

# AstraZeneca receives extended approval for lung cancer blockbuster in India

AstraZeneca has received CDSCO approval for an additional indication of its blockbuster drug osimertinib. The approval covers patients with locally advanced, unresectable (Stage III) Non-Small Cell Lung Cancer (NSCLC) whose disease has not progressed during or after platinum-based chemoradiation therapy.



Bengaluru: AstraZeneca's India arm has received approval from the Central Drugs Standard Control Organisation (CDSCO) for the import, sale, and distribution of osimertinib tablets for an expanded indication.

The oral drug is now approved as monotherapy for patients with locally advanced, unresectable (Stage III) Non-Small Cell Lung Cancer (NSCLC) whose disease has not progressed during or following platinum-based chemoradiation therapy.

The extended approval is based on results from the Phase III LAURA trial, which demonstrated a significant delay in disease progression across multiple sub-groups, including central nervous system (CNS) progression-free survival.

Osimertinib, marketed under the brand name Tagrisso by the UK-based pharma major, selectively inhibits mutated forms of the EGFR protein, effectively blocking signals that promote cancer cell growth and survival, particularly in NSCLC.

According to AstraZeneca's 2024 financial results, osimertinib is the company's best-selling oncology asset, generating global sales of \$6.5 billion (approximately ₹55,250 crore).

“The Phase III LAURA trial demonstrated osimertinib's potential to significantly extend progression-free survival. It sets a new standard of care for individuals with Stage III, locally advanced unresectable EGFR-mutated NSCLC, offering the first targeted treatment in this setting,” said Dr. Sandeep Arora, Director, Medical Affairs, AstraZeneca Pharma India Limited.

Currently, the drug is approved as monotherapy in over 100 countries. The company is also exploring its use across multiple stages of EGFR-mutated NSCLC.

**News Source:**

[https://pharma.economictimes.indiatimes.com/news/drug-approvals-and-launches/astrazenecas-osimertinib-gains-expanded-approval-for-lung-cancer-treatment-in-india/121487931?utm\\_source=whatsapp\\_web&utm\\_medium=social&utm\\_campaign=socialsharebuttons](https://pharma.economictimes.indiatimes.com/news/drug-approvals-and-launches/astrazenecas-osimertinib-gains-expanded-approval-for-lung-cancer-treatment-in-india/121487931?utm_source=whatsapp_web&utm_medium=social&utm_campaign=socialsharebuttons)