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KORU Medical Announces FDA Clearance for Delivery of Hizentra® Prefilled Syringes

KORU Medical's Freedom Edge becomes the only device specifically cleared for delivery of subcutaneous Ig prefilled syringes

CHESTER, N.Y.--(BUSINESS WIRE)-- **Repro Med Systems, Inc. dba 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 easy-to-use specialty infusion solutions that improve quality of life for patients, today announced 510k clearance for use of the KORU Medical FreedomEdge® infusion pump to deliver Hizentra® [immune globulin subcutaneous (human) 20% liquid] 20 mL prefilled syringes. Hizentra® is the most prescribed subcutaneous Ig product and the first to be available in a prefilled syringe format.

“Our patients who use prefilled syringes tell us that their infusions are significantly easier. With the FreedomEdge® they simply place syringes in the pump and infuse, avoiding the drug transfer process that many patients find difficult and stressful. We’re excited to see KORU Medical’s commitment to improve patient satisfaction by getting this important FDA clearance,” said Amy Ehlers, Senior Director of Clinical Programs at NuFactor, a leading specialty infusion pharmacy.

“As the leader in home delivery of subcutaneous immunoglobulin therapy, we are thrilled to add Hizentra® prefilled syringes to our label,” said Linda Tharby, KORU Medical’s Chief Executive Officer. “KORU Medical is committed to improving the patient home infusion experience. The KORU Medical FreedomEdge is the only infusion pump specifically indicated for delivery of a subcutaneous immunoglobulin prefilled syringe product. We will continue to innovate to improve patient comfort and support the innovations developed by our biopharmaceutical relationships such as CSL Behring.”

About KORU Medical Systems

KORU Medical Systems develops, manufactures, and commercializes innovative and easy-to-use specialty infusion solutions that improve quality of life for patients around the world. The FREEDOM Syringe Infusion System currently includes the FREEDOM60® and FreedomEdge® Syringe Infusion Drivers, Precision Flow Rate Tubing™ and HlgH-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.

Trademark Statement

The trademark is property of CSL Behring.

Forward-looking Statements

This press release contains forward-looking statements that involve risks and uncertainties. Forward-looking statements can be identified by words such as “will”, “seeks to”, and “trend”. 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, among others, actual performance of the parties under the collaboration, patient demand for new in-home infusion products, and those risks and uncertainties included under the captions “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2020, which is available on the SEC website at www.sec.gov and on our website at www.korumedical.com/investors. All information provided in this release and in the attachments is as of November 10, 2021 and 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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