Rockwell Medical Presents Data on Diagnosis and Management of Iron Deficiency Anemia in Home Parenteral Nutrition Patients at the NHIA 2021 Annual Conference

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WIXOM, Mich., April 22, 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 presented data from a clinical feasibility study reviewing the practice patterns of iron deficiency anemia (IDA) in home parenteral nutrition patients at the National Home Infusion Association's (NHIA) 2021 Annual Conference, taking place virtually from April 19 to 22, 2021.

"The study results validated our initial assumptions that management of iron deficiency anemia in this home infusion population is suboptimal and remains an unmet clinical need. Although approximately half of the patients in the home infusion setting suffer from iron deficiency anemia, and oral iron is indicated as a first-line therapy, many patients may not tolerate it, or may have unsatisfactory results with this option," said Marc L. Hoffman, M.D., Chief Medical Officer of Rockwell Medical and study author. "Traditional forms of IV iron are rarely administered unsupervised in the home due to risk of hypersensitivity reactions or concerns about incompatibility with other medications, and office visits for infusion of IV iron are costly, inconvenient, and often do not fit the physician practice care model."

Key findings include the following insights:

- More than 85% of physicians and pharmacists would recommend intravenous (IV) iron for home parenteral nutrition patients.
- Oral iron remains first-line therapy in ~50% of respondents in both groups.
- Standard iron panel (Fe, TIBC, ferritin, TSAT) is employed in the home infusion setting for assessment of iron status.
- Validation of literature reports that approximately 50% of home parenteral nutrition patients suffer from IDA, however:
    - There is no clear consensus on treatment or practice patterns;
    - No clear consensus for hemoglobin target to initiate therapy; and
    - No clear consensus from outreach for hemoglobin target for goal-directed therapy.
- Existing treatment plans are indicative of the current therapeutic options available.

Dr. Hoffman added: "Rockwell Medical plans to initiate the first-ever well-controlled randomized clinical trial to evaluate the safety and efficacy of a parenteral iron treatment, in this case FPC, delivered at home. The proposed study design incorporates the considerable knowledge and data that already exist for the FPC molecule, including an extensive safety database of more than 1.3 million administrations in a very frail hemodialysis patient population, and well-established kinetics that provide strong rationale for the doses and dose schedules that have been developed for this setting. We look forward to our upcoming pre-IND meeting with the FDA."

About the clinical feasibility study

Rockwell Medical conducted a clinical feasibility study to assess treatment and practice patterns and attitudes towards management of IDA in the home infusion population. The purpose of the study was to inform the design of future clinical development programs for a novel approach to iron replacement in the home infusion population. Physicians and pharmacists in the United States actively engaged in the identification and management of IDA were identified in conjunction with the Oley Foundation. Outreach was conducted via an online questionnaire developed in cooperation with Key Opinion Leaders in gastroenterology and total parenteral nutrition. The study was conducted in November and December 2020 and included a total of 26 physician responses and 39 pharmacist responses.

Rockwell Medical announced in March 2021 that the U.S. Food and Drug Administration (FDA) accepted its proposed development strategy to pursue an approval via the 505(b)(1) pathway as a novel new drug application for ferric pyrophosphate citrate (FPC) for the treatment of IDA in adult patients in the home infusion setting. Pending a successful outcome of Rockwell Medical's pre-investigational new drug meeting with the FDA, the Company plans to initiate a clinical study during the second half of 2021.

About Rockwell Medical

Rockwell Medical is a biopharmaceutical company dedicated to transforming iron deficiency and anemia management in a wide variety of therapeutic areas and across the globe, improving the lives of very sick patients. The Company's initial focus is the treatment of anemia in end-stage kidney disease and has two products approved for maintenance of hemoglobin in hemodialysis patients. Rockwell Medical is also an established manufacturer, supplier and leader in delivering high-quality hemodialysis concentrates/dialysates to dialysis providers and distributors in the U.S. and abroad.

Forward-Looking Statements

Certain statements in this press release may constitute "forward-looking statements" within the meaning of the federal securities laws, including, but not limited to, Rockwell Medical's intention to conduct clinical trials investigating the use of FPC for IDA in patients receiving home infusion, Rockwell Medical's understanding of the unmet need and commercial opportunity for patients with IDA receiving home infusion, Rockwell Medical's understanding of the medical treatment paradigms employed for treatment of IDA in patients receiving home infusion, and Rockwell Medical's belief that FPC would be an appropriate treatment within the home infusion setting. 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: challenges inherent in new product development and other indications and therapeutic areas for our products; statements around the commercial understanding of the market opportunity of FPC within the home infusion setting; the ability to receive favorable reimbursement of intravenous iron within the home infusion setting; evolving understanding of the home infusion market and commercial opportunity, risks associated with launching a clinical program; legislative changes to the reimbursement structure within the home infusion; the risk that topline clinical data may not demonstrate efficacy and/or safety or may not be predictive of future results the potential impact of the COVID-19 pandemic (including, applicable federal state or local orders) on business and operating results, including our supply chain, dialysis concentrates business and the commercial launch of Triferic AVNU; potential future milestone payments and royalties under our applicable license agreements; 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, 2020 and of our Annual Report on Form 10-K for the year ended December 31, 2019, 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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