Rockwell Medical, Inc. Appoints Industry Veteran John P. McLaughlin to Board of Directors

September 5, 2019

WIXOM, Mich., Sept. 05, 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), today announced the appointment of John P. McLaughlin to its Board of Directors.

Mr. McLaughlin has a strong understanding of the biotechnology industry and over 30 years of experience relating to the development, regulation and commercialization of pharmaceuticals, as well as finance, corporate governance matters and strategic alliances.

“We are delighted to welcome John to our Board of Directors. John’s broad experience in management and board positions for companies in the biopharmaceutical industry make him an ideal addition to our Board. We look forward to benefiting from his perspectives as we continue to advance and execute our business plan,” said Benjamin Wolin, Chairman of the Board of Directors of Rockwell Medical.

“This is an important and exciting 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 pleased to join the Board of Directors and look forward to working with the rest of the Board and Management to ensure that these two clinically important therapeutics are available to all hemodialysis patients and that the healthcare system understands the products’ efficacy, safety and pharmaco-economic attributes. By doing so, we expect to create meaningful value for our shareholders,” stated John McLaughlin.

Mr. McLaughlin served as Chief Executive Officer of PDL BioPharma, Inc, from December 2008 until December 2018. Prior to joining PDL, he was the Chief Executive Officer and a Director of Anesiva, Inc., formerly known as Corgentech, Inc., a publicly traded biopharmaceutical company, from January 2000 to June 2008. From December 1997 to September 1999, Mr. McLaughlin was President of Tularik Inc., a biopharmaceutical company. From September 1987 to December 1997, Mr. McLaughlin held a number of senior management positions at Genentech, Inc., a biopharmaceutical company, including Executive Vice President & General Counsel. From January 1985 to September 1987, Mr. McLaughlin was a partner at a Washington, D.C. law firm specializing in food and drug law and has served as counsel to various subcommittees of the United States House of Representatives, where he drafted several measures that later became law.

Mr. McLaughlin has been a Director of PDL since 2008. He also serves on the Board of Directors of Lensar, Inc., a private medical technology company that develops and commercializes femtosec lasers for the treatment of cataracts, and Noden Pharma, a private company that commercializes two hypertension drugs worldwide. Lensar, Inc. and Noden Pharma are primarily owned by PDL. Mr. McLaughlin co-founded and served as Chairman of the Board of Eyetech Pharmaceuticals, Inc., a publicly traded biopharmaceutical company, which was subsequently acquired by OSI Pharmaceuticals, Inc.; co-founded and served as a Director of Peak Surgical, Inc., a private medical device company, until it was acquired by Medtronic in 2011; served as a director of AxoGen, Inc., a publicly traded biopharmaceutical company until 2014; served as a director of Adverum Biotechnologies, Inc., a publicly traded biopharmaceutical company, until 2016; and served as a director of Seattle Genetics, Inc., a publicly traded biopharmaceutical company, until 2016.

Mr. McLaughlin received a B.A. from the University of Notre Dame and a J.D. from Catholic University of America.

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, 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. 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 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 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.

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; 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; 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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