**Press Release** Dr.Reddy's


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# Dr. Reddy's Laboratories launches NIVORZ® (Nivolumab Biosimilar) in India

### *NIVORZ® marks Dr. Reddy's entry into Biosimilar Immuno-Oncology in India*

### *Developed entirely in-house through Dr. Reddy's end-to-end biosimilar development and manufacturing capabilities*

### *Approved across 12 indications, spanning both solid and hematological malignancies*

**Hyderabad, India; September 15, 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 the launch of NIVORZ® (Nivolumab Biosimilar) in India. NIVORZ® is a biosimilar to Opdivo® (nivolumab).

The launch represents a significant milestone for Dr. Reddy's, with NIVORZ® marking its entry into biosimilar immuno-oncology in India. Developed and manufactured entirely in-house at Dr. Reddy's biologics facility in Bachupally, Hyderabad, it reflects the company's end-to-end capabilities across the biosimilar value chain, from development through commercialization.

Oncology remains an important focus area for Dr. Reddy's. The launch of NIVORZ® further strengthens the company's oncology portfolio and expands its presence in immuno-oncology. The Immuno-Oncology market in India is estimated at approximately ₹3,900 crore in 2025 and is predominantly driven by checkpoint inhibitors such as nivolumab, pembrolizumab and toripalimab[1].

Access to immuno-oncology therapies remains a challenge for many patients due to the cost and duration of treatment. Through NIVORZ®, Dr. Reddy's aims to broaden access to high-quality nivolumab therapy with an affordable biosimilar option for eligible patients.

NIVORZ® was evaluated through a multi-country clinical development programme involving 288 patients, including 252 from India and 36 from Russia, and demonstrated comparable efficacy, safety, pharmacokinetics and immunogenicity to the reference nivolumab. Based on this clinical development programme, NIVORZ® has been approved in India by the Drugs Controller General of India (DCGI).

[1] Source: Ipsos Oncology Sales Monitor, MAT December 2025

**Dr. Sridevi Khambhampaty, Global Head of Biologics, Dr. Reddy’s Laboratories, said:** *"The launch of NIVORZ® marks an important milestone for our biologics business. It reinforces our commitment to expanding patient access to high-quality biologic therapies, strengthens our oncology portfolio and reflects our continued focus on developing complex biosimilars."*

**M.V. Ramana, CEO Global Generics, Dr. Reddy's Laboratories, said:** *"The launch of NIVORZ® strengthens our oncology portfolio and expands our presence in immuno-oncology. As access to immunotherapy continues to be a challenge for many patients, we remain committed to improving access to high-quality treatment options through affordable biosimilars such as NIVORZ®."*

NIVORZ® (Nivolumab) is one of the immunotherapy agents with the broadest range of approved indications in oncology in India, including Metastatic Non-Small Cell Lung Cancer (NSCLC), Renal Cell Carcinoma (RCC), Squamous Cell Carcinoma of the Head and Neck (SCCHN), Melanoma, Classical Hodgkin Lymphoma (cHL), Urothelial Carcinoma (UC), Colorectal Cancer (CRC), Esophageal squamous cell carcinoma (ESCC), Gastric Cancer, Gastroesophageal Junction Cancer and Esophageal Adenocarcinoma (GC, GEJC or EAC), Adjuvant treatment of Resected Esophageal or Gastroesophageal Junction Cancer (EC or GEJC), Malignant Pleural Mesothelioma (MPM) and Hepatocellular Carcinoma (HCC) Together, these approved indications span early-stage, locally advanced, recurrent, and metastatic disease settings across both solid and hematological malignancies.

## About NIVORZ®

NIVORZ® (Nivolumab) is a fully human monoclonal antibody that targets the PD-1 (Programmed Death-1) immune checkpoint, helping restore the immune system's ability to identify and fight cancer cells. It is administered through intravenous infusion and is available in single-dose vial presentations of 40 mg/4 mL, 100 mg/10 mL and 240 mg/24 mL.

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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.

Over the last 25 years, our Biologics team has developed into a fully integrated organization with robust capabilities in the development, manufacture and commercialization of a range of biosimilar products in oncology and immunology. We have a current portfolio of six commercial products marketed in India, with some products marketed in more than 30 other countries. In addition, we have several products in the pipeline in oncology and autoimmune diseases in various stages of development for global launches across developed as well as emerging markets. We are also ramping up manufacturing capacity to support our global expansion plans.

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

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