Rockwell Medical, Inc. Enters into Exclusive License and Supply Agreements with Sun Pharma for the Rights to Commercialize Triferic® in India

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- Sizable and growing market opportunity with 120,000+ patients receiving hemodialysis annually –

WIXOM, Mich., Jan. 14, 2020 (GLOBE NEWSWIRE) -- Rockwell Medical, Inc. (NASDAQ:RMTI) ("Rockwell Medical" or the "Company"), a biopharmaceutical company dedicated to transforming anemia management and improving outcomes for patients around the world, today announced that it has entered into license and supply agreements with a wholly-owned subsidiary of Sun Pharmaceutical Industries Ltd. (together, "Sun Pharma"), for the rights to commercialize Triferic (ferric pyrophosphate citrate) in India.

Under the terms of the agreements, Sun Pharma will be the exclusive development and commercialization partner for Triferic in India and Rockwell Medical will supply the product to Sun Pharma. In consideration for the license, Rockwell Medical will receive an upfront fee, and will be eligible for milestone payments and royalties on net sales.

Sun Pharma is the largest pharmaceutical company in India, with more than $4 billion in annual sales globally. Sun Pharma will leverage its market leading nephrology franchise to promote Triferic to nephrologists in India. A Joint Alliance Committee, comprised of members from Rockwell Medical and Sun Pharma, will guide the development and execution for Triferic in India. Sun Pharma will be responsible for all clinical, regulatory and commercialization activities.

"We are pleased to establish this important relationship with Sun Pharma, which has a strong presence in the nephrology segment in India. With a dedicated business unit, market leading sales force and medical support personnel, together with its experience with license and distribution partnerships with large global pharmaceutical companies, Sun Pharma is well positioned to ensure that hemodialysis patients have access to our innovative therapeutic. This is a meaningful advancement for Triferic as we expand our global footprint and drive the long-term value of Triferic," said Stuart Paul, President and Chief Executive Officer of Rockwell Medical.

About Rockwell Medical
Rockwell Medical is a biopharmaceutical company dedicated to transforming anemia management in a wide variety of therapeutic areas and across the globe, improving the lives of very sick patients. The Company's initial focus is the treatment of anemia in end-stage renal disease (ESRD). Rockwell Medical's exclusive renal drug therapy, Triferic (ferric pyrophosphate citrate), is the only FDA-approved therapeutic indicated for iron replacement and maintenance of hemoglobin in hemodialysis patients. The Company has developed multiple formulations of Triferic (1) FDA-approved Dialysate Triferic, and (2) I.V. Triferic, for which the Company filed a New Drug Application in May 2019. Rockwell Medical is also an established manufacturer, supplier and leader in delivering high-quality hemodialysis concentrates/dialysates to dialysis providers and distributors in the U.S. and abroad. Please visit www.rockwellmed.com for more information.

About Sun Pharmaceutical Industries Ltd. (CIN - L24230GJ1993PLC019050)
Sun Pharma is the world's fourth largest specialty generic pharmaceutical company and India's top pharmaceutical company. A vertically integrated business and a skilled team enables it to deliver high-quality products, trusted by customers and patients in over 100 countries across the world, at affordable prices. Its global presence is supported by manufacturing facilities spread across 6 continents and approved by multiple regulatory agencies, coupled with a multi-cultural workforce comprising over 50 nationalities. Sun Pharma fosters excellence through innovation supported by strong R&D capabilities across multiple R&D centers, with investments of approximately 7% of annual revenues in R&D. For further information, please visit www.sunpharma.com & follow us on Twitter @SunPharma_Live.

About Triferic
Triferic is the only FDA-approved therapy in the U.S. indicated to replace iron and maintain hemoglobin in hemodialysis patients via dialysate during each dialysis treatment. Triferic has a unique and differentiated mechanism of action which has the potential to benefit patients and health care economics. Triferic represents a potential innovative medical advancement in hemodialysis patient iron management– with the potential to become the future standard of care.

Triferic delivers approximately 5-7 mg iron with every hemodialysis treatment to the bone marrow and maintains hemoglobin without increasing iron stores (ferritin). Triferic donates iron immediately and completely to transferrin (carrier of iron in the body) upon entry into the blood and is then transported directly to the bone marrow to be incorporated into hemoglobin, with no increase in ferritin (stored iron and inflammation) and no reports of anaphylaxis in over 1,000,000 patient administrations, addressing a significant medical need in overcoming Functional Iron Deficiency (FID) in ESRD patients. Please visit www.triferic.com to view the Triferic mechanism-of-action (MOA) video and for more information.

Important Safety Information
Serious hypersensitivity reactions, including anaphylactic-type reactions, some of which have been life-threatening and fatal, have been reported in patients receiving parenteral iron products. Patients may present with shock, clinically significant hypotension, loss of consciousness, and/or collapse. Monitor patients for signs and symptoms of hypersensitivity during and after hemodialysis until clinically stable. Personnel and therapies should be immediately available for the treatment of serious hypersensitivity reactions. Hypersensitivity reactions have been reported in 1 (0.3%) of 292 patients receiving Triferic in two randomized clinical trials.

Iron status should be determined on pre-dialysis blood samples. Post dialysis serum iron parameters may overestimate serum iron and transferrin saturation.

The most common adverse reactions (≥3% and at least 1% greater than placebo) in controlled clinical studies include: procedural hypotension (21.6%), muscle spasms (9.6%), headache (9.2%), pain in extremity (6.8%), peripheral edema (6.8%), dyspnea (5.8%), back pain (4.5%), pyrexia

(4.5%), urinary tract infection (4.5%), asthenia (4.1%), fatigue (3.8%), arteriovenous (AV) fistula thrombosis (3.4%), and AV fistula site hemorrhage (3.4%).

For more information, including full prescribing information, visit: http://www.triferic.com.

Forward-Looking Statements
Certain statements in this press release may constitute "forward-looking statements" within the meaning of the federal securities laws, including, but not limited to, Rockwell Medical's intention to bring to market Triferic, and I.V. Triferic. Words such as "may," "might," "will," "should," "believe," "expect," "anticipate," "estimate," "continue," "could," "plan," "potential," "predict," "forecast," "project," "intend" or similar expressions, or statements regarding intent, belief, or current expectations, are forward-looking statements. While Rockwell Medical believes these forward-looking statements are reasonable, undue reliance should not be placed on any such forward-looking statements, which are based on information available to us on the date of this release. These forward-looking statements are based upon current estimates and assumptions and are subject to various risks and uncertainties (including, without limitation, those set forth in Rockwell Medical's SEC filings), many of which are beyond our control and subject to change. Actual results could be materially different. Risks and uncertainties include: statements about the issuance of a unique J code for our Triferic Powder Packet; timing and regulatory approval process for Dialysate Triferic in China; the potential market opportunity and commercialization of Dialysate Triferic in China upon regulatory approval; timing and regulatory approval process of our NDA filing for I.V. Triferic as filed with the FDA; potential market opportunity for I.V. Triferic, as well as other Rockwell Medical products; CMS' announced final rule relating to eligibility criteria for TDAPA; liquidity and capital resources; expected duration of Rockwell Medical's existing working capital; the success of our commercialization of Dialysate Triferic, which commenced in May 2019; and timing and success of our efforts to maintain, grow and improve the profit margin of the Company's concentrate business. Rockwell Medical expressly disclaims any obligation to update or alter any statements whether as a result of new information, future events or otherwise, except as required by law.

Triferic® is a registered trademark of Rockwell Medical, Inc.

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