received osimertinib at a dose of 80 mg daily. The most common adverse events were diarrhea, rash, dry skin, nail toxicity, eye disorders, nausea, decreased appetite, and constipation.

The most common nonfatal serious adverse events (SAEs) included pneumonia and pulmonary embolus. The most frequent adverse reaction leading to dose reductions or interruptions were prolonged QTc and neutropenia. Adverse events leading to discontinuation included ILD/pneumonitis and cerebrovascular accident.

Fatal adverse events occurred in 3.2% of patients, including four cases of pneumonitis attributed to osimertinib.

The recommended dose and schedule for osimertinib is 80 mg given orally once daily.

Medication Monitor Categories:
New Drug Approvals