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Dr. Reddy's Laboratories Receives U.S. FDA Approval for Rituximab Biosimilar

Dr. Reddy's growing global biosimilars portfolio

Fresenius Kabi to exclusively commercialize the product in the United States

Hyderabad, India, August 1, 2026 – Dr. Reddy's Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY, NSEIFSC: DRREDDY) today announced that the U.S. Food and Drug Administration (FDA) has approved its rituximab biosimilar, a biosimilar to Rituxan® (rituximab), for the U.S. market.

The approval further strengthens Dr. Reddy's growing global biosimilars portfolio and advances its biosimilars business in the United States.

The product was developed, manufactured and submitted for approval by Dr. Reddy's Laboratories. The approval follows the successful recent Pre-License Inspection (PLI) conducted by the U.S. FDA at the Company's biologics manufacturing facility in Bachupally, Hyderabad, and reflects the company's capabilities in bringing complex biologic medicines to highly regulated markets and its long-standing commitment to biosimilars.

Under a commercialization agreement, Fresenius Kabi holds the exclusive rights to commercialize the product in the United States, one of the world's most important pharmaceutical markets.

"The approval of the rituximab biosimilar on the FDA's goal date reflects our capabilities in developing and manufacturing complex biologic medicines for global markets," said Sridevi Khambhampaty, Global Head, Biologics, Dr. Reddy's Laboratories.

The rituximab biosimilar has been commercialized in India, the European Union, the United Kingdom and more than 25 emerging markets, and has also received marketing approval in Switzerland and Canada.

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Rituximab is a monoclonal antibody that targets the CD20 antigen expressed on B lymphocytes and is widely used in the treatment of several B-cell malignancies, including non-Hodgkin lymphoma and chronic lymphocytic leukemia, as well as certain autoimmune conditions.

The FDA approval is supported by a comprehensive body of analytical, non-clinical and clinical evidence demonstrating that the biosimilar is highly similar to the reference product, with no clinically meaningful differences in safety, purity and potency, consistent with FDA requirements for biosimilar approval.

About Rituximab

Rituximab is a monoclonal antibody that selectively targets the CD20 protein expressed on B-cells. By binding to CD20, rituximab induces B-cell depletion through multiple immune-mediated mechanisms.

In the United States, rituximab is approved for the treatment of adults with several hematologic malignancies and autoimmune diseases, including non-Hodgkin lymphoma, chronic lymphocytic leukemia, rheumatoid arthritis, granulomatosis with polyangiitis (GPA), and microscopic polyangiitis (MPA).

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. In 2024, we launched our first biosimilar in the United Kingdom, Versavo® (biosimilar bevacizumab). This follows our launch of pegfilgrastim in the U.S. and Europe through our partner. We also launched our rituximab biosimilar in Europe in 2025. Our biosimilars business has a key role to play in driving both near-term and long-term growth.

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

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