Press Release

Dr.Reddy's

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Dr. Reddy's Receives DCGI Approval for Zytorvi® (toripalimab) in Advanced Esophageal Squamous Cell Carcinoma, Its Second Approved Indication in India

The approval expands the use of Zytorvi® beyond its initially approved indication in nasopharyngeal carcinoma (NPC)

Hyderabad, India; October 21, 2026: Dr. Reddy's Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY, NSEIFSC: DRREDDY; along with its subsidiaries together referred to as "Dr. Reddy's,") today 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)**.[1]

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 U.S. Food and Drug Administration (USFDA), the European Medicines Agency (EMA) and the UK Medicines and Healthcare products Regulatory Agency (MHRA).[2] Notably, the EMA approval is for first-line treatment of ESCC irrespective of PD-L1 expression.[3] 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.[1,3]

In 2024, esophageal cancer was the **fourth leading cause of cancer-related death in India**, accounting for approximately **8.1% of all cancer deaths**[4]. ESCC, the predominant subtype, accounts for approximately 80% of all esophageal cancer cases in India. Through Zytorvi®, Dr. Reddy's Laboratories Ltd. aims to expand access to first-line immunotherapy for appropriate patients with advanced ESCC in India.

The approval is supported by the results from the Phase 3 JUPITER-06 trial. In the study, toripalimab in combination with paclitaxel and cisplatin reduced the risk of disease or death by **42%** compared with chemotherapy alone.[7] At the final overall-survival analysis, median overall survival was **17.7 months** with toripalimab plus chemotherapy compared with **12.9 months** with chemotherapy alone. Clinical benefit was observed across PD-L1-expression subgroups.[8]

M.V. Ramana, Chief Executive Officer, Global Generics, Dr. Reddy's Laboratories, said:

"Following the approval of Zytorvi® in nasopharyngeal carcinoma, this second indication marks an important step in extending the reach of immunotherapy to patients with advanced esophageal squamous cell carcinoma. It gives physicians an additional first-line treatment option for appropriate patients. As we continue to build our oncology portfolio, our focus remains on bringing meaningful advances and expanding access to innovative treatment options."

About esophageal squamous cell carcinoma

Esophageal cancer begins in the tissues of the esophagus, the muscular tube that carries food and liquids from the throat to the stomach. ESCC develops from the squamous cells lining the esophagus.

Risk factors associated with ESCC include smoked and smokeless tobacco, alcohol consumption, areca-nut use, consumption of very hot beverages, poor diet and certain environmental and socioeconomic factors. Risk

varies between individuals, and the presence of one or more risk factors does not mean that a person will necessarily develop cancer.

Progressive difficulty in swallowing, pain or discomfort when swallowing, unexplained weight loss, persistent chest discomfort and regurgitation may be associated with esophageal cancer. These symptoms may also be caused by other conditions and require evaluation by a qualified healthcare professional.[5,6]

About Zytorvi® (toripalimab)

Zytorvi® contains toripalimab, a next-generation humanised IgG4 monoclonal antibody[9] directed against programmed death receptor-1, or PD-1. By binding to PD-1, toripalimab blocks its interaction with PD-L1 and PD-L2, supporting T-cell activity against cancer cells.[3]

In 2023, Dr. Reddy's entered into a licence and commercialisation agreement with Shanghai Junshi Biosciences Co., Ltd. for toripalimab. Under this agreement, Dr. Reddy's holds exclusive rights to develop and commercialise toripalimab in 21 countries, including India, South Africa, Brazil and several countries in Latin America, Australia, New Zealand and nine other countries.[2] Dr. Reddy's launched Zytorvi® in India in November 2024 for recurrent or metastatic nasopharyngeal carcinoma, making India the third country in the world, after China and the United States, to receive access to the medicine.[2]

Toripalimab is approved by regulatory authorities including the U.S. Food and Drug Administration (USFDA), the EMA and the UK Medicines and Healthcare products Regulatory Agency (MHRA).[2] The European Commission authorised toripalimab for first-line ESCC in September 2024.[3]

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About Dr. Reddy's: Dr. Reddy's Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY, NSEIFSC: DRREDDY) is a global pharmaceutical company headquartered in Hyderabad, India. Established in 1984, we are committed to providing access to affordable and innovative medicines. Driven by our purpose of 'Good Health Can't Wait', we offer a portfolio of products and services including APIs, generics, branded generics, biosimilars and OTC. Our major therapeutic areas of focus are gastrointestinal, cardiovascular, diabetology, oncology, pain management and dermatology. Our major markets include – USA, India, Russia & CIS countries, China, Brazil and Europe. As a company with a history of deep science that has led to several industry firsts, we continue to plan ahead and invest in businesses of the future. As an early adopter of sustainability and ESG actions, we released our first Sustainability Report in 2004. Our current ESG goals aim to set the bar high in environmental stewardship; access and affordability for patients; diversity; and governance.

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