Rockwell Medical Receives Important Feedback from FDA on its IND Application for Phase 2 Trial of Ferric Pyrophosphate Citrate in Home Infusion

December 14, 2021

WIXOM, Mich., Dec. 14, 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 received feedback from the U.S. Food and Drug Administration (FDA) regarding its Investigational New Drug (IND) application 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.

"We are breaking new ground with this study, which is the first of its kind, evaluating the use of parenteral iron in treating iron deficiency anemia in the rapidly-growing home infusion setting. The study proposal includes a novel dosing regimen, one that is fine-tuned to match the preferences of caregivers and patients receiving health care at home. We are working closely with FDA to ensure that our planned approach is well suited for this patient population," said Russell Ellison, M.D., President and Chief Executive Officer of Rockwell Medical.

FDA requested that additional data related to the microbiology and short-term stability of FPC be submitted to further support the drug administration method proposed for the study. The company expects to run these additional studies, complete the required analysis, and provide the requested data in the first half of 2022. "We have a clear understanding of the request from FDA, and we believe there is a well-defined path forward to generate the data. The effort will help us refine our study approach, which is carefully designed for the home infusion application. We expect that these activities will have a minimal impact on the timing of our planned dosing of the first patient in this study," said Marc Hoffman, M.D., Chief Medical Officer of Rockwell Medical.

"This important feedback from FDA strengthens our confidence in the potential value of this therapy. We are working to ensure that this product is studied with the patient and caregiver preferences in mind. The ultimate success of our project would mean patients will have access to a treatment for iron deficiency anemia in the home, so they could potentially avoid visits to an office or clinic to receive iron. We believe this may be a significant advance in the care of chronically ill patients with iron deficiency anemia who wish to avoid visits to healthcare facilities and the associated risks," said Dr. Ellison.

Once the additional data is submitted, Rockwell must wait 30 calendar days before treating any patients in the clinical trial. During this time, FDA has an opportunity to review the IND and the additional data that is submitted.

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, including without limitation statements relating to the timing of completion of response activities, the impact of the response activities on the timing of dosing the first patient in the trial and the path forward to resolve the FDA's questions, 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: Rockwell's ability to timely lift the clinical hold for the planned home infusion trial, the impact of the COVID-19 pandemic on Rockwell's business, including any clinical trials, and the FDA's response time, the risks of current treatment patterns in the home infusion setting for iron deficiency anemia and whether the FDA will raise any additional issues with the IND during its review period; 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, 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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