

AstraZeneca India receives CDSCO approval for lung cancer drug Durvalumab for specified additional indication

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AstraZeneca Pharma India has received permission to import for sale and distribution of Durvalumab 120 mg/2.4 mL and 500 mg/10 mL solution for infusion from the Central Drugs Standard Control Organisation (CDSCO), Directorate General of Health Services, Government of India for additional indication, subject to the receipt of related statutory approvals, if any.

Durvalumab in combination with chemotherapy as neoadjuvant treatment, followed by Durvalumab as monotherapy after surgery, is indicated for the treatment of patients with resectable (tumours 4 cm and/or node positive) non-small cell lung cancer (NSCLC) and no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements.

According to GLOBOCAN 2022 data, lung cancer remains the fourth most common cause of cancer-related mortality in India. Around 15% of patients with NSCLC in India have resectable disease representing a significant patient population.

Dr Anil Kukreja, Vice-President, Medical Affairs and Regulatory, AstraZeneca Pharma India, said, "We are following the science to understand cancer and all its complexities to discover, develop and deliver life-changing treatments to transform survival. This approval reflects our focus on constantly exploring new novel treatment combinations, to deliver to those patients where we can make huge impact. The AEGEAN trial shows this novel *Imfinzi*-based regimen meaningfully improved outcomes in resectable lung cancer, further validating the importance of moving lung cancer diagnosis and treatment to earlier stages of disease where patients have the highest potential for cure".

Dr Sanjeev Panchal, Managing Director & Country President, AstraZeneca Pharma India, "Patients are at the centre of everything we do. We are constantly pushing the boundaries of science, to provide precision medicines to the patients who

can benefit most from them. We are focused on bringing innovative medicines faster to India for patients and remain committed to bringing novel treatment approaches like AEGEAN to early lung cancer settings”.