



Rockwell Medical, Inc. Commences Commercial Sales of Dialysate Triferic® in the U.S.

May 6, 2019

Company launches first formulation in its Triferic® portfolio

WIXOM, Mich., May 06, 2019 (GLOBE NEWSWIRE) -- Rockwell Medical, Inc. (NASDAQ:RMTI) ("Rockwell Medical" or the "Company"), a global 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 commencement of commercial sales of Dialysate Triferic® in the United States.

Triferic is a novel therapeutic platform for the treatment of anemia that replaces ongoing iron losses by a process similar to that of normal iron metabolism. Triferic is the first and only FDA-approved iron replacement therapy indicated to maintain hemoglobin levels in hemodialysis patients. Its unique and physiologic mechanism of action, excellent safety profile, and potential pharmacoeconomic benefits offer healthcare providers a new alternative in the treatment of anemia in hemodialysis-dependent CKD patients.

The Company has developed multiple formulations of Triferic for the treatment of anemia in adult hemodialysis patients and is now launching the first product, Dialysate Triferic, from its portfolio. The Company expects to file a New Drug Application with the U.S. Food and Drug Administration (FDA) for its next formulation, I.V. Triferic, within the second quarter of 2019.

"Dialysate Triferic is an innovative physiological alternative to existing IV iron formulations," said Marcos Rothstein, M.D., Professor of Medicine in the Division of Nephrology at Washington University School of Medicine in St. Louis. "Dialysate Triferic does not increase iron stores. It has had no cases of anaphylaxis and the infection rate is similar to placebo. Additionally, in patients with reticuloendothelial (RE) block, it overcomes functional iron deficiency."

"We are excited to launch Dialysate Triferic, the first therapeutic in our Triferic portfolio. Our short-term objectives include increasing awareness of Triferic within the dialysis community, building and enhancing relationships with key opinion leaders, and supporting medical education of nephrologists and other clinicians, while generating real-world evidence to support the use of Triferic in adult hemodialysis patients. These efforts are geared towards achieving future and sustained acceptance of Triferic as part of the standard of care in anemia management, and supporting our broader Triferic portfolio," said Stuart Paul, President and Chief Executive Officer of Rockwell Medical.

The Company is initially executing a multi-pronged commercial and medical education approach for Dialysate Triferic, with a focus on dialysis centers that were part of its trial program, as well as select medium-sized, small and independent dialysis organizations that constitute approximately 25% of the U.S. market. Based on the expected sales cycle at dialysis clinics, the Company does not expect material sales for Dialysate Triferic in the second quarter of 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. 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 ($\geq 3\%$ 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 specialty pharmaceutical company targeting end-stage renal disease (ESRD) and chronic kidney disease (CKD) with innovative therapies and products. Rockwell Medical's exclusive renal drug therapies support disease management initiatives to improve the quality of life and care of dialysis patients and are intended to deliver safe and effective therapy, while decreasing drug administration costs and improving patient convenience. The Company has developed multiple formulations of Triferic, 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 Statement

Certain statements in this press release may constitute "forward-looking statements" within the meaning of the federal securities laws. 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 degree of success in marketing Dialysate Triferic, the timing and success of our planned 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, Triferic and other Rockwell Medical products, including eligibility for add-on reimbursement under TDAPA; liquidity and capital resources; expected duration of Rockwell Medical's existing working capital; plans and timing relating to the planned commercialization of Triferic; and timing and success of our efforts to renegotiate economic terms of our 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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