Rockwell Medical Submits Supplemental Data to FDA for IND Application for Phase 2 FPC Home Infusion Trial

May 12, 2022

WIXOM, Mich., May 12, 2022 /PRNewswire/ -- Rockwell Medical, Inc. (Nasdaq: RMTI), a biopharmaceutical company dedicated to transforming the treatment of iron deficiency and anemia management, today announced that it provided the U.S. Food and Drug Administration (FDA) with the supplemental data, requested by the agency in December 2021, for the Company's pending Investigational New Drug (IND) application in support of a proposed Phase 2 clinical trial of Ferric Pyrophosphate Citrate (FPC) for the treatment of iron deficiency anemia and maintenance of hemoglobin in patients receiving infusion therapy in the home setting. The additional data relate to the physical, chemical and microbiological stability of FPC in support of the suggested method of administration in the Phase 2 protocol.

Home Infusion, where various medications are given via infusion therapy in the home, rather than an infusion center, is a rapidly-growing segment of home healthcare. Many patients that are receiving infusion therapy at home suffer from diseases that are associated with iron deficiency, which is difficult to treat with traditional forms of iron.

"We are pleased to provide the FDA with the additional data it requested to support our IND for FPC in patients undergoing infusion therapy at home," said Russell Ellison, M.D., M.Sc., President and CEO of Rockwell Medical. "This is an iterative process with the FDA as this is the first clinical trial of parenteral iron in the treatment of iron deficiency anemia in the home setting, with the goal of enabling patients to avoid visits to a doctor's office or clinic to receive iron, which would represent a significant improvement in the care of these patients. We remain confident in the potential of FPC and are prepared to move forward with the initiation of the Phase 2 trial, pending the review and clearance of our IND"

The FDA has 30 days to review the additional data that have been submitted. In the event that the FDA has no further questions or requirements regarding the submission, the Company would expect the trial to start shortly after the review period ends.

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.

About Home Health and IDA in Home Infusion Therapy
Home health is an area of medicine experiencing explosive growth – a trend that will likely continue over the next decade due to an aging US population, the need to control costs, the desire to improve patient outcomes, and the convenience of home healthcare.

Home infusion therapy, an important part of some home care regimens, allows patients with diseases requiring regular infusions of intravenous medications to be treated in the comfort of their home and has been proven to be a cost-effective, safe, and efficacious alternative to inpatient care for a variety of therapies and disease states, both acute and chronic.

Treating IDA as part of an existing home infusion regimen more effectively, calls for an innovative approach. Rockwell Medical is developing a technology to manage iron in the home infusion setting. Ferric Pyrophosphate Citrate (FPC) is Rockwell's novel next-generation parenteral iron is anticipated to enter a Phase II study for the treatment of IDA in the home infusion setting in the first half of the year.

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 those risks more fully discussed in the "Risk Factors" section of our Annual Report on Form 10-K for the year ended December 31, 2021, 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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