Rockwell Medical, Inc. Announces Completion of Two Clinical Pharmacology Studies of TRIFERIC® in China

August 8, 2019

– Positive data suggests no ethnic difference in Triferic PK in Chinese subjects compared to U.S. subjects –

– China studies indicate similar delivery of iron via dialysate as in U.S. studies –

WIXOM, Mich., Aug. 08, 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 the positive results of two clinical pharmacology trials of Triferic (ferric pyrophosphate citrate) in China.

Rockwell Medical and its partner, Wanbang Biopharmaceuticals (Wanbang), a subsidiary of Shanghai Fosun Pharmaceutical (Group) Co., Ltd., expect to request a meeting with the National Medical Products Administration (NMPA) (formerly, China Food and Drug Administration or CFDA) to review the results of these studies and discuss whether these studies are sufficient to support a submission for regulatory approval for Dialysate Triferic.

The first study was conducted in healthy volunteers to assess the pharmacokinetics of Triferic in the Chinese population. Serum iron levels were assessed in 12 healthy subjects during a baseline period and after a 4-hour infusion of Triferic 6.5 mg intravenously. Data from this study suggest that when compared to Triferic administered to healthy western (U.S.) subjects, PK parameters in Chinese subjects were similar. Although Chinese subjects have a lower lean body mass as compared to western subjects, plasma clearance of the administered Triferic iron was the same.

The second study, conducted in Chinese hemodialysis (HD) patients, assessed the Triferic iron delivery via dialysate. This was a 12 patient two-period crossover study. The PK parameters assessed included serum iron and transferrin saturation (TSAT). Data from this study suggest that administration of Dialysate Triferic in this population shows the same iron transfer as demonstrated in western (U.S.) hemodialysis patients. When compared to U.S. HD patients, Chinese HD patients had a lower lean body mass, but the clearance of Triferic iron was the same.

“We are very encouraged by the results of the two studies. Triferic was well tolerated in both studies with no new safety issues identified. If approved, Triferic could be available in China, one of the largest and fastest growing ESRD markets in the world. This would follow our launch of Dialysate Triferic in the U.S. earlier this year, and significantly expand our global Triferic portfolio,” said Stuart Paul, President and Chief Executive Officer of Rockwell Medical.

In 2016, the Company licensed the commercialization rights for Dialysate Triferic for the Chinese market to Wanbang. Pursuant to Rockwell Medical’s license agreement with Wanbang, the Company is entitled to receive up to $35.0 million of regulatory and sales-based milestone payments, including an $8.0 million milestone payment upon regulatory approval of Triferic in China. Rockwell Medical will supply the finished dosage form of Triferic to Wanbang at transfer price comprising cost of goods sold, mark-up and a percentage of net sales in the low-to-mid 20% range. Under the terms of the licensing agreement, Wanbang is responsible for the cost of the clinical trials and regulatory approval program in China. Rockwell Medical retains manufacturing responsibilities for Triferic for China.

The People’s Republic of China has one of the largest ESRD populations in the world, with more than 400,000 hemodialysis patients. The Company anticipates that commercial sales activity in this market will commence following regulatory or registration approval.

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.

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.

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 timing and regulatory approval process for Dialysate Triferic in China before the NMPA; potential market opportunity and commercialization of Dialysate Triferic in China, as well as for other Rockwell Medical products; the timing and the regulatory approval process of the FDA for I.V. Triferic; 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 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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