Rockwell Medical Announces Regulatory Approval of Triferic® Dialysate in South Korea

January 20, 2022

Two product forms of Triferic® are now approved in South Korea

WIXOM, Mich., Jan. 20, 2022 (GLOBE NEWSWIRE) -- Rockwell Medical, Inc. (Nasdaq: RMTI), a biopharmaceutical company dedicated to transforming the treatment of iron deficiency and anemia management worldwide, today announced that its partner in South Korea, Jeil Pharmaceutical Co., Ltd. ("Jeil"), has received a second regulatory approval by the Ministry of Food and Drug Safety of the Republic of Korea for Triferic® Dialysate (ferric pyrophosphate citrate sodium sulfate co-precipitate hydrate) for maintaining hemoglobin in adult patients with hemodialysis-dependent chronic kidney disease (HDD-CKD).

"*Chronic kidney disease continues to be a growing problem in South Korea, where Global comparative data shows that it ranks 4th in the world in prevalence of end-stage kidney disease[1]. This approval of Triferic Dialysate gives nephrologists another option for administration where needed to treat adult patients with HDD-CKD,*" said Marc Hoffman, M.D., Chief Medical Officer at Rockwell Medical. "*Administration of Triferic ampules via dialysis concentrates has the potential to decrease nursing time needed to administer IV iron and may reduce patient-nurse contact time. This change in workflow may help manage the risk of disease spread in dialysis clinics, including COVID-19.*"

Rockwell Medical has an exclusive license agreement with Jeil for the rights to commercialize Triferic in South Korea. Under the terms of the license agreement, Jeil is the exclusive development and commercialization partner for both formulations under the Triferic brand in South Korea. Rockwell Medical will supply the product to Jeil.

About Triferic Dialysate and Triferic AVNU

Triferic Dialysate (ferric pyrophosphate citrate) and Triferic AVNU (ferric pyrophosphate citrate injection) 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 AVNU is not intended for use in patients receiving peritoneal dialysis. TRIFERIC AVNU has 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 ≥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.

About Rockwell Medical

Rockwell Medical is a commercial-stage biopharmaceutical company developing and commercializing its next-generation parenteral iron technology platform, Ferric Pyrophosphate Citrate (FPC), which has the potential to lead transformative treatments for iron deficiency in multiple disease states, reduce healthcare costs and improve patients' lives. The Company has two FDA-approved therapies indicated for patients undergoing hemodialysis, which are the first two products developed from the FPC platform. Rockwell Medical is also advancing its FPC platform by developing FPC for the treatment of iron deficiency anemia in patients outside of dialysis, who are receiving intravenous medications in the home infusion setting. In addition, Rockwell Medical is one of two major suppliers of life-saving hemodialysis concentrate products to kidney dialysis clinics in the United States. For more information, visit www.RockwellMed.com.

Rockwell Medical Forward-Looking Statements

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," "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 those risks more fully discussed in the "Risk Factors" section of our Quarterly Report on Form 10-Q for the period ended September 30, 2021 and of our Annual Report on Form 10-K for the year ended December 31, 2020, 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.

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1. United States Renal Data System: 2018 USRDS annual data report. *Chapter 11: International Comparisons.* https://www.usrds.org/media/1738/v2_c11_intcomp_18_usrds.pdf (cited 2020 Oct 16)

Source: Rockwell Medical, Inc.