Rockwell Medical Announces Submission of Triferic® New Drug Application in South Korea by Partner, Jeil Pharmaceutical Co., Ltd.

February 1, 2021

>82,000 patients receiving hemodialysis annually

WIXOM, Mich., Feb. 01, 2021 (GLOBE NEWSWIRE) -- Rockwell Medical, Inc. (Nasdaq: RMTI), a biopharmaceutical company dedicated to transforming the treatment of iron deficiency and iron deficiency anemia management, today announced that its partner in South Korea, Jeil Pharmaceutical Co., Ltd., filed New Drug Applications (NDA) with the Ministry of Food and Drug Safety (MFDS) of the Republic of Korea for Triferic AVNU and Triferic Dialysate for the replacement of iron to maintain hemoglobin in adult patients with hemodialysis-dependent chronic kidney disease.

“The NDA submissions by our partner, Jeil Pharmaceutical, is an important milestone for Rockwell Medical as well as for the more than 82,000 patients in South Korea undergoing hemodialysis,” said Russell Ellison, M.D., M.Sc., President and Chief Executive Officer of Rockwell Medical. “We expect Triferic to become an important new treatment option for dialysis clinics and the patients they serve, if approved by the MFDS. We look forward to continuing our productive relationship with Jeil as they advance both Triferic presentations through the regulatory process.”

In September 2020, Rockwell Medical entered into an exclusive license agreement with Jeil for the rights to commercialize Triferic in South Korea. Under the terms of the license agreement, Jeil will be the exclusive development and commercialization partner for Triferic in South Korea. In consideration for the license, Rockwell Medical received an upfront fee and will be eligible for milestone payments and royalties on net sales.

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.

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

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).

TRIFERIC is not intended for use in patients receiving peritoneal dialysis. TRIFERIC has not been studied in patients receiving home hemodialysis.

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.

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.

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 receipt milestone payments and royalties by Rockwell Medical, the timing of product sales in South Korea, the receipt of regulatory approvals in South Korea and the potential market opportunity for Triferic in South Korea. 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; receipt of regulatory approval for Triferic in South Korea; our ability to successfully launch both formulations of Triferic which will impact Rockwell's ability to achieve milestones and receive royalty payments; the ability to manufacturer the product in accordance with South Korean regulations, anticipated market opportunity in South Korea; and those risks more fully discussed in the "Risk Factors" section of our Quarterly Report on Form 10-Q for the period ended June 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.

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