Rockwell Medical, Inc. Expands Medical Capabilities

November 20, 2019

– Company adds experienced medical executive to management team and leading nephrologists to Medical Advisory Board –

– Objective to become a leading medical organization in the field of dialysis –

WIXOM, Mich., Nov. 20, 2019 (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 the Company is expanding its medical capabilities, with the initial goal of building a leading medical organization in the field of dialysis. The Company believes that its Triferic® (ferric pyrophosphate citrate) platform has the potential to transform the way anemia is treated in end-stage renal disease (ESRD) patients. As a result, the Company is making investments in its medical organization, real-world data and medical educational programs, and clinical development capabilities.

Through the ongoing development and commercialization of Dialysate Triferic, and in preparation for the potential approval of I.V. Triferic in 2020, the Company has identified the following key medical priorities to establish and position Triferic as the standard of care in anemia over the next three to five years:

- Development of relationships with Centers of Excellence to assist the Company with real- world data collection, education of the dialysis community, and guidance for various aspects of anemia management and the use of Triferic;
- Collection and analysis of additional retrospective and prospective data to support the real-world impact of Triferic on clinical and health-economic outcomes;
- Enhancement of, and investment in, the Company’s medical affairs capabilities, including engagement with Key Opinion Leaders (KOLs), increased interaction with patient and physician advocacy groups, data publications and abstracts to drive expanded awareness of Triferic;
- Expansion of the Company’s medical education capabilities to challenge an entrenched standard of care and educate clinicians about the unique scientific attributes and benefits of Triferic; and
- Addition of global clinical development expertise to: (1) guide the development of Triferic in key geographies in collaboration with current and future partners; and (2) further explore the clinical and pharmacoeconomic attributes of Triferic to address anemia in ESRD and other medical indications.

With the establishment of these priorities, Rockwell Medical has appointed Marc Hoffman, MD as Chief Medical Officer (CMO). Dr. Hoffman’s skillset will complement the Company’s existing medical capabilities and enable the Company to drive these key medical priorities. Dr. Hoffman has extensive experience building and providing medical affairs and clinical development capabilities for pharmaceutical companies, through both in-house roles at companies such as Baxter and Hospira and in senior leadership positions at various contract research organizations (CROs), including Covance and, most recently, Celerion Inc. Throughout his distinguished 30-year career, Dr. Hoffman has established medical affairs capabilities in order to harness the data needed to develop and commercialize pharmaceutical products worldwide. The Company believes that Dr. Hoffman’s expertise will further complement and enable the Company to accelerate the execution of the Company’s key medical initiatives.

Dr. Raymond Pratt, the Company’s current CMO, will transition to a new role as Chief Development Officer. In this role, Dr. Pratt will be responsible for managing the global clinical development and regulatory approval pathway of Triferic in ESRD. Dr. Pratt has significant experience in drug development in nephrology, including leading the development and FDA approval of Dialysate Triferic. Specifically, Dr. Pratt will continue to work on the New Drug Application for I.V. Triferic, which is currently under review by the FDA with a PDUFA date of March 28, 2020, and the development and regulatory submission for Triferic in various countries across the globe in coordination with the Company’s partners.

Dr. Ajay Gupta, the Company’s Chief Scientific Officer, will continue to focus on the scientific foundation and applications of the Triferic platform. As a nephrologist with deep knowledge of the physiology of anemia and in the mechanism of action of Triferic, Dr. Gupta works closely with worldwide KOLs in anemia to advance clinical approaches to improve patient outcomes.

In addition, Rockwell Medical is adding several leading nephrologists to its Medical Advisory Board. The members of the Medical Advisory Board will provide critical advice to the Company as it seeks to accomplish the goals identified above. The additions include:

- Steven Fishbane, MD, Chief of Nephrology of Northwell Health and Professor of Medicine at the Zucker School of Medicine. Dr. Fishbane is a nephrologist with over 25 years of clinical experience and over 24 years as a medical researcher with more than 210 peer-reviewed publications. He has received multiple honors and holds several appointments, including to the National Quality Forum’s Standing Committee of Admissions and Readmissions. Through his clinical research, Dr. Fishbane has become renowned for advancement and innovation in the treatment of chronic kidney disease patients.

- Jay Wish, MD, Professor of Clinical Medicine at Indiana University School of Medicine in Indianapolis and Chief Medical Officer for Dialysis at Indiana University Health. Dr. Wish has a distinguished career in the field of nephrology and dialysis, which includes serving on the Board of Directors of Renal Physicians Association and the American Association of Kidney Patients (AAKP), where he received AAKP’s Visionary Award in 2005. Dr. Wish is Vice Chairman of the Editorial Advisory Board for Nephrology News & Issues and serves on the editorial boards of the Journal of the American Society of Nephrology and Clinical Journal of the American Society of Nephrology. At the American Society of Nephrology Conference on November 8, 2019, Dr. Wish presented on Triferic in a symposium entitled “Advances in Hemodialysis-Associated Anemia Management: The Benefits of Physiologic Iron Replacement Therapy.”

- Anatole Besarab, MD, a nephrologist who has served as the Chair and Co-Chair of the NKF Workgroup on Vascular Access. Dr. Besarab has

also served on various committees for the FORUM of ESRD networks, the ASN, NKF, ASAIO, and the NIH. He is the author of more than 215 peer reviewed papers, 28 chapters, and 17 monographs. His work has focused primarily on optimizing the management of anemia, particularly on the proper balance between erythropoiesis and iron delivery. He has also served as lead investigator on clinical trials involving HIF-PHI inhibitors.

“To achieve our goal of transforming anemia management for dialysis patients, we are making specific investments in our medical expertise, real world and clinical data, as well as medical education programs,” said Stuart Paul, President and Chief Executive Officer of Rockwell Medical. “We are thrilled to welcome Dr. Hoffman to our executive leadership team, and we expect his proven track record in building, managing and globalizing medical teams and expertise in data management will be an asset as we position our Company for growth. In parallel, I am delighted that we have assembled a Medical Advisory Board of world-renowned experts in anemia and ESRD who can contribute their significant experience to help guide the further development and commercialization of Triferic,” concluded Mr. Paul.

“I am delighted to join the Rockwell Medical team at this pivotal time and to lead the effort to expand the Company’s real-world evidence dataset, educate the renal community about the innovative attributes of Triferic in managing anemia in ESRD patients, and advance the Company’s medical affairs strategy. Triferic, in its various formulations, is innovative and offers both clinical and potential pharmacoeconomic benefits. I look forward to working with Dr. Pratt and Dr. Gupta, while contributing to the development of a strong medical and clinical support team and to advancing adoption of this important therapeutic,” stated Dr. Hoffman.

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, 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 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 provide significant benefits to patients and health care economics. Triferic represents one of the most innovative medical advancements in patient iron management in the past few decades – with the potential to be 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). Unlike traditional IV iron products, 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.

Notice of Issuance of Inducement Grants
Pursuant to his employment agreement, Dr. Hoffman will be awarded stock-based compensation representing the right to acquire shares of common stock (the “Inducement Grants”). The Inducement Grants will consist of options to purchase up to 250,000 shares of common stock, subject to time-based vesting conditions. The Inducement Grants will be issued upon Dr. Hoffman’s commencement of employment (the “Grant Date”), and all stock options included within the Inducement Grants will have an exercise price equal to the fair value of the common stock on the Grant Date. The Inducement Grants have been approved by the Company’s Board of Directors and the Compensation Committee of the Board of Directors. The Inducement Grants will be issued outside of the Company’s shareholder-approved equity incentive plans as an inducement grant, in accordance with Nasdaq Listing Rule 5635(c)(4).

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; the pricing and reimbursement status for I.V. Triferic under CMS' final rule relating to TDAPA as announced by CMS on October 31, 2019; 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.

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