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Rockwell Medical Enters into Exclusive License Agreement with ARAM Medical to Commercialize Triferic® in Saudi Arabia, Egypt and Middle East Territories

- Territory Covers 375,000 CKD-HD patients; Rockwell Receives Upfront Licensing Fee, High Double-digit Royalty and Annual Contractual Minimum Product Purchases -

WIXOM, Mich., Aug. 16, 2016 (GLOBE NEWSWIRE) -- Rockwell Medical, Inc. (NASDAQ:RMTI), a fully-integrated biopharmaceutical company targeting end-stage renal disease (ESRD) and chronic kidney disease (CKD) with innovative products and services for the treatment of iron replacement, secondary hyperparathyroidism and hemodialysis, announced today that it has signed an exclusive license and manufacturing supply agreement with Saudi-based ARAM Medical for the rights to commercialize Rockwell's Triferic and Calcitriol in the Middle East to serve a market of approximately 375,000 hemodialysis patients. Triferic is Rockwell's proprietary iron replacement and hemoglobin maintenance drug for treating anemia in hemodialysis patients. Calcitriol is Rockwell's generic (active vitamin D) injection for treatment of secondary hyperparathyroidism in dialysis patients.

Under the terms of the agreement, ARAM Medical will become the exclusive distributor for Triferic and Calcitriol in 13 countries, including the Kingdom of Saudi Arabia, Kuwait, Bahrain, Qatar, Oman, Lebanon, Jordan, United Arab of Emirates, Yemen, Syria, Algeria, Tunisia and Egypt for an initial commercial term of 10 years. In consideration for the exclusive rights, ARAM will pay to Rockwell upfront licensing fees, a high double-digit royalty on product sales and commit to annual minimum purchase quantities. ARAM will also assume responsibility for all clinical and regulatory expenses for the territories. Rockwell retains manufacturing responsibilities for both Triferic and Calcitriol. Commercial product availability is expected within approximately 12 months in Saudi Arabia and 12 to 18 months in Egypt and all other territories.

"We are excited to establish this strategic partnership with ARAM Medical to treat the large, growing ESRD population in the Middle East," commented Robert L. Chioini, Founder, Chairman and CEO of Rockwell Medical. "This agreement, like the others before it, further validates Triferic's potential to become the world-wide standard of care in iron maintenance therapy for treating renal anemia. We continue to be focused on securing strategic partnerships that enable us to commercialize Triferic on a global scale. We believe Triferic is the only iron product that can effectively address the severe anemia dialysis patients worldwide suffer from. Working with our partner ARAM, we look forward to offering our life-changing therapy to this large ESRD population representing approximately 375,000 patients in the territory."

Mr. Mahmoud al Nahas, CEO of ARAM Medical, stated, "We are very happy and appreciative to secure this commercialization agreement with Rockwell Medical. We believe Triferic will become the standard of care for the treatment of anemia for all dialysis patients. The dialysis population in Saudi Arabia exceeds 25,000 and we strive to provide the best therapies to help patients improve their lives. ARAM Medical is a leading agent in the pharmaceutical field in Saudi Arabia and we have strong relationships throughout the territory. We value this new partnership with Rockwell U.S.A. As the exclusive agent in the Middle East, we will use our vast experience to ensure our efforts are successful in providing our patients with unique products to improve their quality of life."

About Triferic

Triferic is the only FDA approved drug indicated to replace iron and maintain hemoglobin in hemodialysis patients suffering from anemia. Via dialysate during each dialysis treatment, Triferic replaces the 5-7 mg iron loss that occurs in all patients, effectively maintaining their iron balance. Unlike IV iron products, Triferic binds iron immediately and completely to transferrin (carrier of iron in the body) upon entering the blood and it 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 unmet 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 fully-integrated biopharmaceutical company targeting end-stage renal disease (ESRD) and chronic kidney disease (CKD) with innovative products and services for the treatment of iron replacement, secondary hyperparathyroidism and hemodialysis.

Rockwell's recent FDA approved drug Triferic is 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 manufacturing/distribution facilities located in the U.S.

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.

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

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