

## Press Release

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### **Fresenius Accelerates Momentum in its (Bio)Pharma Business and Launches Tyenne<sup>®\*</sup>, its Third Approved Biosimilar in the U.S.**

- **Tyenne<sup>®</sup> is the first tocilizumab biosimilar by Fresenius Kabi, an operating company of Fresenius, with an intravenous and subcutaneous formulation approved by the FDA.**
- **The tocilizumab biosimilar provides increased access and an affordable, high-quality, and safe treatment option for U.S. patients.**
- **Encouraging trajectory of the (Bio)Pharma business in 2024 so far.**
- **The launch of the tocilizumab biosimilar contributes directly to growing Fresenius' (Bio)Pharma platform, a substantial cornerstone of the #FutureFresenius strategy.**

Fresenius, via its operating company Fresenius Kabi, announced today the immediate U.S. availability of Tyenne<sup>®</sup> (tocilizumab-aazg), a biosimilar of Actemra<sup>®\*\*</sup> (tocilizumab). Tyenne<sup>®</sup>, for use in the treatment of chronic autoimmune diseases, is available in an intravenous (IV) formulation.

Michael Sen, CEO of Fresenius: "With the launch of Tyenne<sup>®</sup> in the U.S., we have reached another important milestone in accelerating our strong (Bio)Pharma

momentum going into 2024. Growing this platform is a substantial cornerstone of our #FutureFresenius journey. Overall, we have seen an encouraging performance of our (Bio)Pharma business so far. We are particularly happy with the good progress of our majority-owned biotechnology company mAbxience and the traction of Tyenne®.”

Tyenne® is the first tocilizumab biosimilar with an intravenous and subcutaneous formulation approved by the FDA. The biosimilar received FDA approval on March 5, 2024. Tyenne® is Fresenius’ third approved biosimilar available in the U.S. and the second within its immunology portfolio. The biologic medicine is indicated for the treatment of several autoimmune diseases, including rheumatoid arthritis, giant cell arteritis, polyarticular juvenile idiopathic arthritis, and systemic juvenile idiopathic arthritis.

Pierluigi Antonelli, CEO of Fresenius Kabi: “Tyenne® will impact the treatment landscape for inflammatory and immune diseases in the U.S. Reaching ever more patients with our state-of-the-art biopharma portfolio signals a clear growth path in a highly promising market segment. We will continue to roll out our comprehensive pipeline of autoimmune and oncology biosimilars with several molecules in late-stage development.”

Supported by Fresenius Kabi’s holistic support program for health care professionals and patients, the company’s biologic medicine provides wider access to more treatment options and contributes to the viability of health care systems. Next to its two available biosimilars, Idacio®\*\*\* (adalimumab) and Stimufend®\*\*\*\* (pegfilgrastim), Fresenius Kabi has a growing pipeline of autoimmune and oncology biosimilars with several molecules in late-stage development.

To learn more about how Fresenius Kabi provides comprehensive patient support for Tyenne® in the U.S. please click [here](#).

With #FutureFresenius, Fresenius successfully set the course last year to become a leading therapy-focused company. In line with the strategy, Fresenius has simplified its structure, is sharpening its focus by concentrating on its operating companies Fresenius Kabi and Fresenius Helios and is continuously enhancing its performance.

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\*Tyenne® is a registered trademark of Fresenius Kabi Deutschland GmbH.

## About Tyenne<sup>®</sup>, a Tocilizumab Biosimilar

Tyenne<sup>®</sup> (tocilizumab-aazg), a biosimilar to Actemra<sup>®</sup> (tocilizumab), is a prescription medicine called an Interleukin-6 (IL-6) receptor antagonist. It was developed by Fresenius Kabi using advanced analytical and manufacturing technologies for use in the treatment of several autoimmune diseases, including rheumatoid arthritis, giant cell arteritis, polyarticular juvenile idiopathic arthritis, and systemic juvenile idiopathic arthritis. Serious infections leading to hospitalization or death including tuberculosis (TB), bacterial, invasive fungal, viral, and other opportunistic infections have occurred in patients receiving the product. Tyenne<sup>®</sup> is contraindicated in patients with known hypersensitivity to tocilizumab products. For more information about Tyenne<sup>®</sup>, please see the full prescribing information for the U.S. [here](#).

Tyenne<sup>®</sup> demonstrates Fresenius Kabi's commitment to providing access to affordable and cost-effective biosimilars to more patients living with autoimmune diseases around the world while enabling savings for health care systems. KabiCare, Fresenius Kabi's comprehensive patient support program, will be available to patients and health care providers in the U.S. from launch.

## About Fresenius Kabi

Fresenius Kabi is a global healthcare company that specializes in lifesaving medicines and technologies for infusion, transfusion and clinical nutrition. The company's products and services are used for the therapy and care of critically and chronically ill patients.

Its product portfolio comprises a range of highly complex biopharmaceuticals, clinical nutrition, medical technologies, and I.V. generic drugs. Within biopharmaceuticals, Fresenius Kabi offers, among others, biosimilar drugs with a focus on autoimmune diseases and oncology. The company's clinical nutrition offering includes a wide selection of enteral and parenteral nutrition products. In the segment of medical technologies, its offering includes vital disposables, infusions pumps, apheresis machines, cell therapy devices, and more. Fresenius

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\*\*Actemra<sup>®</sup> is a registered trademark of Chugai Seiyaku Kabushiki Kaisha Corp., a member of the Roche Group.

\*\*\*Idacio<sup>®</sup> is a registered trademark of Fresenius Kabi Deutschland GmbH in selected countries

\*\*\*\*Stimufend<sup>®</sup> is a registered trademark of Fresenius Kabi Deutschland GmbH in selected countries

Kabi puts essential medicines and technologies in the hands of people who help patients and finds the best answers to the challenges they face.

Following its strategy "Vision 2026", which is a key part of the #FutureFresenius program of the Fresenius healthcare group, the company is furthermore committed to increase efficiencies in the therapy and care of patients and improve access to high-quality healthcare around the globe. Fresenius Kabi aspires to be leading globally in its product segments – all for the benefit of patients, its customers, and its stakeholders.

# # #

Fresenius SE & Co. KGaA (Frankfurt/Xetra: FRE) is a global healthcare company headquartered in Bad Homburg v. d. Höhe, Germany. In the 2023 fiscal year, Fresenius generated €22.3 billion in annual revenue with its more than 190,000 employees. Fresenius offers solutions to the social challenges posed by a growing and ageing population and the resulting need for affordable, high-quality healthcare. The Fresenius Group comprises the operating companies Fresenius Kabi and Fresenius Helios as well as the investment companies Fresenius Vamed and Fresenius Medical Care. With 140 hospitals and countless outpatient facilities, Fresenius Helios is the leading private hospital operator in Germany and Spain, treating around 26 million patients every year. Fresenius Kabi's product portfolio includes a range of highly complex biopharmaceuticals, clinical nutrition, medical technology, and generic intravenous drugs. 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 website at [www.fresenius.com](http://www.fresenius.com).  
Follow us on social media: [www.fresenius.com/socialmedia](http://www.fresenius.com/socialmedia)

This release contains forward-looking statements that are subject to various risks and uncertainties. Future results could differ materially from those described in these forward-looking statements due to certain factors, e.g. changes in business, economic and competitive conditions, regulatory reforms, results of clinical trials, foreign exchange rate fluctuations, uncertainties in litigation or investigative proceedings, the availability of financing and unforeseen impacts of international conflicts.

Fresenius does not undertake any responsibility to update the forward-looking statements in this release.

Fresenius SE & Co. KGaA

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