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Rockwell Medical Signs Exclusive License Agreement with Quimica Europea to Commercialize Triferic® in Peru

- Estimated Market Launch 2nd-half 2018 Provides Access to 13,000 Dialysis Patients -

WIXOM, Mich., Dec. 12, 2017 (GLOBE NEWSWIRE) -- Rockwell Medical, Inc. (NASDAQ:RMTI), announced today that it has signed an exclusive license and manufacturing supply agreement with privately held Quimica Europea for the rights to commercialize Rockwell's Triferic for End-Stage-Renal-Disease (ESRD) patients in Peru. Rockwell's Triferic is the only FDA approved therapy to replace iron and maintain hemoglobin in hemodialysis patients suffering from anemia.

"We are thrilled to establish this strategic partnership with Quimica Europea," stated Robert L. Chioini, Founder, Chairman and CEO of Rockwell. "With approximately 13,000 patients currently receiving hemodialysis, market growth of +6% and a regulatory process that does not require additional clinical studies to obtain marketing approval, Peru represents an excellent near-term revenue opportunity for Rockwell. We are excited to work with Quimica Europea, a leading dialysis distributor in the Peruvian healthcare market focused on ensuring patients get access to transformative therapies. Quimica Europea and their experienced team are highly skilled and intensely focused on leveraging their business into the forefront of the rapidly growing domestic dialysis market in Peru, and we expect them to have great success selling Triferic."

Mr. Ricardo Vecco, CEO of Quimica Europea, added, "We are very excited to have partnered with Rockwell Medical and to have the opportunity to offer such an innovative therapy as Triferic to the Peruvian hemodialysis market. We believe Triferic is a revolutionary iron replacement product that will greatly improve the lives of dialysis patients and we intend to work in partnership with Rockwell management to offer it to patients as fast as possible. Quimica Europea is committed to addressing the needs of patients and healthcare providers with innovative products that can improve lives. This partnership enhances Quimica Europea's product portfolio."

Under the terms of the agreement, Quimica Europea will become the exclusive distributor for Triferic in Peru for an initial commercial term of five years, with an extended term of five additional years based on the achievement of annual minimum purchase requirements. In addition to the assumption of all expenses related to the sales and marketing of Triferic in Peru, Quimica Europea will assume all regulatory responsibilities and related expenses in obtaining government commercial marketing approval for Triferic. Rockwell retains manufacturing responsibility of all products. Quimica Europea is required to achieve annual minimum purchase requirements to retain exclusive commercialization rights."

Founded in 1999, Quimica Europea is a privately held distributor of drugs and devices for the hemodialysis market in Peru. Quimica currently maintains nearly 40% market share of all dialysis products distributed in Peru and in some product categories controls nearly 90% market share.

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 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.

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

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