October 25, 2017

Rockwell Update on Calcitriol Post-Approval Manufacturing Submission to FDA

WIXOM, Mich., Oct. 25, 2017 (GLOBE NEWSWIRE) -- Rockwell Medical, Inc. (NASDAQ:RMTI), today provided an update on the commercial launch of Calcitriol, stating that the FDA has requested extra time to review its post-approval drug manufacturing submission that was filed with the FDA September 28, 2017. The FDA was required to provide Rockwell with a determination on its September 28th submission within 30 days. The Company expects to have an answer from the FDA in approximately four months. Calcitriol is Rockwell's FDA approved active Vitamin D injection for the management of hypocalcemia in patients undergoing chronic renal dialysis. Rockwell intends to sell Calcitriol commercially once the FDA approves its post-approval drug manufacturing submission

"We believe the Agency required more time to review the submission package than the 30-day window required," stated Raymond Pratt, MD, Chief Medical Officer of Rockwell. "Our data remains robust. We will also submit additional helpful data that we have gathered since our initial submission September 28, 2017."

About Rockwell Medical
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 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.

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 sell and market Calcitriol and Triferic. Words such as "may," "might," "will," "should," "believe," "expect," "anticipate," "estimate," "continue," "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's SEC filings. Thus, actual results could be materially different. Rockwell Medical expressly disclaims any obligation to update or alter statements whether as a result of new information, future events or otherwise, except as required by law.

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