

DCGI Approves Dr Reddy's Cancer Drug Zytorvi for Advanced Esophageal Cancer

Hyderabad: Dr. Reddy's Laboratories Ltd. has received approval from the Central Drugs Standard Control Organisation (CDSCO), under the Drugs Controller General of India (DCGI), for Zytorvi (toripalimab) in combination with cisplatin and paclitaxel for the first-line treatment of adults with unresectable advanced, recurrent or metastatic esophageal squamous cell carcinoma (ESCC).

Dr. Reddy's entered into a licensing and commercialisation agreement with Shanghai Junshi Biosciences Co. Ltd. in 2023, securing rights to develop and commercialise toripalimab in 21 countries, including India. The drug has also received approvals from regulatory authorities such as the US Food and Drug Administration (USFDA), the European Medicines Agency (EMA) and the UK Medicines and Healthcare products Regulatory Agency (MHRA).

The approved indication in India does not require patient selection based on PD-L1 expression, allowing eligible patients to be considered for treatment regardless of their biomarker status.

Esophageal cancer remains a significant health concern in India. In 2024, it was the fourth leading cause of cancer-related deaths in the country, accounting for approximately 8.1% of such deaths. ESCC is the predominant subtype, representing around 80% of esophageal cancer cases in India.

The approval of Zytorvi is expected to expand treatment options for eligible patients with advanced ESCC.

The approval is supported by findings from the Phase 3 JUPITER-06 clinical trial. In the study, toripalimab combined with paclitaxel and cisplatin reduced the risk of disease progression or death by 42% compared with chemotherapy alone.

At the final overall survival analysis, median overall survival was 17.7 months among patients receiving toripalimab plus chemotherapy, compared with 12.9 months among those receiving chemotherapy alone. Clinical benefits were observed across different PD-L1 expression subgroups.

M.V. Ramana, Chief Executive Officer, Global Generics, Dr. Reddy's Laboratories, said the approval marks another step in expanding access to immunotherapy for patients with advanced ESCC, following the approval of Zytorvi for nasopharyngeal carcinoma.

He added that the new indication provides physicians with an additional first-line treatment option for eligible patients and reflects the company's continued focus on expanding its oncology portfolio and access to innovative therapies.

Zytorvi contains toripalimab, a humanised IgG4 monoclonal antibody targeting programmed death receptor-1 (PD-1). By blocking the interaction between PD-1 and its ligands PD-L1 and PD-L2, the drug helps support T-cell activity against cancer cells.

Dr. Reddy's launched Zytorvi in India in November 2024 for recurrent or metastatic nasopharyngeal carcinoma. Under its agreement with Junshi Biosciences, the company holds exclusive development and commercialisation rights for toripalimab across 21 countries.

Esophageal squamous cell carcinoma develops in the squamous cells lining the esophagus, the muscular tube that carries food and liquids from the throat to the stomach.

Risk factors include tobacco use, alcohol consumption, areca-nut use, consumption of very hot beverages, poor diet and certain environmental and socioeconomic factors. Symptoms may include difficulty or pain while swallowing, unexplained weight loss, persistent chest discomfort and regurgitation. These symptoms can have other causes and should be evaluated by a qualified healthcare professional.

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