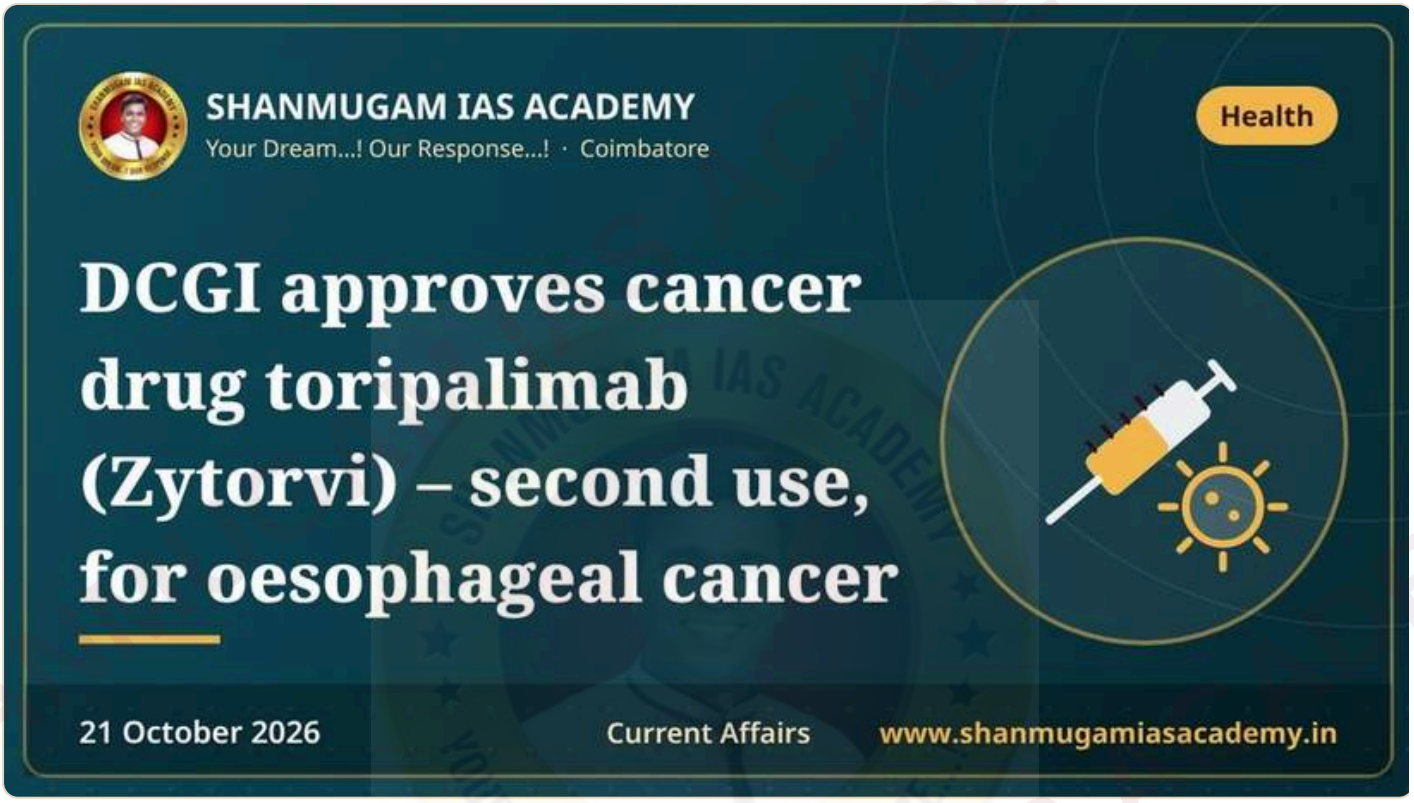
DCGI approves cancer drug toripalimab (Zytorvi) – second use, for oesophageal cancer

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News

The Drugs Controller General of India (DCGI) has approved Dr. Reddy's Laboratories' 'Zytorvi' (toripalimab) as first-line treatment, with the chemotherapy drugs cisplatin and paclitaxel, for adults with unresectable advanced, recurrent or metastatic oesophageal squamous cell carcinoma (ESCC) (the company announced it on 21 Oct 2026). This is the drug's second indication in India; the first – nasopharyngeal carcinoma – was launched in Nov 2024. Note: the drug was first approved back in 2024; this is approval for a new disease.

Key facts

Drug	Toripalimab (brand Zytorvi) – anti-PD-1 monoclonal antibody; immunotherapy
Developer / rights	Shanghai Junshi Biosciences (China); Dr. Reddy's (Hyderabad) holds rights in 21 countries incl. India under a 2023 deal
New indication	Oesophageal squamous cell carcinoma (ESCC) – with cisplatin + paclitaxel; no PD-L1 test required
Trial	JUPITER-06 (Phase 3): 42% lower risk of progression or death; median survival 17.7 months (chemo alone 12.9)

First indication	Nasopharyngeal carcinoma (NPC) – launched Nov 2024; first immuno-oncology drug approved in India for NPC
Burden	ESCC is about 80% of oesophageal cancers in India; 4th leading cause of cancer death (company data)

Background

- Regulation: the DCGI heads the Central Drugs Standard Control Organisation (CDSCO), under the Directorate General of Health Services (DGHS), Union Health Ministry. Legal basis – Drugs and Cosmetics Act, 1940; New Drugs and Clinical Trials Rules, 2019. CDSCO HQ – New Delhi.
- Science: PD-1 is an 'immune checkpoint' brake on T-cells. Cancer cells switch it on via PD-L1 to escape the immune system. Toripalimab blocks PD-1 so T-cells can attack the tumour. Monoclonal antibody names end in '-mab' (e.g., nivolumab, pembrolizumab).
- Nobel Prize 2018 (Physiology or Medicine): James P. Allison (USA – CTLA-4) and Tasuku Honjo (Japan – PD-1), for cancer therapy by inhibition of negative immune regulation.
- Diseases: nasopharyngeal carcinoma (NPC) is linked to the Epstein–Barr virus (EBV); in India it is commonest in the North-East (Kohima, Nagaland). Tobacco and alcohol are major risk factors for oesophageal cancer.

Tamil Nadu link: CDSCO's South Zone office is in Chennai (other zonal offices include Ghaziabad – North, Kolkata – East, Mumbai – West). On 31 Aug 2024 TN Health Minister Ma. Subramanian announced that cancer screening would be made mandatory for all above 18; the State recorded about 82,000 cancer cases in 2023.

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