Rockwell Medical Provides Corporate and Clinical Update

June 22, 2022

- Closes $7.5 Million Second Tranche Investment from DaVita

- $30 Million in Total Capital Raised This Quarter

- Receives Additional Feedback from FDA on its IND Application

WIXOM, Mich., June 22, 2022 /PRNewswire/ -- Rockwell Medical, Inc. (Nasdaq: RMTI), a biopharmaceutical company dedicated to transforming the treatment of iron deficiency and anemia management and improving outcomes for patients, today provided an update on its recent capital raise and a clinical update on safety enhancements to its planned Phase 2 clinical trial of Ferric Pyrophosphate Citrate (FPC) in home infusion patients.

On June 16, 2022 Rockwell Medical closed the second $7.5 million tranche of the previously announced DaVita, Inc (NYSE:DVA) stock purchase agreement under which DaVita agreed to purchase up to $15 million in convertible preferred stock in two tranches. This investment, in addition to the recently announced $15 million financing, brings the total gross amount raised by Rockwell this quarter to $30 million. There were no commissions paid on either investment.

"This capital, when combined with the initiatives we completed earlier this year, will extend our cash runway meaningfully, during which time we will continue advancing our Ferric Pyrophosphate Citrate (FPC) development programs and improving our dialysis business," said Russell Skibsted, Executive Vice President, CFO and CBO. "We plan to restructure and grow our dialysis business to generate improved gross margins and cash flow. On the development side, with the rapidly growing trend toward medical care at home, we are preparing to conduct our Phase 2 clinical trial of FPC in home infusion patients, a population with a significant unmet burden from iron deficiency anemia, pending submission of additional CMC microbial data in support of FDA clearance to begin this trial."

Due to the fact that the eventual commercial presentation of FPC) for the treatment of iron deficiency anemia and maintenance of hemoglobin in patients receiving infusion therapy in the home setting, a single dose sterile unit, is still in development, the planned Phase 2 proof of concept study design requires that three units of the existing FDA-approved IV product be compounded into a single unit for each patient dose. Because of this necessary step, the U.S. Food and Drug Administration (FDA) requested that Rockwell perform a microbial challenge study, a standard study testing the potential for microbial growth. Successful completion of this study will add an additional layer of safety for clinical trial patients.

"We are pleased to provide the FDA with the additional data requested and fully support the generation of any data that will further assure the safety of the patients that will participate in our study," said Marc Hoffman, M.D., Chief Medical Officer of Rockwell Medical. "We continue to make progress toward clearance of our IND. We believe the requested microbial challenge study will have minimal impact on our proposed Phase 2 program timeline or cost as the tests will be conducted in parallel with the clinical study start-up activities."

Home infusion therapy is a rapidly growing segment of home healthcare. Many patients receiving home infusion therapy have diseases that are associated with a high rate of iron deficiency and anemia, and current treatment options are not well suited for use in the home setting.

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 significant 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 2022.

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," "look forward to," "remain confident" or the negative of these terms, and similar expressions, or statements regarding intent, belief, or current expectations, are forward looking statements. There can be no assurance that Rockwell Medical will be able to, among other things, receive FDA clearance for its planned clinical trial of FPC in home infusion patients or the timing of any such approval, have sufficient capital to complete a trial in home infusion patients, or maintain timing for planned clinical trials and regulatory filings. 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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