Rockwell Medical, Inc. to Sponsor Triferic® Exhibitor Spotlight Presentation at American Society of Nephrology Conference

November 7, 2019

WIXOM, Mich., Nov. 07, 2019 (GLOBE NEWSWIRE) -- Rockwell Medical, Inc. (NASDAQ:RMTI) (“Rockwell Medical” or the “Company”), a biopharmaceutical company dedicated to improving outcomes for patients with anemia, with an initial focus on end-stage renal disease (ESRD), today announced that the Company will sponsor a Triferic (ferric pyrophosphate citrate) Exhibitor Spotlight presentation at the American Society of Nephrology (ASN) Kidney Week 2019 Conference in Washington, D.C. on Friday, November 8, 2019.

Presentation Title:	Advances in Hemodialysis-Associated Anemia Management: The Benefits of Physiologic Iron Replacement Therapy
Presenter:	Jay B. Wish, MD, Professor of Clinical Medicine, Chief Medical Officer for Dialysis, Indiana University Health
Date:	Friday, November 8, 2019
Time:	10:00 am – 11:00 am
Location:	Walter E. Washington Convention Center, Exhibit Hall, Theater #1, Washington, D.C.

In today’s clinical practice, it is very common to use traditional intravenous (IV) iron for repeated replacement of ongoing iron losses in chronic hemodialysis patients. This practice results in increased iron stores together with systemic inflammation.[1] The long-range safety of such regular weekly or monthly traditional intravenous iron dosing regimens is a subject of some concern and controversy.[2] Adverse effects of traditional intravenous iron may be concealed by their resemblance to common comorbidities in dialysis patients, such as infection, cardiovascular disease, and early mortality.[3] Evidence of the negative effects of iron overload and other risks associated with long-term use of intravenous iron continues to build.[3]

Unlike traditional IV iron, Triferic replaces dialysis patients’ ongoing iron losses by providing iron with every hemodialysis treatment that is 100% bioavailable and maintains hemoglobin without increasing iron stores (ferritin). Triferic has a safety profile similar to placebo, with few Triferic-related serious adverse events reported in over 1,000,000 patient administrations.[4,5]

“We are very excited to have a clinician of Dr. Wish’s distinction and expertise speak on behalf of Triferic and believe this will be an extremely valuable presentation for all nephrologists who deal with issues around anemia management. Educating the medical community about the profile of Triferic through engagement with esteemed medical leaders is critical to get this important therapeutic to more patients,” said Stuart Paul, President and Chief Executive Officer of Rockwell Medical.

About Triferic
Triferic is the only FDA-approved therapy indicated to replace iron and maintain hemoglobin in hemodialysis patients via dialysate during each dialysis treatment. 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. 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 with a PDUFA date of March 28, 2020. Please visit www.TRIFERIC.com to view the Triferic mode-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.

About Rockwell Medical
Rockwell Medical is a biopharmaceutical company dedicated to improving outcomes for patients with anemia, with an initial focus on end-stage renal disease (ESRD) and chronic kidney disease (CKD). Rockwell Medical's exclusive renal drug therapy, Triferic, supports disease management initiatives

to improve the quality of life and care of dialysis patients and is intended to deliver safe and effective therapy, while decreasing drug administration costs and improving patient convenience. The Company has developed multiple formulations Triferic: (1) Dialysate Triferic; and (2) I.V. Triferic. Dialysate Triferic is the only FDA-approved therapeutic indicated for iron replacement and maintenance of hemoglobin in hemodialysis patients. The Company's strategy is to bring its therapeutics to market in the United States and to utilize partners to develop and commercialize such therapeutics in international markets. 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.

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," "potential," "predict," "forecast," "project," "plan," "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 timing of data readouts; the timing for the ruling from CMS; potential market opportunity for I.V. Triferic, as well as other Rockwell Medical products; pricing and reimbursement status for I.V. Triferic and other Rockwell Medical products, including the eligibility of I.V. Triferic for add-on reimbursement under TDAPA; liquidity and capital resources; expected duration of Rockwell Medical's existing working capital; success of our recently announced commercialization of Dialysate Triferic; 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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Source: Rockwell Medical, Inc.

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1. Monitor DP: DOPPS 6. In, 2019
2. Macdougall IC, White C, Anker SD, et al. Intravenous Iron in Patients Undergoing Maintenance Hemodialysis. *The New England Journal of Medicine* 2019; 380: 447-458.
3. Kalantar-Zadeh K, Regidor DL, McAllister CJ, Michael B, Warnock DG. Time-dependent associations between iron and mortality in hemodialysis patients. J Am Soc Nephrol. 2005;16(10):3070-3080
4. Fishbane SN, Singh AK, Cournoyer SH,et al. Ferric pyrophosphate citrate (Triferic®) administration via the dialysate maintains hemoglobin and iron balance in chronic hemodialysis patients. Nephrol Dial Transplant. 2015;30(12):2019-2026.
5. Data on file. Wixom, MI; Rockwell Medical, Inc.

Source: Rockwell Medical, Inc.