

July 2, 2024



# KORU Medical Systems Receives Regulatory Clearance for FreedomEdge® Infusion System in Japan

MAHWAH, N.J.--(BUSINESS WIRE)-- **KORU Medical Systems, Inc. (NASDAQ: KRMD)** ("**KORU Medical**" or the "**Company**"), a leading medical technology company focused on development, manufacturing, and commercialization of innovative and patient-centric large volume subcutaneous infusion solutions, today announced that its state-of-the-art FreedomEdge® System has received regulatory clearance in Japan for the delivery of multiple drugs, including CSL Behring's Hizentra subcutaneous immunoglobulin (SCIg), Takeda Pharmaceutical's Cuvitru SCIg, and Sobi's Aspaveli paroxysmal nocturnal hemoglobinuria (PNH).

The regulatory milestone marks a significant advancement in patient care in Japan, providing patients and healthcare providers with access to cutting-edge treatment options for Subcutaneous Immunoglobulin therapy (SCIg) and Paroxysmal Nocturnal Hemoglobinuria (PNH). The FreedomEdge® System, known for its reliability, precision, and patient-friendly design, offers convenient and efficient administration of large volume subcutaneous therapies at home and in the clinic.

"We are very pleased to have received regulatory clearance for the FreedomEdge® System in Japan," said Linda Tharby, President and CEO of KORU Medical. "This accomplishment underscores our commitment to advancing healthcare solutions that enhance patients' lives worldwide and further strengthens KORU's expansion into international markets. With the approval of the FreedomEdge System in Japan, we are proud to broaden access to critical therapies, empowering patients and healthcare providers with a reliable and user-friendly drug delivery platform."

The FreedomEdge System is designed to meet the diverse needs of patients and healthcare professionals, offering customizable features for personalized treatment experiences. Its compact and portable design allows for flexibility in treatment administration, enabling patients to manage their therapy effectively in various settings.

## About KORU Medical Systems

KORU Medical Systems develops, manufactures, and commercializes innovative and patient-centric large volume 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 HlgH-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 an ambulatory infusion center by

a healthcare professional. Through its Novel Therapies 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](http://www.korumedical.com).

## **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, including but not limited to those relating to the success of the feasibility study and the commercialization timing of a device for the oncology biologic drug. Actual results may differ materially from these statements due to potential risks and uncertainties such as, among others, results of the feasibility study, successful development of the system, obtaining regulatory clearances, and by those risks and uncertainties included under the captions "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2023, which is on file with the SEC and available on our website at [www.korumedical.com/investors](http://www.korumedical.com/investors) and on the SEC website at [www.sec.gov](http://www.sec.gov). All information provided in this release and in the attachments is as of July 2, 2024. 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.

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