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KORU Medical Systems, Inc. Announces 510(K) Submission for Freedom60® Infusion System With Hizentra® 50 mL Prefilled Syringes

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 easy-to-use specialty subcutaneous infusion solutions that improve quality of life for patients, today announced that it has submitted a 510(k) premarket notification submission to the U.S. Food and Drug Administration for the use of its FREEDOM60® Infusion System with Hizentra® 50 mL prefilled syringes.

"This submission is another milestone in KORU Medical's mission to make subcutaneous therapy radically simpler and easier for patients. Through this application for the use of the Freedom60 Infusion System with Hizentra 50 mL prefilled syringes and our earlier prefilled syringe clearance, we will be able to deliver benefits to all patients who are self-administering subcutaneous immunoglobulin treatment in the home," said Linda Tharby, KORU Medical's President and CEO. "Our studies show up to an 80% reduction in drug preparation tasks for patients using prefilled syringes with the FREEDOM™ Infusion System as compared to vials. With market data showing significant uptake in prefilled syringe market growth, this 510(k) submission is another innovation milestone for KORU Medical that will further enhance the patient experience and potentially be an additional growth driver for home subcutaneous therapy."

The FDA approved the 50 mL Hizentra prefilled syringe in April 2023. Hizentra is the most prescribed subcutaneous immunoglobulin and the first to be available in prefilled syringes.

About KORU Medical Systems

KORU Medical Systems develops, manufactures, and commercializes innovative and easy-to-use subcutaneous drug delivery systems that improve quality of life for patients around the world. The FREEDOM Infusion System currently includes the FREEDOM60® and FreedomEdge® Syringe Infusion Drivers, Precision Flow Rate Tubing™ and HIgH-Flo Subcutaneous Safety Needle Sets™. These devices are used for infusions administered in the home and alternate care settings. For more information, please visit www.korumedical.com.

Forward Looking Statements

This press release contains certain forward-looking statements regarding KORU Medical's

510(k) premarket notification for the use of its FREEDOM60 Infusion System with Hizentra 50 mL prefilled syringes and the growth of the prefilled syringe market and home subcutaneous therapy. Forward-looking statements involve risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statements, and there can be no assurance that KORU Medical will obtain 510(k) clearance or as to the timing of any such clearance. Many of these risks and uncertainties are beyond KORU Medical's control, including without limitation, risks relating to regulatory clearance and market acceptance of the use of the FREEDOM60 Infusion System with Hizentra 50 mL prefilled syringes. KORU Medical expressly disclaims any undertaking to update any forward-looking statements set forth herein to reflect events or circumstances after the date hereof, except as required by applicable laws or regulations.

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