Rockwell Medical Submits Investigational New Drug Application with FDA for its Proposed Clinical Trial of FPC as a Treatment for Iron Deficiency Anemia in Patients Receiving Home Infusion

November 11, 2021

WIXOM, Mich., Nov. 11, 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 an Investigational New Drug (IND) application 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,” said Marc Hoffman, M.D., Chief Medical Officer of Rockwell Medical. “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.”

“We are very pleased to have achieved another development milestone with the submission of this IND for our FPC home infusion program as we expand our efforts to develop FPC outside of dialysis,” said Russell Ellison, M.D., President and Chief Executive Officer of Rockwell Medical.

Once the IND is submitted, a sponsor must wait 30 calendar days before initiating any clinical trials. During this time, FDA has an opportunity to review the IND.

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 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: 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 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 June 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.

ROCKWELL MEDICAL CONTACTS

Investors:
Argot Partners
212.600.1902
Rockwell@argotpartners.com

Media:
David Rosen
Argot Partners
212.600.1902
david.rosen@argotpartners.com

Source: Rockwell Medical, Inc.