Rockwell Medical Provides Update on IV Triferic

October 12, 2018

WIXOM, Mich., Oct. 12, 2018 /PRNewswire/ -- Rockwell Medical, Inc. (NASDAQ: RMTI) (the "Company" or "Rockwell Medical") today provided an update on the status of the Company's development of an intravenous ("IV") formulation of the Company's proprietary drug Triferic®, which is the only FDA-approved therapy indicated to replace iron and maintain hemoglobin in adult hemodialysis patients with chronic kidney disease. The Company is in the process of preparing a New Drug Application ("NDA") for IV Triferic and anticipates that it will file the NDA in the fourth quarter of 2018, which would result in a Prescription Drug User Fee Act ("PDUFA") action date in late 2019.

"Based on feedback from a pre-NDA meeting with the FDA, we believe that we have an NDA package, including bioequivalence data, that would enable the FDA to review and act on this application before the end of 2019," said Stuart Paul, Rockwell Medical President and Chief Executive Officer. "We are excited about our planned NDA submission as it represents an important milestone in this process. The entire Rockwell Medical team is dedicated to maximizing the opportunity with IV Triferic, which has great potential to help patients both in the U.S. and abroad."

In addition, the Company recently clarified and extended additional intellectual property ("IP") rights related to IV Triferic, which, if approved, is expected to support the planned commercialization of this product. Details regarding the acquisition of these IP rights will be disclosed in a Current Report on Form 8-K, to be filed by the Company.

The Company intends to provide additional information regarding IV Triferic and the planned NDA submission on the Company's third quarter earnings call on November 9, 2018.

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's FDA approved generic drug Calcitriol (active vitamin D) is for treating secondary hyperparathyroidism in patients undergoing chronic renal dialysis. 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 Calcitriol. 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 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's SEC 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 submission for IV Triferic; the potential market opportunity for IV Triferic and other Rockwell products; pricing and reimbursement status for IV Triferic, Triferic and other Rockwell products; liquidity and capital resources; and plans relating to the commercialization of Triferic and Calcitriol. Rockwell 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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