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Dr. Reddy's launches Toripalimab in India for treatment of Nasopharyngeal Carcinoma

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First & only immuno-oncology drug approved by various regulatory authorities around the world



Dr. Reddy's Laboratories has announced the launch of Toripalimab in India. Toripalimab is a New Biological Entity (NBE). It is the only immuno-oncology drug approved by various regulatory authorities around the world such as United States Food and Drug Administration (USFDA), European Medicines Agency (EMA), Medicines and Healthcare products Regulatory Agency (MHRA), and others for the treatment of adults with recurrent or metastatic nasopharyngeal carcinoma (RM-NPC).

In 2023, Dr. Reddy's entered into a license and commercialisation agreement with Shanghai Junshi Biosciences for Toripalimab. Under this agreement, Dr. Reddy's obtained exclusive rights to develop and commercialise Toripalimab in 21 countries including India, South Africa, Brazil and various countries in Latin America.

Additionally, the agreement allows Dr. Reddy's to expand the scope of the license to cover Australia, New Zealand and nine other countries. With this launch by Dr. Reddy's, India becomes the third country in the world after China and United States to receive access to this next generation PD-1 inhibitor. Dr. Reddy's will market it under the brand name Zytorvi® in India.

The standard of care for RM-NPC in India before Toripalimab was chemotherapy (gemcitabine and cisplatin). Toripalimab is indicated as first-line treatment of adults with metastatic or recurrent locally advanced NPC in combination with gemcitabine and cisplatin. This combination has shown a 48% reduction in risk of progression or death. Additionally, Toripalimab has also been approved as monotherapy for the treatment of adults with recurrent unresectable or metastatic NPC with disease progression on or after platinum-containing chemotherapy.

Toripalimab is an anti-PD-1 monoclonal antibody developed for its ability to block PD-1 interactions with its ligands, PD-L1 and PD-L2, and for enhanced receptor internalization (endocytosis function). Blocking PD-1 interactions with PD-L1 and PD-L2 promotes the immune system's ability to attack and kill tumour cells.

NPC is a malignant tumour that arises from the epithelium of the nasopharynx. According to GLOBOCAN 2022 statistics, the number of newly diagnosed NPC cases in 2022 exceeded 120,000 worldwide. In India, there were 6,519 newly diagnosed cases of NPC in 2022. The highest age-adjusted rates for NPC were found in the north-eastern states in India, with Kohima in Nagaland having an incidence of 19.4/100,000 population.