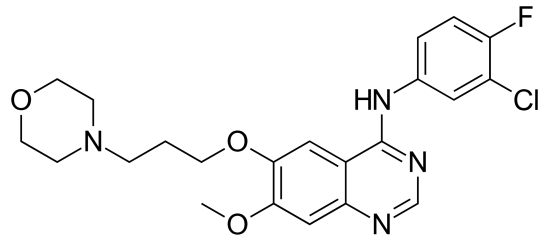
Brand Name: Iressa
Generic: gefitinib
Type: small molecule
Year Accepted/Phase: 2003

Mechanism:

Gefitinib inhibits the tyrosine kinase activity of the EGFR, which is often overexpressed or mutated in NSCLC, leading to uncontrolled cell growth and survival.

Chemical Structure:



Indication:

Iressa is indicated for the first-line treatment of patients with metastatic NSCLC whose tumors have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations.

Clinical trials:

IPASS Trial (Phase III)
Pubmed: https://pubmed.ncbi.nlm.nih.gov/28885881/
Purpose: Compare the efficacy and safety of gefitinib versus carboplatin/paclitaxel as first-line treatment in patients with advanced NSCLC who were never-smokers or former light smokers.
Dates: Conducted from 2004 to 2007.
Results: The IPASS trial showed that gefitinib was superior to carboplatin/paclitaxel in terms of progression-free survival (PFS) in never-smokers or former light smokers with advanced NSCLC, particularly those with EGFR mutations.
Impact: These results led to the approval of Iressa as a first-line treatment for NSCLC in patients with EGFR mutations.

WJTOG3405 Trial (Phase II)
Pubmed: https://pubmed.ncbi.nlm.nih.gov/20022809/
Purpose: Evaluate the efficacy and safety of gefitinib in Japanese patients with NSCLC who had failed prior platinum-based chemotherapy.
Dates: Conducted in the early 2000s.
Results: The WJTOG3405 trial demonstrated significant tumor response rates and disease control rates with gefitinib in Japanese patients with NSCLC who had failed prior chemotherapy, particularly those with EGFR mutations.
Impact: These results supported the use of Iressa in Japanese patients with NSCLC who had failed prior chemotherapy.

IRESSA Survival Evaluation in Lung Cancer (ISEL) Trial (Phase III)
Pubmed: https://pubmed.ncbi.nlm.nih.gov/16257339/
Purpose: Evaluate the efficacy and safety of gefitinib compared to placebo in patients with advanced NSCLC who had failed at least two prior chemotherapy regimens.
Dates: Conducted in the mid-2000s.
Results: The ISEL trial did not show a significant improvement in overall survival with gefitinib compared to placebo in patients with advanced NSCLC who had failed prior chemotherapy.
Impact: These results led to a change in the labeling for Iressa, restricting its use to patients with NSCLC who have EGFR mutations.