Rockwell Medical, Inc. Receives FDA Approval for Triferic® AVNU (Ferric Pyrophosphate Citrate), Intravenous Formulation of Triferic for Replacement of Iron and Maintenance of Hemoglobin in Hemodialysis Patients

March 27, 2020

– Enhances Triferic platform by providing patients with greater access to Rockwell Medical's innovative therapeutic by expanding administration options for clinicians –

– Major milestone supports the potential for expanding global adoption of Triferic and transforming the standard of care for anemia management in hemodialysis patients –

WIXOM, Mich., March 27, 2020 (GLOBE NEWSWIRE) -- Rockwell Medical, Inc. (NASDAQ:RMTI) ("Rockwell Medical" or the "Company"), a biopharmaceutical company dedicated to transforming anemia management and improving outcomes for patients around the world, today announced that the U.S. Food and Drug Administration ("FDA") has approved its New Drug Application ("NDA") for its intravenous formulation of Triferic, Triferic AVNU. With this approval, Triferic AVNU joins Triferic Dialysate as the only FDA-approved products indicated to replace iron and maintain hemoglobin in adult patients with hemodialysis-dependent chronic kidney disease.

Triferic is a novel, physiologic iron maintenance therapy that provides bioavailable iron to replace iron lost during every dialysis treatment and maintain hemoglobin. While Triferic Dialysate is designed to be administered via liquid bicarbonate, Triferic AVNU is designed for direct intravenous infusion, which provides hemodialysis patients with greater access to the Triferic platform and expands administration options for clinicians. Triferic AVNU can be administered regardless of a dialysis center's mode of bicarbonate delivery. Many dialysis centers in international markets and an increasing number of dialysis centers in the U.S. have converted to the use of dry bicarbonate cartridges or bags and on-line dialysate generation, which is not compatible with Triferic Dialysate.

"The approval of Triferic AVNU is a major milestone as we further progress toward our goal of transforming anemia management across the globe. With Triferic AVNU, more adult hemodialysis patients in the U.S will have access to the benefits of this unique therapeutic, regardless of the way their clinic generates bicarbonate. Clinicians will now have the added flexibility to administer Triferic intravenously to a broader group of patients who can benefit from physiologic iron maintenance therapy to manage their anemia," stated Stuart Paul, President and Chief Executive Officer of Rockwell Medical.

"Clinical trials have demonstrated that patients treated with Triferic receive steady and consistent bioavailable iron to replace the iron that is lost at every dialysis treatment and hemoglobin is maintained. Now, even in clinics where delivering Triferic through the dialysate is not operationally possible, Triferic AVNU is an option. This may be especially important for patients who are difficult to manage, or for other special patient populations," added Dr. Steven Fishbane, Chief of Nephrology of Northwell Health and Professor of Medicine at the Zucker School of Medicine.

Over the next several months, the Company plans to initiate a commercial strategy that leverages the experience gained from the 2019 launch of Triferic Dialysate and lays the groundwork for the commercial introduction of Triferic AVNU. The Company expects to launch Evaluation Programs during the third quarter of 2020 to allow clinics to gain direct experience with Triferic AVNU, and the Company expects Triferic AVNU to be available commercially following the completion of the initial Evaluation Programs.

About Rockwell Medical

Rockwell Medical is a biopharmaceutical company dedicated to transforming anemia management in a wide variety of therapeutic areas and across the globe, improving the lives of very sick patients. The Company's initial focus is the treatment of anemia in end-stage renal disease (ESRD). Rockwell Medical's exclusive renal drug therapy, Triferic (ferric pyrophosphate citrate), is the only FDA-approved therapeutic indicated for iron replacement and maintenance of hemoglobin in hemodialysis patients. 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.

About Triferic

Triferic is the only FDA-approved therapy in the U.S. indicated to replace iron and maintain hemoglobin in hemodialysis patients during each dialysis treatment. Triferic has a unique and differentiated mechanism of action which has the potential to benefit patients and health care economics. Triferic represents a potential innovative medical advancement in hemodialysis patient iron management– with the potential to become the future standard of care. The Company has two FDA-approved formulations of Triferic (1) Triferic Dialysate and (2) Triferic AVNU.

Triferic delivers between 5-7 mg iron with every hemodialysis treatment to the bone marrow and maintains hemoglobin without increasing iron stores (ferritin). 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.

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%).

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 expectations regarding the consummation of the offering, the terms of the offering, and the satisfaction of customary closing conditions with respect to the offering and the anticipated use of the net proceeds of the offering. Words such as “may,” “might,” “will,” “should,” “believe,” “expect,” “anticipate,” “estimate,” “continue,” “could,” “plan,” “potential,” “predict,” “forecast,” “project,” “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 issuance of a unique J code for our Triferic powder packet; timing and regulatory approval process for Triferic Dialysate in China; the potential market and commercialization opportunity of Triferic Dialysate in China upon regulatory approval; the timing, as well as commercialization opportunity and process for Triferic AVNU; the potential domestic and international market opportunity for Triferic AVNU, as well as other Rockwell Medical products; CMS’ announced final rule relating to the eligibility criteria for TDAPA; liquidity and capital resources; expected duration of Rockwell Medical’s existing working capital; the success of our commercialization of Triferic Dialysate, which commenced in May 2019; and the timing and success of our efforts to maintain, grow and improve the profit margin of the Company’s concentrate business; and the impact of general economic, industrial or political conditions, as well as recent health conditions in the United States or internationally, as well as those risks more fully discussed in Rockwell Medical’s SEC filings. Accordingly, you should not place undue reliance on these forward-looking statements. 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.

Contact
Investor Relations:
Lisa M. Wilson, In-Site Communications, Inc.
T: 212-452-2793
E: lwilson@insitecony.com

Source: Rockwell Medical, Inc.

Source: Rockwell Medical, Inc.