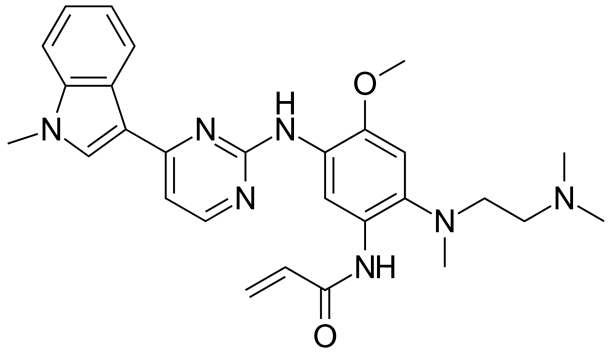
Brand Name: Tagrisso
Generic: osimertinib
Type: small molecule
Year Accepted/Phase: 2024

Mechanism:

Osimertinib irreversibly binds to mutated forms of EGFR, including T790M, inhibiting the signaling pathways that promote cancer cell growth and survival.

Chemical Structure:



Indication:

Tagrisso is indicated for the first-line treatment of patients with metastatic NSCLC whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations and for the treatment of patients with metastatic NSCLC whose tumors have EGFR T790M mutations.

Clinical trials:

FLAURA Trial (Phase III)
Pubmed: https://pubmed.ncbi.nlm.nih.gov/29151359/
Purpose: Compare the efficacy and safety of osimertinib to standard EGFR-TKIs (erlotinib or gefitinib) as first-line treatment in patients with EGFR mutation-positive advanced NSCLC.
Dates: Conducted from 2014 to 2017.
Results: The FLAURA trial demonstrated that osimertinib significantly prolonged progression-free survival (PFS) compared to standard EGFR-TKIs in patients with EGFR mutation-positive advanced NSCLC, with a manageable safety profile.
Impact: These results supported the approval of Tagrisso as a first-line treatment for patients with EGFR mutation-positive advanced NSCLC.

AURA3 Trial (Phase III)
Pubmed: https://pubmed.ncbi.nlm.nih.gov/27959700/
Purpose: Evaluate the efficacy and safety of osimertinib compared to platinum-based doublet chemotherapy in patients with EGFR T790M mutation-positive advanced NSCLC who had progressed on prior EGFR-TKI therapy.
Dates: Conducted from 2014 to 2016.
Results: The AURA3 trial demonstrated that osimertinib significantly improved PFS compared to chemotherapy in patients with EGFR T790M mutation-positive advanced NSCLC who had progressed on prior EGFR-TKI therapy, with a favorable safety profile.
Impact: These results supported the approval of Tagrisso for the treatment of patients with EGFR T790M mutation-positive advanced NSCLC who have progressed on or after EGFR-TKI therapy.

FLAURA2 Trial (Phase III)
Pubmed: https://pubmed.ncbi.nlm.nih.gov/27959700/
Purpose: Evaluate the efficacy and safety of osimertinib as adjuvant therapy in patients with completely resected EGFR mutation-positive NSCLC.
Dates: Ongoing, started in 2019.
Status: The FLAURA2 trial is ongoing to assess the potential benefits of osimertinib in the adjuvant setting for patients with completely resected EGFR mutation-positive NSCLC.