Rockwell Medical and Drogsan Pharmaceuticals Enter into Exclusive License Agreement for the Rights to Commercialize Triferic® in Turkey

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- With approximately 65,000 patients receiving hemodialysis annually, Turkey represents a significant and expanding market opportunity -

WIXOM, Mich. and ANKARA, Turkey, June 08, 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, and Drogsan Pharmaceuticals, a leading pharmaceutical company in Turkey with an established presence in the nephrology space having launched the first locally manufactured biosimilar in 2014 and building it to be the leader in the Epoetin Alfa market in Turkey, today announced that the Companies entered into an exclusive license agreement for the rights to commercialize Triferic AVNU (ferric pyrophosphate citrate injection) in Turkey.

Under the terms of the license agreement, Drogsan will be the exclusive development and commercialization partner for Triferic in Turkey and Rockwell Medical will supply the product to Drogsan. The agreement also allows for Drogsan to negotiate further geographic expansion into the surrounding region. In consideration for the license, Rockwell Medical will receive an upfront fee and will be eligible for milestone payments based on reimbursement price approval.

“As we continue to drive opportunities to bring Triferic to patients around the world, this agreement represents important progress to address the needs of iron deficient patients in Turkey,” said Russell Ellison, M.D., President and Chief Executive Officer of Rockwell Medical. “Drogsan is our partner of choice, with 45 years of pharmaceutical experience and a robust infrastructure, deep relationships and substantial coverage of nephrologists, key opinion leaders and dialysis centers across Turkey. Their highly experienced nephrology commercial team has a strong track record of successful new product launches. We look forward to working closely with Drogsan to bring Triferic to patients in need.”

“We welcome this opportunity to collaborate with Rockwell Medical and bring Triferic to hemodialysis patients in Turkey,” said Mustafa Karpuzcu, Chairman and Chief Executive Officer of Drogsan Pharmaceuticals. “With approximately 65,000 patients receiving hemodialysis every year in Turkey and the number of these patients expected to continue to increase, we believe this partnership is vital to bridging the unmet need for innovative medicine to address iron deficiency in these patients.”

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 to 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.

About Drogsan Pharmaceuticals

Established in 1975 as a member of Nevzat Group – active in the health sector for 59 years with 1,400 employees and $400 million turnover in total, Drogsan has become a leading pharmaceutical company in Turkey. Drogsan brings an established presence in the nephrology space having launched the first locally manufactured biosimilar in 2014 and building it to be the leader in the Epoetin Alfa market in Turkey. Drogsan with its long-standing experience has a strong commercial team active in selected therapeutic fields in Turkey, as well as a wide network of distribution in several countries in Eastern & Southern Europe, CIS, Middle East, Africa, Central & Southeast Asia.

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 ≥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.

Rockwell Medical 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 Turkey, the receipt of regulatory approvals in Turkey and the potential market opportunity for Triferic in Turkey. 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 Turkey; Drogsan’s ability to successfully launch Triferic which will impact Rockwell’s ability to achieve milestones and receive royalty payments; the ability to manufacture the product in accordance with Turkey’s regulations, international relations between the United States and Turkey, currency fluctuation of the Turkish Lira, anticipated market opportunity in Turkey; and those risks more fully discussed in the “Risk Factors” section of our Quarterly Report on Form 10-Q for the period ended March 31, 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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