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Dr. Reddy's launches Toripalimab in India, the first and only immuno-oncology drug approved for the treatment of nasopharyngeal carcinoma

- *Only immuno-oncology drug approved by various regulatory authorities around the world such as the USFDA, DCGI, EMA, MHRA, NMPA and others for the treatment of adults with recurrent or metastatic nasopharyngeal carcinoma (RM-NPC)*
- *Combination of Toripalimab and standard of care chemotherapy has shown a 48% reduction in risk of progression or death*
- *Launched in India in the same year as its launch in the U.S., making India the third country in the world to receive access to this New Biological Entity (NBE)*

Hyderabad, India; November 28, 2024 – Dr. Reddy's Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY, NSEIFSC: DRREDDY; along with its subsidiaries together referred to as "Dr. Reddy's"), 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 the 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 Co. Ltd 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 the United States to receive access to this next generation PD-1 inhibitor¹. 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 death². Additionally, Toripalimab has also been approved as

¹ Ravindranathan S, Wang X, et al. Characteristics of toripalimab: a next generation anti-PD-1 antibody with potent T cell activation and enhanced clinical efficacy irrespective of PD-L1 status. J Immunother Cancer 2023;11(Suppl 1):A1–A1731

² Mai, HQ., Chen, QY., Chen, D. et al. Toripalimab or placebo plus chemotherapy as first-line treatment in advanced nasopharyngeal carcinoma: a multicenter randomized phase 3 trial. Nat Med 27, 1536–1543 (2021).

monotherapy for the treatment of adults with recurrent unresectable or metastatic NPC with disease progression on or after platinum-containing chemotherapy.

M.V. Ramana, Chief Executive Officer, Branded Markets (India and Emerging Markets), Dr. Reddy's, said: *"The launch of Toripalimab is a significant milestone for patients diagnosed with nasopharyngeal carcinoma (NPC) in India. NPC is a rare form of head and neck cancer. However, the prognosis of the disease for patients in advanced stages is poor, and India is among the top five countries in the world in terms of disease burden³. As the next generation PD-1 inhibitor, Toripalimab has demonstrated superior outcomes for RM-NPC versus standard of care, thereby meeting a significant unmet need for patients with NPC in India.*

This launch is also a major milestone for us as a company. Oncology has been a top focus therapy area for us. Our offerings aim to build an end-to-end ecosystem of care – access to current standard of care cancer medicines across multiple countries globally, innovation in formulations, strategic collaborations for novel innovative molecules particularly in India and other emerging markets, beyond-the-pill support such as nutrition and digital tools. Our portfolio of standard of care small molecules and biosimilars across cancer types in India and other emerging markets has included Reditux™, Versavo®, Lenangio™, and Hervycta™.

Additionally, under our innovation agenda, access to novel molecules through collaborations is a key pillar, since access to meaningful innovation and the latest standard of care remains a challenge for patients in emerging markets. Thanks to the relentless efforts of our cross-functional teams, we have been able to launch Toripalimab in India in the same year as its launch in the U.S. We will continue to work hard to serve our patients and stakeholders to remain their partner of choice, and progress towards our goal of serving over 1.5 billion patients by 2030."

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 2022⁴. 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 population⁵.

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 internalisation (endocytosis function). Blocking PD-1 interactions with PD-L1 and PD-L2 promotes the immune system's ability to attack and kill tumour cells⁶.

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

³ Chen YP, Chan AT, Le QT, Blanchard P, Sun Y, Ma J. Nasopharyngeal carcinoma. The Lancet. 2019 Jul 6;394(10192):64-80.

⁴ Ferlay J, Ervik M, Lam F, Laversanne M, Colombet M, Mery L, Piñeros M, Znaor A, Soerjomataram I, Bray F (2024). Global Cancer Observatory: Cancer Today. Lyon, France: International Agency for Research on Cancer. Available from: <https://gco.iarc.who.int/today>.

⁵ Mailankody, Sharada, et al. "Epidemiology of rare cancers in India and South Asian countries—remembering the forgotten." The Lancet Regional Health-Southeast Asia 12 (2023).

⁶ Chen YP, Chan AT, Le QT, Blanchard P, Sun Y, Ma J. Nasopharyngeal carcinoma. The Lancet. 2019 Jul 6;394(10192):64-80.

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. For more information, log on to: www.drreddys.com.

Disclaimer: This press release may include statements of future expectations and other forward-looking statements that are based on the management's current views and assumptions and involve known or unknown risks and uncertainties that could cause actual results, performance or events to differ materially from those expressed or implied in such statements. In addition to statements which are forward-looking by reason of context, the words "may", "will", "should", "expects", "plans", "intends", "anticipates", "believes", "estimates", "predicts", "potential", or "continue" and similar expressions identify forward-looking statements. Actual results, performance or events may differ materially from those in such statements due to without limitation, (i) general economic conditions such as performance of financial markets, credit defaults, currency exchange rates, interest rates, persistency levels and frequency / severity of insured loss events, (ii) mortality and morbidity levels and trends, (iii) changing levels of competition and general competitive factors, (iv) changes in laws and regulations and in the policies of central banks and/or governments, (v) the impact of acquisitions or reorganization, including related integration issues, and (vi) the susceptibility of our industry and the markets addressed by our, and our customers', products and services to economic downturns as a result of natural disasters, epidemics, pandemics or other widespread illness, including coronavirus (or COVID-19), and (vii) other risks and uncertainties identified in our public filings with the Securities and Exchange Commission, including those listed under the "Risk Factors" and "Forward-Looking Statements" sections of our Annual Report on Form 20-F for the year ended March 31, 2024. The company assumes no obligation to update any information contained herein.

