Rockwell Medical, Inc. Appoints John P. McLaughlin Chairman of the Board of Directors

October 31, 2019

WIXOM, Mich., Oct. 31, 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 the appointment of John P. McLaughlin as its Chairman of the Board, effective immediately. Mr. McLaughlin, who joined the Board on September 5, 2019, succeeds Benjamin Wolin, who will remain on the Board of Directors.

“This is a truly pivotal time for Rockwell Medical with the recent commercial launch of Dialysate Triferic® (ferric pyrophosphate citrate) and the filing for approval of I.V. Triferic. I am honored to serve as Chairman of the Board of Directors and look forward to working with the rest of Rockwell Medical’s talented Board and management team as the Company works to transform anemia management in a variety of disease states around the globe and establish Triferic as the standard of care for anemia management in ESRD patients. We are grateful to Ben for his service as Chairman, and we are excited that he will remain an active member of the Board,” said John P. McLaughlin, Chairman of the Board.

Mr. McLaughlin currently also serves on the Board of PDL BioPharma, Inc. where he was Chief Executive Officer for 10 years; Noden Pharma DAC, a Dublin-based pharma company that commercializes hypertension drugs worldwide; and Lensar Inc., a medical technology company that commercializes lasers for refractive cataract surgery worldwide. He has previously co-founded and sold, as well as served on the boards of, a number of biotechnology and medical technology companies.

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 of 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," "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'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, pursuant to 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 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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