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AstraZeneca India receives CDSCO approval for additional indication for Osimertinib

29 May 2025 | News

New approval addresses a significant unmet need in post-chemoradiation NSCLC patients



AstraZeneca India Pharma Ltd. (AZPIL), a global, science-led, patient focused pharmaceutical company, has received approval from the Central Drugs Standard Control Organisation (CDSCO), for the import, sale, and distribution of Osimertinib 40mg and 80mg tablets for an additional indication.

The approval marks a critical step forward with Osimertinib as monotherapy in the treatment of patients with locally advanced, unresectable (Stage III) Non-Small Cell Lung Cancer (NSCLC) harbouring EGFR exon 19 deletions or exon 21 (L858R) substitution mutations and whose disease has not progressed during or following platinum-based chemoradiation therapy.

This new indication represents a first-in-class treatment option in a setting for EGFR-mutated NSCLC post-chemoradiation. The approval follows compelling evidence from the Phase III LAURA trial, and demonstrated significant clinical benefits in delaying disease progression across different sub-groups, including CNS progression free survival with Osimertinib.

Lung cancer continues to pose a major public health challenge in India, ranking as the fourth leading cause of cancer-related deaths, according to GLOBOCAN 2022. NSCLC accounts for approximately 85% of all lung cancers, with EGFR mutations seen in 33–37% of Indian patients with adenocarcinoma—a major subtype of NSCLC. The introduction of Osimertinib in EGFR+ locally advanced NSCLC offers renewed hope for a substantial patient population with limited options.