



Rockwell Medical Presents Triferic® Real World Evidence Update at ASN Kidney Week 2021

November 4, 2021

-Results from pilot observational analysis demonstrate maintenance of hemoglobin and reduction of total IV iron requirement in adult patients on Triferic receiving chronic hemodialysis-

-Findings align with pivotal trials of Triferic and prior Real World Evidence-

WIXOM, Mich., Nov. 04, 2021 (GLOBE NEWSWIRE) -- Rockwell Medical, Inc. (Nasdaq: RMTI), a biopharmaceutical company dedicated to transforming the treatment of iron deficiency and anemia management and improving outcomes for patients around the world, today presented new Real World Evidence from a Mid-Sized Dialysis Organization (MDO) pilot observational analysis program at the American Society of Nephrology (ASN) Kidney Week 2021 in San Diego, California. Results indicated that Triferic (Ferric Pyrophosphate Citrate, FPC) is well-tolerated for the replacement of iron to maintain hemoglobin in adult patients with hemodialysis-dependent chronic kidney disease (HDD-CKD), findings which are consistent with prior Real World Evidence of Triferic and pivotal clinical trials. The abstract can be viewed [online here](#).

"This new Real World Evidence confirms findings from our prior Real World Evidence publications and from our pivotal clinic trials, namely, that the integration of Triferic into anemia management protocols results in the reduction of IV iron and ESA use, and potentially to a significant reduction in overall cost of treatment," said Marc Hoffman, M.D., Chief Medical Officer at Rockwell Medical. "Today's results are relevant not only for patients and caregivers but for dialysis clinics and the medical community, and further strengthen Triferic's position as an important part of the treatment arsenal for patients on hemodialysis."

In the study, Triferic was added to centrally delivered liquid bicarbonate to provide 110 µg Fe/L dialysate, and all patients received Triferic at each dialysis appointment. Anonymized prospective data were provided between September 2020 and April 2021. During the first three months of administration of Triferic, clinics in the study observed a modest 23 percent reduction of IV iron. Subsequently, a new iron management protocol was released specifically designed to guide IV iron use in conjunction with Triferic; this was adopted by nine clinics while five clinics chose to maintain their standard of care. Within three months of initiation of the new protocol, iron utilization in the Triferic group decreased by 81 percent, while iron utilization increased by 19 percent in the standard of care group. During this same period, hemoglobin remained stable in both groups (+/- 0.2 g/dL from baseline). Concurrent with these changes, Mircera® (methoxy polyethylene glycol-epoetin beta) dose remained stable in the standard of care group but was reduced 37 percent (from post-adoption baseline) in the Triferic group.

Additional clinics continued to adopt the new protocol over time. Taking into account the staggered adoption of the protocol, after eight months, the aggregate iron utilization across all 14 clinics was reduced by 51 percent and trending lower. Mircera dose was stable (decreased 5 percent) and hemoglobin remained stable.

For more information about real-world evidence related to Triferic or to directly access the publications, please visit www.triferic.com/resources.

About Rockwell Medical

Rockwell Medical is a commercial-stage biopharmaceutical company developing and commercializing its next-generation parenteral iron technology platform, Ferric Pyrophosphate Citrate (FPC), which has the potential to lead transformative treatments for iron deficiency in multiple disease states, reduce healthcare costs and improve patients' lives. The Company has two FDA-approved therapies indicated for patients undergoing hemodialysis, which are the first two products developed from the FPC platform. The Company is developing FPC for the treatment of iron deficiency in patients outside of dialysis, who are receiving intravenous medications in the home infusion setting, a large and rapidly growing segment of healthcare, and where these patients suffer from chronic diseases associated with high incidence of iron deficiency and anemia. In addition, Rockwell Medical is one of two major suppliers of life-saving hemodialysis concentrate products to kidney dialysis clinics in the United States. For more information, visit www.rockwellmed.com.

CONTACTS

Investors:

Argot Partners

212.600.1902

Rockwell@argotpartners.com

Media:

David Rosen

Argot Partners

212.600.1902

david.rosen@argotpartners.com



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