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AstraZeneca receives CDSCO nod for new indication for treatment of limited-stage small cell lung cancer

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Becomes only approved â??immuno-oncologyâ?? therapy across limited and extensive stage SCLC in India



AstraZeneca Pharma India, a science-led biopharmaceutical company, has received a Central Drugs Standard Control Organisation (CDSCO) approval to import for sale and distribution of Durvalumab 120 mg/2.4 mL and 500 mg/10 mL solution for infusion.

This approval pertains to a new indication - the treatment of patients with limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following platinum-based chemoradiation therapy (CRT).

Durvalumab is now the only approved consolidation therapy for LS-SCLC patients post-CRT, marking a pivotal shift in treatment strategy for this aggressive lung cancer subtype, which constitutes approximately 15% of all lung cancer cases. While most SCLC cases are diagnosed at advanced stages, nearly 25% of Indian patients present with LS-SCLC, highlighting an urgent need for enhanced early-stage interventions.

GLOBOCAN 2022 data identifies lung cancer as the fourth leading cause of cancer-related mortality in India. Historically, treatment for LS-SCLC was confined to platinum-based CRT. The ADRIATIC clinical trial, which included Indian participants, demonstrated that Durvalumab post-CRT significantly improves progression-free and overall survival compared to a placebo, reinforcing its role in optimising early-stage treatment outcomes.

Dr Hardik Vasnawala, Director Medical Affairs, AstraZeneca Pharma India Limited said, "This new Durvalumab indication approval is a pivotal step forward in improving outcomes for patients with LS-SCLC in the country and helps address the unmet patient needs".