Rockwell Medical Announces Dosing of First Patient in Pivotal Triferic® Phase 3 Trial by Partner, Wanbang Biopharmaceuticals, in China

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China is a sizable and growing market, with more than 600,000 patients receiving hemodialysis annually

WIXOM, Mich., Jan. 13, 2021 (GLOBE NEWSWIRE) -- Rockwell Medical, Inc. (Nasdaq: RMTI), a biopharmaceutical company dedicated to transforming the treatment of iron deficiency and iron deficiency anemia management and improving outcomes for patients around the world, today announced that its partner in China, Wanbang Biopharmaceuticals, a subsidiary of Shanghai Fosun Pharmaceutical (Group) Co., Ltd., enrolled the first patient in a pivotal Phase 3 trial for Triferic Dialysate to support a new drug application for regulatory approval in that country.

“The initiation of this pivotal trial is an important milestone in our strategic plan to expand global access to Triferic,” said Russell Ellison, M.D., M.Sc., President and Chief Executive Officer of Rockwell Medical. “In China, hemodialysis has continued to increase at a rapid rate in recent years, with more than 600,000 patients receiving hemodialysis every year, making it the largest single market in the world. Wanbang Biopharmaceuticals is a leading pharmaceutical company and an outstanding partner to bring our therapy to patients in China.”

“We believe Triferic has the potential to greatly improve the lives of patients on dialysis in China, and we are pleased to have dosed the first patient in our pivotal trial,” said Mr. Shibin Wu, Chief Executive Officer of Wanbang Biopharmaceuticals. “Wanbang Biopharmaceuticals is committed to addressing the needs of CKD patients and healthcare providers with a comprehensive range of therapeutic options across home, in-center and hospital dialysis settings. We value our partnership with Rockwell Medical, and our collaboration enhances Wanbang Biopharmaceuticals’ pipeline of innovative product candidates.”

The Phase 3 trial [RMFPC-13] is a prospective, randomized, single-blind (patient), parallel two-arm, placebo-controlled, multicenter, study of the efficacy and safety of Triferic® administered via hemodialysate in maintaining iron delivery and hemoglobin concentration in anemic adult patients with chronic kidney disease requiring hemodialysis. The objective of the study is to confirm the efficacy and safety of Triferic administered at each hemodialysis treatment via hemodialysate in maintaining iron delivery for erythropoiesis in anemic iron-replete Chinese CKD-5HD patients.

Rockwell Medical signed exclusive licensing and manufacturing supply agreements in 2016 with Wanbang Biopharmaceuticals for the rights to commercialize Triferic in China. Under the terms of the agreement, Wanbang Biopharmaceuticals became the exclusive distributor for Triferic in China for an initial commercial term of 10 years, with an extended term of 10 or more years based on achievement of annual minimum purchase requirements. Wanbang Biopharmaceuticals is required to achieve annual minimum purchase requirements to retain exclusive commercialization rights. In consideration for the exclusive rights, Rockwell received an upfront fee and is entitled to a regulatory approval milestone, revenue milestone payments, and Rockwell is entitled to receive ongoing earnings from product sales of Triferic and other additional Triferic therapeutic indications that Wanbang Biopharmaceuticals may develop. In addition to the hemodialysis indication, Wanbang Biopharmaceuticals has the exclusive right to develop and commercialize Triferic for new therapeutic indications for the Chinese market. Wanbang Biopharmaceuticals is responsible for all clinical, regulatory and marketing expenses for Triferic in China as well as development and regulatory costs for new Triferic indications. Rockwell retains manufacturing responsibility of all products.

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

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. Importantly, there have been no reports of anaphylaxis in over 1.2 million patient administrations.

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, the impact of COVID-19 on Rockwell Medical's business and operations, patient enrollment in a clinical trial and regulatory filings in China, the success of Triferic Dialysate and Triferic AVNU within clinical trials, the commercialization of Triferic Dialysate and Triferic AVNU in China, the potential approval of Triferic and Triferic AVNU in China, potential future sales within China and anticipated market sizes and future growth, future milestone payments and reliance upon approval and sales, and the development plans and timing for Rockwell Medical's FPC pipeline candidates in new indications. 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, and the ability to enroll patients in clinical trials, the ability to have governmental agencies review submissions in a timely manner, and the ability to commercialize Triferic and Triferic AVNU; the potential for modifications of regulatory requirements in both internationally and domestically; 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 and Triferic AVNU; the success and timing of international clinical trials for Triferic Dialysate; 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.

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