Rockwell Medical, Inc. Provides Business Update

February 27, 2020

-- Continued progress for Triferic® portfolio --
-- 77% increase in the number of clinics under contract --

WIXOM, Mich., Feb. 27, 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 provided a business update and information related to the launch of Dialysate Triferic® (ferric pyrophosphate citrate).

Key Business Updates and Highlights for the Quarter Ended December 31, 2019

- 77% sequential-quarter increase in the number of clinics contracted to purchase Dialysate Triferic, and a 67% increase in the number of annualized treatments under contract.
- 75% of the clinics that completed an Evaluation Program for Dialysate Triferic in the fourth quarter have converted to commercial customers.
- Signed an agreement with a Medium-Sized Dialysis Organization (MDO) for the purchase of Dialysate Triferic in late November 2019. As of December 31, 2019, five clinics within this MDO had purchased Dialysate Triferic, and Rockwell Medical expects clinic adoption to accelerate during the first half of 2020. Approximately 160 clinics within the MDO are candidates for Dialysate Triferic.
- Strengthened and expanded medical capabilities, including the hiring of Marc Hoffman, MD, as Chief Medical Officer, appointment of Russell Ellison, MD, to the Board of Directors, and the appointment of three world-renowned nephrologists to the Company’s Medical Advisory Board.

“We are encouraged by the positive trends in adoption we are seeing as we roll out the Triferic platform in the U.S. The recent signing of a Medium-Sized Dialysis Organization is a meaningful accomplishment, as it extends our reach in transforming anemia management for hemodialysis patients and represents a sizable sales opportunity. To support our commercial activities, we continue to build out our medical capabilities through the additions of prominent anemia and ESRD experts to our management team, Board of Directors and Medical Advisory Board. Our near-term efforts remain focused on driving adoption of our innovative therapeutic and to ensuring that Triferic is available to the patients who can benefit,” stated Stuart Paul, President and Chief Executive Officer of Rockwell Medical.

Rockwell Medical will host its quarterly earnings call on March 12, 2020, at which time it will provide a more detailed business update and discuss financial results for the three and twelve months ended December 31, 2019.

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.

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.

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.

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 expectations regarding the consummation of the offering, the terms of the offering, and the satisfaction of customary closing conditions with respect to the offering and the anticipated use of the net proceeds of the offering. 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: changes to the offering as a result of market conditions or for other reasons, the risk that the offering will not be consummated, and the impact of general economic, industrial or political conditions in the United States or internationally, as well as those risks more fully discussed in Rockwell Medical’s SEC filings. Accordingly, you should not place undue reliance on these forward-looking statements. 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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