

KORU Medical Systems Announces Phase III Clinical Trial Collaboration for a New Drug Indication in Nephrology

MAHWAH, N.J.--(BUSINESS WIRE)-- KORU Medical Systems (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 a collaboration with a global pharmaceutical manufacturer on a Phase III clinical trial for an expanded indication of a commercialized drug therapy. The expanded indication is intended to treat a rare renal disorder in a population of approximately 30,000 patients with a projected 300,000 annual infusions.

This announcement highlights an additional collaboration between KORU Medical and its partners in the development of novel therapies and enhanced drug delivery experiences for patients living with rare conditions. The Phase III trial aims to assess the safety, efficacy, and performance of the drug to treat patients with complications from kidney transplants.

"We continue to see growth in the overall large volume subcutaneous market with multiple new drugs entering clinical trials and several others receiving regulatory approval. With over 2 million infusions administered on the KORU Freedom Infusion System every year, KORU continues to be a leading collaboration partner for large volume subcutaneous drug therapies in both the home and infusion clinic settings," said Linda Tharby, President and CEO of KORU Medical. "Assuming successful completion and results from this Phase III clinical trial, this drug's expanded indication will give us access to a new patient base and enable the delivery of a therapy to improve the lives of those with rare renal disorder."

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 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 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.

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 the success of the Phase III trial, success of the regulatory clearance, number of potential infusions available to the Freedom Infusion System. Actual results may differ materially from these statements due to potential risks and uncertainties such as 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 and on the SEC website at www.sec.gov. All information provided in this release and in the attachments is as of January 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.

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