Rockwell Medical, Inc. Files Pre-IND Meeting Request with FDA for its Proposed Clinical Trial of FPC as a Treatment for Iron Deficiency Anemia in Patients Receiving Home Infusion

June 28, 2021

WIXOM, Mich., June 28, 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 it has submitted a pre-IND (Investigational New Drug) meeting request with the U.S. Food and Drug Administration (FDA) in support of its proposed Phase 2 clinical trial of Ferric Pyrophosphate Citrate (FPC), designed for the treatment of iron deficiency anemia and maintenance of hemoglobin in patients receiving infusion therapy in the home setting.

Home infusion represents a large and rapidly growing segment of healthcare. Many patient groups requiring home infusion therapies suffer from chronic diseases that are associated with a high incidence of iron deficiency and anemia. For example, it is estimated that 40%-55% of all home parenteral nutrition patients are iron deficient. Current treatment patterns can be inadequate for patients on home infusion therapy with iron deficiency anemia, causing them to suffer extreme fatigue and can result in serious health risks, such as, poor immune function and heart failure.

“This is an important step for Rockwell Medical and home infusion patients as we believe that FPC is uniquely suited to address this important unmet clinical need,” said Russell Ellison, M.D., President and Chief Executive Officer of Rockwell Medical. “We expect to finalize our Phase 2 clinical study design and protocol with the advice and guidance of the FDA.”

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. The Company is developing FPC for the treatment of iron deficiency in patients outside of dialysis, who are receiving intravenous medications in the home infusion setting, a large and rapidly growing segment of healthcare, and where these patients suffer from chronic diseases associated with high incidence of iron deficiency and anemia. 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, expectations and beliefs and are subject to various risks and uncertainties (including, without limitation, those set forth in Rockwell Medical’s SEC filings), that could cause actual results to differ materially from those described in the forward-looking statements. Actual results could be materially different. Risks and uncertainties include, but are not limited to statements regarding the therapeutic benefits, plans and objectives for regulatory approval of the Company’s product(s); ability to obtain FDA approval and advance our product to market; risks associated with our development work, including delays, or changes to the timing, cost and success of our product development activities and clinical trials; risks of delay in the FDA approval of FPC; risks inherent in the marketing, sales and commercializing a new product; risks relating to the size and growth of the home infusion market and acceptance of FPC; risks of sufficient capital and cash resources, including access either debt or equity financing to fund such product development; and the risk of compliance with all FDA and other government requirements relating to the development and manufacturing of our product; the impact of the COVID-19 pandemic (including, applicable international or domestic orders) on our ability to operate Rockwell’s manufacturing facilities in a manner that avoids any disruptions, 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 March 31, 2021 and of our Annual Report on Form 10-K for the year ended December 31, 2020, as such descriptions 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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