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Rockwell Medical Announces Triferic Human Intravenous (IV) Pharmacokinetic Study Published in Journal of Clinical Pharmacology

- Publication Highlights Human Dose Response, Lack of Non-Transferrin Bound Iron and Labile Plasma Iron -

WIXOM, Mich., Oct. 04, 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 for the treatment of iron replacement, secondary hyperparathyroidism and hemodialysis, announced today that the Triferic Phase-1 Healthy Volunteer Intravenous (IV) Pharmacokinetic Study has been published in the Journal of Clinical Pharmacology. Triferic is the Company's new and innovative FDA approved anemia therapy indicated to replace iron-and maintain hemoglobin in chronic kidney disease patients receiving hemodialysis.

The published study examined the pharmacokinetics of Triferic administered to 49 healthy volunteers. The dose range spanned 2.5 to 10 mg of iron IV over 4 hours, and 15 and 20 mg of iron IV over 12 hours. Serum total iron, transferrin bound iron (TBI), hepcidin-25 and markers of oxidative stress and inflammation were obtained. The results demonstrate that Triferic iron is rapidly bound to transferrin and rapidly cleared from the circulation, with a half-life of between 1.2 and 2 hours. Triferic was completely bound to transferrin as there was no non-transferrin-bound iron found. Triferic did not induce oxidative stress at any dose. Triferic administered IV was well tolerated with a safety profile similar to placebo. The article and supplemental materials are available as open access at the Journal of Clinical Pharmacology website:

Pratt RD, Swinkels D, Ikizler TA and Gupta A: Pharmacokinetics of Ferric Pyrophosphate Citrate, a novel iron salt, administered intravenously to healthy volunteers: J Clinical Pharmacology DOI: 10:1002/jcph.819.
http://onlinelibrary.wiley.com/doi/10.1002/jcph.819/full

Rob Chioini, Founder, Chairman and CEO of Rockwell Medical, stated "This study publication contributes to our ongoing work to expand the use of Triferic to new indications, such as Peritoneal Dialysis (PD) and Total Parenteral Nutrition (TPN). The results also highlight that Triferic, upon administration, immediately donates iron to transferrin and is transported to the bone marrow for incorporation into hemoglobin, avoiding entrapment in the liver, iron overload and cardiovascular toxicity. This is one of the key advantages that Triferic has over the traditional IV iron products that have been used in dialysis patients."

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 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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Source: Rockwell Medical, Inc.