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AstraZeneca receives CDSCO approval for Durvalumab in combination with FLOT Chemotherapy

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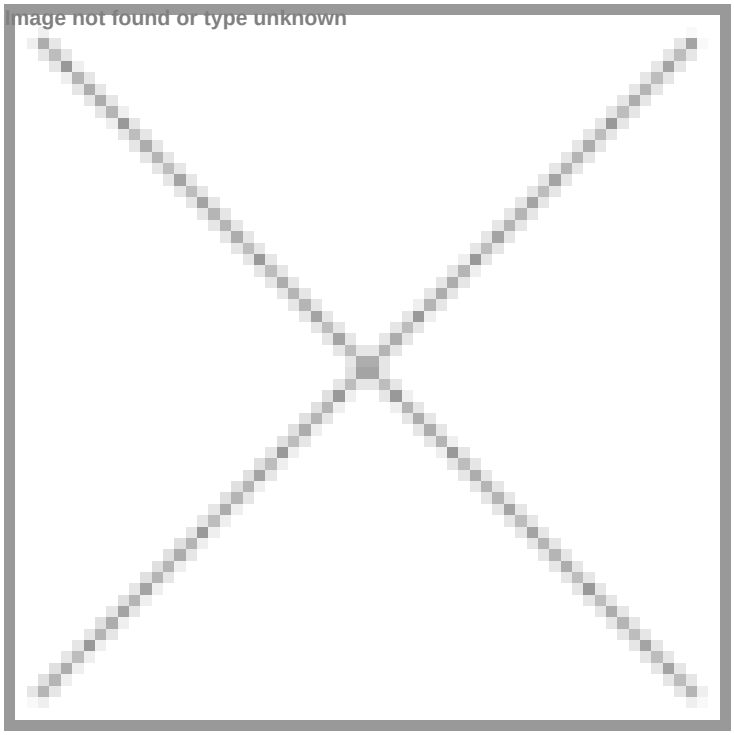
For the treatment of gastric cancer remains a major health challenge in India



AstraZeneca Pharma India has announced the Central Drugs Standard Control Organisation (CDSCO) approval for Durvalumab in combination with FLOT chemotherapy (fluorouracil, leucovorin, oxaliplatin and docetaxel) as the first and only perioperative immunotherapy approach for adult patients with resectable gastric or gastroesophageal junction adenocarcinoma (GC/GEJC), showing survival benefit.

Based on the results from the phase III MATTERHORN study, the approval allows the addition of Durvalumab to FLOT chemotherapy for patients in the neoadjuvant and adjuvant settings, followed by single agent durvalumab, reflecting a comprehensive perioperative approach aimed at reducing recurrence risk and improving long-term outcomes.

Gastric cancer remains a major health challenge in India, ranking as the seventh most common cancer with over 64,000 new cases diagnosed annually, and the sixth leading cause of cancer-related deaths. Around half of gastric and gastroesophageal junction cancers are diagnosed at a resectable stage, where surgery combined with peri-operative chemotherapy is the standard of care. Despite treatment with FLOT, five-year survival remains below 50%, and recurrence rates are high within two years of surgery, underscoring the need for more effective peri-operative options.

Durvalumab is a human immunoglobulin G1 kappa (IgG?) monoclonal antibody that selectively blocks the interaction of

programmed death-ligand 1 (PD-L1) with programmed death-1 (PD-1) and CD80, enhancing anti-tumour immune responses through T-cell activation. By optimising immunotherapy use in the peri-operative setting, AstraZeneca aims to redefine standards of care in gastrointestinal cancers and improve long-term outcomes for patients in India.