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Dr. Reddyâ??s receives DCGI approval for ZytorviÂ® (toripalimab) in advanced esophageal squamous cell carcinoma treatment

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Approval expands the use of ZytorviÂ® beyond its initially approved indication in nasopharyngeal carcinoma (NPC)



Hyderabad-based Dr. Reddy’s Laboratories has announced that the Central Drugs Standard Control Organisation (CDSCO), under the Drugs Controller General of India (DCGI), has approved Zytorvi® (toripalimab) in combination with cisplatin and paclitaxel for the first-line treatment of adult patients with unresectable advanced, recurrent or metastatic esophageal squamous cell carcinoma (ESCC).

Dr. Reddy’s entered into a licensing and commercialization agreement with Junshi Biosciences in 2023 for toripalimab across 21 countries. Globally, Toripalimab is approved by regulatory authorities including the US Food and Drug Administration (USFDA), the European Medicines Agency (EMA) and the UK Medicines and Healthcare products Regulatory Agency (MHRA).

Notably, the EMA approval is for first-line treatment of ESCC irrespective of PD-L1 expression.The approved indication in India similarly does not require patient selection based on PD-L1 expression, enabling appropriate patients to be considered for treatment regardless of their biomarker status.

In 2024, esophageal cancer was the fourth leading cause of cancer-related death in India, accounting for approximately 8.1% of all cancer deaths. ESCC, the predominant subtype, accounts for approximately 80% of all esophageal cancer cases in India. Through Zytorvi®, Dr. Reddy’s Laboratories aims to expand access to first-line immunotherapy for appropriate patients with advanced ESCC in India.