

Supplemental Approvals

Generic Name (Trade Name—Company)

May 7, 2018

Osimertinib

(Tagrisso—AstraZeneca)

Osimertinib approved as first-line treatment for EGFR-mutated non-small cell lung cancer

Uses/Notes

AstraZeneca announced FDA approval of [osimertinib](#) for first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumours have epidermal growth factor receptor (EGFR) mutations (exon 19 deletions, or exon 21 L858R mutations), as detected by an FDA-approved test.

Approval was based on results from the Phase III FLAURA trial, which compared osimertinib to current first-line EGFR tyrosine kinase inhibitors, erlotinib or gefitinib, in previously untreated patients with locally advanced or metastatic EGFR-mutated (EGFRm) NSCLC. The agent met the primary endpoint of progression-free survival.

The agent was previously approved for second-line treatment of patients with metastatic EGFRm NSCLC whose disease has progressed on or after a first-line EGFR-TKI therapy and who have developed the secondary T790M mutation, as detected by an FDA-approved test.

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