CMS Issues Preliminary Recommendation to Establish a New J-Code for Triferic® Powder Packet

May 1, 2019

--Final CMS Decision Anticipated Later This Year--

WIXOM, Mich., May 01, 2019 (GLOBE NEWSWIRE) -- Rockwell Medical, Inc. (NASDAQ:RMTI) (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 that the Centers for Medicare & Medicaid Services (CMS) has issued a preliminary recommendation that, if finalized, would establish a new Level II Healthcare Common Procedure Coding System (HCPCS) code, or J-code (J1444), for the Company's Triferic ® powder packet. If finalized, this unique J-code for the powder packet would be separate and distinct from the existing J-code (J1443) that describes Triferic® solution.

In its preliminary recommendation, CMS proposes an effective date of July 1, 2019 for establishing J1444, and proposes the following descriptor: "Injection, ferric pyrophosphate citrate powder, 0.1 mg of iron". Rockwell Medical plans to participate in the CMS HCPCS Public Meeting on May 15, 2019, during which CMS' preliminary HCPCS coding recommendations will be discussed.

"We are pleased that CMS has issued a preliminary recommendation to establish a new J-code to identify the Triferic powder packet. If finalized, the recommended J-code would help provide additional clarity for coding and claims processing in connection with distinct Triferic products. We look forward to continuing our work and discussions with CMS regarding coding considerations for our Triferic products," said Stuart Paul, President and Chief Executive Officer of Rockwell Medical.

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.

Important Safety Information
Serious hypersensitivity reactions, including anaphylactic-type reactions, some of which have been life-threatening and fatal, have been reported in patients receiving parenteral iron products. Patients may present with shock, clinically significant hypotension, loss of consciousness, and/or collapse. Monitor patients for signs and symptoms of hypersensitivity during and after hemodialysis until clinically stable. Personnel and therapies should be immediately available for the treatment of serious hypersensitivity reactions. Hypersensitivity reactions have been reported in 1 (0.3%) of 292 patients receiving Triferic in two randomized clinical trials.

Iron status should be determined on pre-dialysis blood samples. Post dialysis serum iron parameters may overestimate serum iron and transferrin saturation.

The most common adverse reactions (≥3% and at least 1% greater than placebo) in controlled clinical studies include: procedural hypotension (21.6%), muscle spasms (9.6%), headache (9.2%), pain in extremity (6.8%), peripheral edema (6.8%), dyspnea (5.8%), back pain (4.5%), pyrexia (4.5%), urinary tract infection (4.5%), asthenia (4.1%), fatigue (3.8%), arteriovenous (AV) fistula thrombosis (3.4%), and AV fistula site hemorrhage (3.4%).

https://www.triferic.com/wp-content/uploads/2019/01/final-labeling-text-March-2018.pdf

About Rockwell Medical, Inc.
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 Medical's intention to bring to market Triferic, and I.V. 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 issuance of a unique J code for our Triferic Powder Packet; timing and success of our planned NDA submission for I.V. Triferic; the potential market opportunity for I.V. Triferic and other Rockwell products; pricing and reimbursement status for I.V. Triferic, Triferic and other Rockwell products, including eligibility for add-on reimbursement under TDAPA; liquidity and capital resources; expected duration of Rockwell Medical's existing working capital; plans and timing relating to the 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.

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