Fresenius Kabi Receives FDA 510(k) Clearance for Adaptive Nomogram, Enhancing Plasma Collection Efficiency with the Aurora Xi Plasmapheresis System

January 28, 2025

LAKE ZURICH, Ill. – January 28, 2025 – Fresenius Kabi, an operating company of Fresenius, specializing in lifesaving medicines and technologies, announced today that the U.S. Food and Drug Administration (FDA) has granted 510(k) clearance for its Adaptive Nomogram - an alternate algorithm that will be available in the Aurora Xi Plasmapheresis System - designed to optimize plasma collection efficiency.

The newly cleared Adaptive Nomogram considers each donor's individual characteristics in calculating the volume of plasma to collect, enabling an average 11.5% increase in plasma collection per donation while maintaining safe and

effective operation. The Aurora Xi Plasmapheresis System now benefits from enhanced capabilities that allow plasma centers to improve collection efficiency and support a greater supply of plasma-derived therapies.

“This FDA clearance marks a significant step forward for Fresenius Kabi in advancing the efficiency and sustainability of plasma collection,” said Dr. Christian Hauer, President, MedTech at Fresenius Kabi. "The Adaptive Nomogram represents a breakthrough in donor experience innovation, leveraging donor data to deliver one of the most personalized and optimized plasma collection processes available today."

The 510(k) clearance was supported by a multicenter, prospective randomized controlled clinical trial, conducted to evaluate the Adaptive Nomogram in Aurora Xi Software Version 2.0 as compared to Aurora Xi with the existing Optimized Nomogram. The trial entailed more than 52,400 procedures at three of Takeda’s BioLife Plasma donation centers. The primary endpoint - to demonstrate that the overall rate of significant hypotensive adverse events (SHAEs, IQPP DAE Classification 1.2-1.6) in donors using the Aurora Xi Adaptive Nomogram algorithm was less than double the SHAE rate in donors using the Aurora Xi Optimized Nomogram algorithm - was met. The trial also demonstrated that the Adaptive Nomogram increased the volume of plasma collected per completed donation by an average of 88.0 mL (11.5%, plasma without anticoagulant) while increasing procedure time an average of 3 minutes 37 seconds (9.7%).

“This new Adaptive Nomogram will help us personalize each plasma donation and improve our efficiency, while our organization continues to safeguard the health of our donors," said Hema Tallman, Global Head of BioLife Plasma Services at Takeda. "We were grateful for the opportunity to collaborate with Fresenius Kabi on the clinical trial, and we look forward to being the first company to introduce it in our plasma donation centers in the coming months."

Plasma-derived therapies are essential for treating a wide range of conditions, including immune deficiencies, bleeding disorders, and neurological diseases. By increasing plasma collection efficiency, Fresenius Kabi reinforces its commitment to improving access to these critical therapies while supporting the global plasma supply chain.

“The approval of the Adaptive Nomogram testifies to Fresenius Kabi’s dedication to continuous innovation in the field of apheresis,” said Bryan Blickhan, Executive Vice President, MedTech R&D at Fresenius Kabi. “We remain focused on providing state-of-the-art solutions that enable plasma centers to help improve outcomes for both donors and patients.”

Key Facts About the Adaptive Nomogram with Aurora Xi

- Increased Plasma Yield – Enables the collection of an average of 11.5% more plasma per donation, supporting higher production of plasma derived therapies.
- Maintained Donor Safety – The nomogram adjusts collection parameters based on individual donor characteristics, to provide a safe and comfortable experience.
- The Adaptive Nomogram will debut in Takeda’s BioLife plasma donation centers in the United States.

About The Aurora Xi Plasmapheresis System

The Aurora Xi Plasmapheresis System, consisting of the Aurora Xi instrument (hardware and software) and a Plasmacell Xi disposable set, is an automated plasmapheresis system intended for source plasma collection. Whole blood is drawn from the donor and plasma is separated from concentrated cells using a rapidly rotating separator (membrane filter). The plasma is collected in a collection container and residual cellular components are then returned to the donor.

Source Plasma Collection

Source plasma collection is a process in which human plasma is obtained directly from donors, typically through a procedure called plasmapheresis. This plasma is crucial for creating plasma-based therapies used to treat immune deficiencies, blood disorders, and other medical conditions.

About Fresenius Kabi

As a global health care company, Fresenius Kabi is Committed to Life. The company's products, technologies, and services are used for the therapy and care of patients with critical and chronic conditions. With more than 43,000 employees and present in more than 100 countries, Fresenius Kabi's expansive product portfolio focuses on providing access to high-quality and lifesaving medicines and technologies.

In Biopharma, Fresenius Kabi offers cutting-edge biosimilars for autoimmune diseases and oncology. With leading market positions in Clinical Nutrition, a broad portfolio of enteral and parenteral products makes a distinct difference in patients' nutritional status – notably as the only corporation offering both product groups. In MedTech, the company provides vital infusion pumps, cell and gene therapy devices, disposables, and more. Fresenius Kabi is a global leader in supplying blood collection bags and devices, supporting blood banks and health care facilities worldwide. The company's I.V. Generics and Fluids for infusion therapy help save millions of lives every year, in emergency medicine, surgery, oncology, and intensive care.

Fresenius Kabi takes a holistic approach to health care and uniquely combines experience, expertise, innovation, and dedication – making a difference in the lives of almost 450 million patients annually. With Vision 2026, as part of the #FutureFresenius strategy, the company is developing, producing, and selling new products and technologies and aspires to expand its position as a leading global provider of therapies, improve patient care, generate sustainable value for stakeholders – shaping the future of health care.

Fresenius Kabi is an operating company of the Fresenius Group, founded in 1912, along with Helios and Quirónsalud. As ONE team, the companies in the Fresenius Group are committed to providing lifesaving and life-changing health care solutions on a global scale.

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

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, and the availability of financing. Fresenius Kabi does not undertake any responsibility to update the forward-looking statements in this release.

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