AstraZeneca's gets CDSCO nod for Imfinzi combo in gastric cancer

The regulatory approved has granted based on the results from a phase III study, where the drug combo demonstrated a 28 per cent reduction in the risk of event-free survival events or deaths.

Bengaluru: UK pharma major, AstraZeneca has secured the Central Drugs Standard Control Organisation (CDSCO) approval for its PD-L1 blockbuster durvalumab (Imfinzi) in combination with FLOT chemotherapy for treating gastric cancer.

The regulatory approved has granted based on the results from the phase III MATTERHORN study, where the drug combo demonstrated a 28 per cent reduction in the risk of event-free survival events or death compared to 21 per cent reduction reported with placebo.

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.

Durvalumab, marketed under the brand name Imfinzi, is PD-L1 inhibitor, initially approved by regulators to treat a type of lung cancer called non-small cell lung cancer (NSCLC) and currently is the second-best-selling oncology asset of the company following Tagrisso.

The novel biologic is the second-highest-selling cancer drug at AstraZeneca, which clocked over $1.6 billion in the third quarter of 2025.

Imfinzi's FLOT combination approval in India follows FDA clearance in November 2025, making it the first and only drug for the targeted indication.

"This approval brings immunotherapy earlier in the treatment pathway, significantly improving survival and advances our purpose to address unmet needs," said Praveen Rao Akkinepally, Country President and MD, AstraZeneca Pharma India Limited.

News Source:

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