Calcitriol New Contract Manufacturing Submission Receives FDA Approval and Allows Rockwell Medical Commercialization of Calcitriol

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WIXOM, Mich., July 16, 2018 /PRNewswire/ -- Rockwell Medical, Inc. (NASDAQ: RMTI) (the "Company") today provided an update regarding Calcitriol, the Company's FDA approved active vitamin D injection for the management of hypocalcemia in patients undergoing chronic hemodialysis.

On July 11, 2018, Rockwell Medical received FDA approval of its Prior Approval Supplement for manufacturing Calcitriol. This approval was necessary in order to market and commercialize Calcitriol in the United States. Calcitriol is FDA approved under an Abbreviated New Drug Application and is manufactured through a contract manufacturing organization ("CMO"). As previously announced, the Company submitted a manufacturing update to the FDA to approve the CMO and the FDA had provided a target date for a response to Rockwell Medical's submission no later than August 19, 2018.

The Company will provide additional information regarding its plans for commercial production and sales of Calcitriol in the United States as it moves forward. The Company does not expect Calcitriol sales to have a material impact on its total revenue for 2018.

About Rockwell Medical, Inc.

Rockwell Medical is a fully-integrated biopharmaceutical company targeting end-stage renal disease (ESRD) and chronic kidney disease (CKD) with innovative products for the treatment of iron replacement, secondary hyperparathyroidism and hemodialysis.

Rockwell's anemia drug Triferic is the only FDA-approved product indicated for iron replacement and maintenance of hemoglobin in hemodialysis patients. Triferic delivers iron to patients during their regular dialysis treatment, using dialysate as the delivery mechanism. Triferic has demonstrated that it safely and effectively delivers sufficient iron to the bone marrow and maintains hemoglobin, without increasing iron stores (ferritin). Rockwell intends to market Triferic to hemodialysis patients in the U.S. dialysis market and other major markets globally.

Rockwell's FDA approved generic drug Calcitriol is for treating secondary hyperparathyroidism in dialysis patients. Calcitriol (active vitamin D) injection is indicated in the management of hypocalcemia in patients undergoing chronic renal dialysis. It has been shown to significantly reduce elevated parathyroid hormone levels. Reduction of PTH has been shown to result in an improvement in renal osteodystrophy. Rockwell intends to market Calcitriol to hemodialysis patients in the U.S. dialysis market.

Rockwell is also an established manufacturer and leader in delivering high-quality hemodialysis concentrates/dialysates to dialysis providers and distributors in the U.S. and abroad. As one of the two major suppliers in the U.S., Rockwell's products are used to maintain human life by removing toxins and replacing critical nutrients in the dialysis patient's bloodstream. Rockwell has three U.S. manufacturing/distribution facilities.

Rockwell'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 is developing a pipeline of drug therapies, including extensions of Triferic for indications outside of hemodialysis. Please visit www.rockwellmed.com for more information.

Forward-Looking Statement

Certain statements in this press release 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: the ongoing litigation with Rockwell's former Chief Executive Officer, Chief Financial Officer and certain current and former directors; the timing for the appointment of a successor Chief Executive Officer, Chief Financial Officer and independent auditor; Rockwell's ability to maintain compliance with SEC and NASDAQ rules and requests; and whether Rockwell can successfully execute on its new business strategy. 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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