



Rockwell Medical Announces U.S. Availability of Triferic® AVNU for Replacement of Iron and Maintenance of Hemoglobin in Patients on Hemodialysis

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WIXOM, Mich., Feb. 09, 2021 (GLOBE NEWSWIRE) -- Rockwell Medical, Inc. (Nasdaq: RMTI), a biopharmaceutical company dedicated to transforming the treatment of iron deficiency and anemia management and improving outcomes for patients around the world, today announced that Triferic AVNU (ferric pyrophosphate citrate injection), the intravenous (IV) formulation of Triferic, is now available to patients in the United States. Triferic AVNU was approved by the U.S. Food and Drug Administration (FDA) in March 2020 and is indicated for the replacement of iron to maintain hemoglobin in adult patients with hemodialysis-dependent chronic kidney disease (HDD-CKD).

"The commercial availability of Triferic AVNU is good news for patients with chronic kidney disease on hemodialysis and their healthcare providers. This IV formulation is an important line extension of Triferic Dialysate," said Russell Ellison, M.D., M.Sc., President and Chief Executive Officer of Rockwell Medical. "With Triferic AVNU, more patients will have access to the benefits of Triferic as providers will have added flexibility to administer the IV formulation to their patients who may benefit from physiologic iron maintenance therapy to manage their anemia."

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 IV 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 online dialysate generation, which is not compatible with Triferic Dialysate.

Triferic AVNU is available for commercial purchase directly through Rockwell Medical and our exclusive distributor, Metro Medical™, a Cardinal Health company, to expand market availability and ease of ordering. Metro Medical has a long history as a leading distributor of pharmaceuticals and medical supplies to nephrology practices and clinic-based dialysis centers in the U.S., the focus market for Triferic ANVU.

About Triferic Dialysate and Triferic AVNU

Triferic Dialysate and Triferic AVNU are the only FDA-approved therapies in the U.S. indicated to replace iron and maintain hemoglobin in hemodialysis patients during each dialysis treatment. Triferic Dialysate and Triferic AVNU have a unique and differentiated mechanism of action, which has the potential to benefit patients and health care economics. Triferic Dialysate and Triferic AVNU represent a potential innovative medical advancement in hemodialysis patient iron management – with the potential to become the future standard of care.

Triferic Dialysate and Triferic AVNU both deliver approximately 5-7 mg iron with every hemodialysis treatment to replace the ongoing losses to maintain hemoglobin without increasing iron stores. Both formulations donate iron immediately and completely to transferrin (carrier of iron in the body), which is then transported to the bone marrow to be incorporated into hemoglobin. Because of this unique mechanism of action, there is no increase in ferritin (a measure of stored iron). Triferic and Triferic AVNU address a significant medical need in treating functional iron deficiency in end-stage kidney disease patients.

The safety profile of Triferic is similar to placebo in controlled clinical trials in patients with end-stage kidney disease. Since approval, there have been no safety related changes to the product labeling.

IMPORTANT SAFETY INFORMATION FOR TRIFERIC AND TRIFERIC AVNU

INDICATION

TRIFERIC and TRIFERIC AVNU are indicated for the replacement of iron to maintain hemoglobin in adult patients with hemodialysis-dependent chronic kidney disease (HDD-CKD).

Limitations of Use

TRIFERIC and TRIFERIC AVNU are not intended for use in patients receiving peritoneal dialysis. TRIFERIC and TRIFERIC AVNU have not been studied in patients receiving home hemodialysis.

Warnings and Precautions

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.

Adverse Reactions

Most common adverse reactions (incidence $\geq 3\%$ and at least 1% greater than placebo) in controlled clinical studies include: headache, peripheral edema, asthenia, AV fistula thrombosis, urinary tract infection, AV fistula site hemorrhage, pyrexia, fatigue, procedural hypotension, muscle spasms, pain in extremity, back pain, and dyspnea.

To report an Adverse Events (AE) or Product Quality Control (PQC) please call the Medical Information Department at (855) 333-4315 or e-mail at rockwell.pharmacovigilance@propharmagroup.com.

For full Safety and Prescribing Information please visit www.Triferic.com and www.Trifericavnu.com.

About Rockwell Medical

Rockwell Medical is a biopharmaceutical company dedicated to transforming iron deficiency and 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 kidney disease. Rockwell Medical's exclusive renal drug therapies, Triferic (ferric pyrophosphate citrate) Dialysate and Triferic AVNU, are the only FDA-approved therapeutics indicated for 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.

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, the impact of COVID-19 on Rockwell Medical's business and operations, the commercialization of Triferic Dialysate, the launch and commercialization of Triferic AVNU, the commercialization and applicability of Triferic AVNU in international markets, and the development plans and timing for Rockwell Medical's FPC pipeline candidates. Words such as, "may," "might," "will," "should," "believe," "expect," "anticipate," "estimate," "continue," "could," "can," "would," "develop," "plan," "potential," "predict," "forecast," "project," "intend" or the negative of these terms, and 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, but are not limited to: the impact of the COVID-19 pandemic (including, applicable federal state or local orders) on business and operating results, including our supply chain, dialysis concentrates business, the commercial launch of Triferic AVNU, and the ability to secure international partners; the challenges inherent in new product development and other indications and therapeutics areas for our products; the success of our commercialization strategy; the success and timing of our commercialization of Triferic Dialysate; the success and timing of international clinical trials for Triferic Dialysate and Triferic AVNU; the success and timing of our commercial launch of Triferic AVNU in the United States; the ability to manufacture Triferic Dialysate and Triferic AVNU in a cost effective manner; the reimbursement of Triferic Dialysate and Triferic AVNU in international markets; the success and timing of the development of our FPC pipeline candidates, the risk that topline clinical data and real world results may not be predictive of future results; expected financial performance, including cash flows, revenues, growth, margins, funding, liquidity and capital resources; and those risks more fully discussed in the "Risk Factors" section of our Quarterly Report on Form 10-Q for the period ended September 30, 2020 and of our Annual Report on Form 10-K for the year ended December 31, 2019, as such description may be amended or updated in any future reports we file with the SEC. Rockwell Medical expressly disclaims any obligation to update our forward-looking statements, except as may be required by law.

Triferic® is a registered trademark of Rockwell Medical, Inc. Triferic AVNU is pending with the U.S. Patent and Trademark Office. All other product names, logos, and brands are property of their respective owners in the United States and/or other countries. All company, product and service names used on this website are for identification purposes only. Use of these names, logos, and brands does not imply endorsement.

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A photo accompanying this announcement is available at <https://www.globenewswire.com/NewsRoom/AttachmentNg/0f76fe57-5fe6-4f9e-b2ad-b78737f253a9>



Source: Rockwell
Medical, Inc. **Triferic AVNU**



Triferic® AVNU (ferric pyrophosphate citrate injection), the intravenous (IV) formulation of Triferic, is now available in the United States.