Rockwell Medical Announces I.V. Triferic® and Peritoneal Dialysis Study Abstracts Selected as Best-in-Category at the Annual Dialysis Conference

March 18, 2019

I.V. Triferic Data to Support Upcoming New Drug Application

Intraperitoneal Triferic Effectively Delivers Iron to Patients with Kidney Failure in Outpatient Setting

WIXOM, Mich., March 18, 2019 (GLOBE NEWSWIRE) -- Rockwell Medical, Inc. (NASDAQ: RMTI) ("Rockwell Medical" or the "Company"), a global biopharmaceutical company dedicated to improving outcomes for patients with end-stage renal disease (ESRD) and chronic kidney disease (CKD), today announced positive data from two studies evaluating intravenous (I.V.) and peritoneal dialysate (PD) formulations of Triferic® (ferric pyrophosphate citrate), the only therapy approved by the U.S. Food and Drug Administration (FDA) indicated to replace iron and maintain hemoglobin in adult hemodialysis (HD) patients with chronic kidney disease. The data from the studies will be presented at the Annual Dialysis Conference, the largest multi-disciplinary conference on dialysis, held March 16-19 in Dallas, Texas.

"We are encouraged by the data from this study, which demonstrates that I.V. Triferic delivers the same quantity of iron to patients as Triferic delivered via hemodialysate," said Raymond D. Pratt, M.D., Chief Medical Officer of Rockwell Medical. "We believe Triferic has the potential to transform anemia management for all patients with hemodialysis-dependent chronic kidney disease. An I.V. formulation would give us the opportunity to integrate the use of Triferic at all dialysis centers— in the U.S. and abroad—regardless of the mode of bicarbonate delivery being used."

I.V. Triferic for adult HD patients was developed pursuant to a Special Protocol Assessment (SPA), at which time the FDA confirmed that an equivalence approach to Triferic delivered via hemodialysate (Dialysate Triferic) would be acceptable for I.V. Triferic. The Company expects to submit a New Drug Application (NDA) for I.V. Triferic to the FDA during the second quarter of 2019, in which the study below will be submitted for FDA review.

I.V. Infusion of Triferic Delivers Same Quantity of Iron as Delivery via Hemodialysate

An open-label, randomized, multiple-period single dose study was conducted in 24 CKD-5HD patients to establish the equivalence of doses between dialysate and I.V. administration. Each patient received a baseline iron treatment and three randomized treatments of either Triferic 6.75 mg Fe I.V. pre-dialyzer; Triferic 6.75 mg Fe I.V. post-dialyzer; or Triferic 2 µM (110 µg Fe/L of hemodialysate). Serum and plasma iron were drawn at specified time points over 12 hours and analyzed for total iron (Fe) and Transferrin Bound Iron (TBI). Results from the study were as follows:

- Intravenous infusion of 6.5 mg iron as ferric pyrophosphate citrate (FPC) during three hours of hemodialysis delivers the same quantity of iron as when Triferic is delivered via hemodialysate;
- In Phase 3 clinical studies, Dialysate Triferic maintained iron status and hemoglobin concentrations;
- The amount of iron delivered in the pivotal clinical trials for Dialysate Triferic is now established as 6.5 mg Fe/treatment; and
- Administration of FPC into the pre-dialyzer blood line extends the ability to provide Triferic iron to all patients receiving hemodialysis or hemodiafiltration.

"Triferic administered via dialysate provides a safe and effective method to replace iron and maintain hemoglobin concentration in adults living with hemodialysis-dependent chronic kidney disease," said Stuart Paul, President and Chief Executive Officer of Rockwell Medical. "Based upon results from our equivalency study, which demonstrate consistent results for I.V. Triferic, we plan to submit our data for review by the FDA as a part of our NDA. The NDA is expected to be submitted with the FDA during the second quarter of 2019. Additionally, the delivery of Triferic to peritoneal dialysis patients via the dialysate may improve patients' ability to manage their anemia, typically in the home setting."

Intraperitoneal Triferic May Serve as Effective and Simple Iron Replacement Option for Chronic Peritoneal Dialysis Patients

In a second study, 30 patients were enrolled in an open-label, randomized, two-period, single ascending dose study of Triferic administered in peritoneal dialysis fluid (PDF). Results demonstrated iron absorption from PDF was dose-dependent with peak serum iron profile (sFe) at approximately six hours with return to baseline over the next approximately eight hours. Clearance was similar to Triferic I.V. administration.

"The iron requirements in patients receiving peritoneal dialysis are less than hemodialysis patients; however, they still require supplemental iron to manage their anemia," said Dr. Pratt. "This single-ascending dose study shows that Triferic can deliver iron to the systemic circulation when added to peritoneal dialysis fluid and may serve as an important means to managing anemia in an outpatient setting."

Additional studies of Triferic in peritoneal dialysis patients will be required prior to submission of an NDA.

About Triferic
Triferic is the only FDA-approved therapy indicated to replace iron and maintain hemoglobin in hemodialysis patients via dialysate during each dialysis treatment, Triferic delivers approximately 5-7 mg iron with every hemodialysis treatment to the bone marrow and maintains hemoglobin without increasing irons stores (ferritin). Unlike IV iron products, Triferic binds iron immediately and completely to transferrin (carrier of iron in the body) upon entry into the blood and is then transported directly to the bone marrow to be incorporated into hemoglobin, with no increase in ferritin (stored iron and inflammation) and no anaphylaxis, addressing a significant medical need in overcoming Functional Iron Deficiency (FID) in ESRD patients. Please visit www.triferic.com to view the Triferic mode-of-action (MOA) video and for more information.

About Rockwell Medical
Rockwell Medical is a biopharmaceutical company targeting end-stage renal disease (ESRD) and chronic kidney disease (CKD). Rockwell Medical's exclusive renal drug therapies support disease management initiatives to improve the quality of life and care of dialysis patients and are intended to deliver safe and effective therapy, while decreasing drug administration costs and improving patient convenience. Rockwell Medical's anemia drug Triferic is the only FDA-approved product indicated for iron replacement and maintenance of hemoglobin in hemodialysis patients. Rockwell Medical is also an established manufacturer, supplier and leader in delivering high-quality hemodialysis concentrates/dialysates (used to maintain human life by removing toxins and replacing critical nutrients in the dialysis patient's bloodstream) to dialysis providers and distributors in the U.S. and abroad. Please visit www.rockwellmed.com for more information.

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's intention to bring to market Triferic, and IV Triferic. Words such as "may," "might," "will," "should," "believe," "expect," "anticipate," "estimate," "continue," "could," "plan," "potential," "predict," "forecast," "project," "plan", "intend" or 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'sSEC filings), many of which are beyond our control and subject to change. Actual results could be materially different. Risks and uncertainties include: statements about the timing and success of our planned NDA filing to be submitted to the FDA for IV Triferic; the potential market opportunity for IV Triferic and other Rockwell products; pricing and reimbursement status for IV Triferic, including eligibility for add-on reimbursement under TDAPA; liquidity and capital resources; expected duration of Rockwell Medical's existing working capital; plans, timing and success of our planned commercialization of Triferic; and timing and success of our efforts to renegotiate economic terms of our concentrate business. Rockwell Medical expressly disclaims any obligation to update or alter any statements whether as a result of new information, future events or otherwise, except as required by law.

Triferic® is a registered trademark of Rockwell Medical, Inc.

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