Fresenius

Investor News

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Fresenius Announces FDA Approval of Rituximab Biosimilar for the U.S. Market

Fresenius Kabi, an operating company of Fresenius, announced today that the U.S. Food and Drug Administration (FDA) has approved a rituximab biosimilar developed by Dr. Reddy's Laboratories (DRL), a biosimilar to Rituxan®* (rituximab).[1]

Under an exclusive commercialization agreement, Fresenius Kabi holds exclusive rights to commercialize the biosimilar in the United States. The product was developed, manufactured, and submitted for approval by Dr. Reddy's Laboratories.

"FDA approval of rituximab biosimilar represents an important milestone for Fresenius Kabi, further strengthening our U.S. biosimilars footprint with a well-established molecule that strategically complements our oncology and immunology portfolios. This reinforces our commitment to expanding patient access to high-quality, affordable biologic medicines in the U.S. market," said Dr. Sang-Jin Pak, President Biopharma at Fresenius Kabi.

Rituximab is a monoclonal antibody that targets the CD20 antigen expressed on B lymphocytes. It is widely used in the treatment of adults with several B-cell malignancies, including non-Hodgkin lymphoma and chronic lymphocytic leukemia, as well as certain autoimmune conditions.[2]

The FDA approval is supported by a totality of the evidence approach, including analytical, non-clinical, and clinical data demonstrating that the product is highly similar to and has no clinically meaningful differences from the reference product, Rituxan®, consistent with U.S. FDA requirements for biosimilar approval.

Biopharma is a core pillar of Fresenius' #FutureFresenius strategy. The company is building a vertically integrated, end-to-end biopharma business covering the entire value chain, from research and development to manufacturing and global commercialization. By combining strong technical capabilities, global production expertise, and a balanced commercial footprint, Fresenius is well positioned to expand access to high-quality, affordable biologic therapies. The approval of the rituximab biosimilar represents another important step in strengthening Fresenius Kabi's growing biosimilars portfolio.

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.

Rituximab is approved for the treatment of adults with several hematologic malignancies and autoimmune diseases in the United States, including non-Hodgkin lymphoma, chronic lymphocytic leukemia, rheumatoid arthritis, granulomatosis with polyangiitis (GPA), and microscopic polyangiitis (MPA).[2]

The rituximab biosimilar was developed and manufactured by Dr. Reddy's Laboratories. Fresenius Kabi holds exclusive commercialization rights in the United States.

The biosimilar development program was designed to demonstrate high similarity to the reference product through comprehensive analytical, non-clinical, pharmacokinetic, and clinical studies, in line with FDA requirements for biosimilar approval.

About Fresenius Kabi

Fresenius Kabi, an operating company of the Fresenius Group, is a global healthcare company providing integrated medicines, technologies, and services for critically and chronically ill patients. With more than 41,000 employees and present in over 100 countries, the company's broad portfolio enables access to high-quality care across

emergency medicine, surgery, oncology, intensive care, and at home, reaching 450 million patients each year.

Through complementary business areas, Fresenius Kabi offers highly complex biopharmaceuticals for cancer, autoimmune and endocrine diseases; leading enteral, parenteral and homecare solutions within clinical nutrition; cutting-edge medical technology; and intravenous generic drugs and fluids that advance essential patient care worldwide.

For more information, please visit www.fresenius-kabi.com.

About Fresenius

Fresenius SE & Co. KGaA (Frankfurt/Xetra: FRE) is a global healthcare company headquartered in Bad Homburg v. d. Höhe, Germany. In the 2025 fiscal year, Fresenius generated €22.6 billion in annual revenue. Fresenius currently counts over 178,000 employees. The Fresenius Group comprises the operating companies Fresenius Kabi and Fresenius Helios as well as an investment in Fresenius Medical Care. With around 140 hospitals and numerous outpatient facilities, Fresenius Helios is the leading private hospital operator in Germany and Spain, treating around 27 million patients every year. Fresenius Kabi's product portfolio touches the lives of 450 million patients annually and includes a range of highly complex biopharmaceuticals, clinical nutrition, medical technology, and intravenous generic drugs and fluids. Fresenius was established in 1912 by the Frankfurt pharmacist Dr. Eduard Fresenius. After his death, Else Kröner took over management of the company in 1952. She laid the foundations for a global enterprise that today pursues the goal of improving people's health. The largest shareholder is the non-profit Else Kröner Fresenius Foundation, which is dedicated to advancing medical research and supporting humanitarian projects.

For more information visit the Company's website at www.fresenius.com.
Visit our media center: www.fresenius.com/media-center.

References

[1] U.S. Food and Drug Administration approval information for rituximab biosimilar developed by Dr. Reddy's Laboratories.
[2] Rituxan® (rituximab) U.S. Prescribing Information. Rituxan® is a registered trademark of Genentech, Inc.

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Fresenius (XFRA: FRE, OTC: FSNUY) is a global, therapy-focused healthcare company dedicated to saving and improving human lives around the world. Through Fresenius Kabi and Fresenius Helios, the company delivers system-critical, innovative and affordable healthcare across the full continuum of care: Fresenius Kabi is a leading provider of lifesaving medicines, clinical nutrition, and medical technologies for critically and chronically ill patients, reaching around 450 million people each year. Fresenius Helios is Europe's largest private hospital operator, treating around 27 million patients annually.

With more than 178,000 employees and operating in more than 60 countries, Fresenius generated €22.6 billion in revenue in 2025.

For more information, visit www.fresenius.com and follow Fresenius on LinkedIn.

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