December 30, 2025

KORU Medical Systems Announces 510(k) Submission for Clearance of the FreedomEDGE® System with a Commercialized Oncology Biologic

MAHWAH, N.J.--(BUSINESS WIRE)-- **KORU Medical Systems, Inc. (NASDAQ: KRMD) ("KORU Medical" or the "Company"),** a leading medical technology company focused on the development, manufacturing, and commercialization of innovative and patient-centric large volume subcutaneous infusion solutions, today announced the submission of a 510(k) premarket notification to the U.S. Food and Drug Administration (FDA) seeking clearance for the use of KORU Medical's FreedomEDGE® infusion system to subcutaneously administer PHESGO® (pertuzumab/trastuzumab/hyaluronidase-zzxf), a co-formulated therapy for HER2+ breast cancer.[1]

The submission represents a key milestone in KORU Medical's strategy to expand the use of the FreedomEDGE® system beyond its current immunoglobulin (Ig) indications and into the broader oncology infusion center market. The increasing shift from intravenous (IV) to subcutaneous (SC) drug delivery for cancer therapies allows for faster drug administration, reduced patient chair time, and aligns with a movement towards a more efficient care model.[2]

However, despite these advances, infusion centers continue to face unmet needs related to nursing satisfaction with drug administration, including workflow complexity associated with treatment protocol, time constraints for set up and physical discomfort for both patients and nurses during infusions. [3] The FreedomEDGE® system is designed to address these challenges by enabling consistent, controlled large-volume SC delivery while supporting more streamlined clinical workflows.

"The submission of our 510(k) for clearance of the FreedomEDGE® with a subcutaneous oncology biologic is a pivotal milestone for KORU. It sets the foundation for future growth and underscores our strategy to expand KORU's leadership into the growing drug delivery device market for oncology therapies," said Linda Tharby, KORU Medical's President and CEO. "This regulatory filing and expected clearance represents an exciting opportunity to enter a new point of care where we believe our technology can address a meaningful unmet need by improving the administration experience for nurses while supporting greater efficiency in oncology infusion centers."

KORU Medical anticipates a market entry upon FDA 510(k) clearance.

KORU Medical's Freedom Infusion System enables, simplifies, and enhances the delivery of large-volume subcutaneous drugs. Supporting drug products with various requirements for

viscosity, flow rate, and delivered drug volume, the Freedom System is market proven with:

- 15+ years on the market
- 45,000+ patients and over 2M infusions annually[4]
- 97% adherence rate and 8 on-label Subcutaneous drugs across 30+ countries[5]

Forward-looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve risks and uncertainties. All statements that are not historical fact are forward-looking statements, including, but not limited to, anticipated 510(k) clearance. Actual results may differ materially from the results predicted. The potential risks and uncertainties that could cause actual results to differ from the results predicted include those risks and uncertainties included under the captions "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2024 and our Quarterly Report on Form 10-Q for the quarter ended September 30, 2025, which are on file with the SEC and available on our website at www.korumedical.com/investors and on the SEC website at www.sec.gov. All information provided in this release and in the attachments is as of December 30, 2025. Undue reliance should not be placed on the forward-looking statements in this press release, which are based on information available to us on the date hereof. We undertake no duty to update this information unless required by law.

About KORU Medical Systems

KORU Medical develops, manufactures, and commercializes innovative and patient-centric subcutaneous infusion solutions that improve quality of life for patients around the world. The Freedom Syringe Infusion System (the "Freedom System") currently includes the Freedom60® and FreedomEDGE® Syringe Infusion Drivers, Precision Flow Rate Tubing™ and High-Flo Subcutaneous Safety Needle Sets™. The Freedom System, which received its first FDA clearance in 1994, is used for self-administration in the home by the patient and/or delivery in a clinical setting by a healthcare professional. Through its Pharma Services and Clinical Trials business, KORU Medical provides products for use by biopharmaceutical companies in feasibility/clinical trials during the drug development process and, as needed, is capable of customizing the Freedom System for clinical and commercial use across multiple drug categories. For more information, please visit **www.korumedical.com.**

References

1. PHESGO® (pertuzumab / trastuzumab / hyaluronidase-zzfx) | A Treatment for HER2-Positive Breast Cancer
2. Wu A, Rutland B, Southworth C. et al. (2025) The Transformative Potential of Large-Volume Subcutaneous Drug Delivery: A Discussion of Current Capabilities and Future Prospects for Pharmaceutical Manufacturers. Discover Pharmaceutical Sciences 1:11. https://doi.org/10.1007/s44395-025-00012-6
3. Majapuro-Hirvonen A, Wilkinson M, Bosshard J, Rutland B. Comparing Mechanical Pump and Manual Push for Short-Duration Subcutaneous Infusions: A Nursing Preference Survey Study. Poster presented at ESID EHA SIOPE Focused Symposium 2025; November 18-20, 2025; Vienna, Austria.
4. KORU Medical Estimates and Third-Party Data on File

5. Rutland B, Bosshard J, Southworth C. Enhancing Drug Adherence and Patient Outcomes: The Role of SCIG Pump Selection in Subcutaneous Immunoglobulin Therapy for Primary Immunodeficiency Disease. Poster presented at: National Home Infusion Association Annual Conference; March 23-27, 2024; Austin TX.

View source version on businesswire.com:
https://www.businesswire.com/news/home/20251230163792/en/

Investor Contact:
Louisa Smith
investor@korumedical.com

Source: KORU Medical Systems