Rockwell Medical, Inc. Announces Acceptance by FDA of New Drug Application for I.V. TRIFERIC®

August 6, 2019

–FDA establishes PDUFA date of March 28, 2020 for I.V. Triferic –

WIXOM, Mich., Aug. 06, 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) and chronic kidney disease (CKD), announced today that the U.S. Food and Drug Administration (FDA) has accepted for filing the Company's New Drug Application (NDA) for its Intravenous (I.V.) formulation of TRIFERIC® with a PDUFA (Prescription Drug User Fee Act) date of March 28, 2020.

In May 2019, the Company launched the first product from its portfolio, Dialysate Triferic. Dialysate Triferic is mixed with liquid bicarbonate to deliver iron to patients via the dialysate, while I.V. Triferic is designed for intravenous administration to patients. As a result, if approved, I.V. Triferic would allow dialysis centers to administer Triferic to patients regardless of the mode of bicarbonate delivery being used.

"We are pleased to announce the FDA's acceptance of our I.V. Triferic NDA. This announcement follows shortly after the commercial launch of Dialysate Triferic. If approved, the I.V. formulation would complement Dialysate Triferic and expand the global market potential of our Triferic portfolio," said Stuart Paul, President and Chief Executive Officer of Rockwell Medical.

I.V. Triferic for adult hemodialysis patients was developed pursuant to a Special Protocol Assessment (SPA), through which the FDA agreed that an equivalence approach to Triferic delivered via hemodialysate (Dialysate Triferic) would be acceptable for review. The NDA is supported by data from the Company's equivalence study, which demonstrated that I.V. Triferic delivers the same quantity of iron to patients as the Company's FDA-approved Dialysate Triferic formulation. An open-label, randomized, multiple-period single dose study was conducted to establish the equivalence of doses between dialysate and I.V. administration. Results of this study were presented at the Annual Dialysis Conference ("ADC") on March 18, 2019.

Information regarding the I.V. Triferic Study Abstract presented at ADC can be found in the Company's Press Release, dated March 18, 2019.

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 675,000 patient administrations, addressing a significant medical need in overcoming Functional Iron Deficiency (FID) in ESRD patients. The Company has developed multiple formulations: (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, Inc.
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: (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 about the Company.

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," "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'sSEC 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; the period of review and approval by the FDA of our NDA submission for I.V. Triferic; the potential market opportunity for I.V. Triferic and other Rockwell Medical products; pricing and reimbursement status for I.V. Triferic, Dialysate Triferic and other Rockwell Medical products, including, the eligibility of I.V. Triferic for add-on reimbursement under TDAPA under CMS' preliminary proposed rules as announced by CMS on July 29, 2019; liquidity and capital resources; expected duration of Rockwell Medical's existing working capital; success of our recently announced commercialization plans for 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.

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