

Next Generation BioPharma with Advanced Treatments for Anemia & FDA-Approved Therapies: Rockwell Medical (NASDAQ: RMTI)

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WIXOM, MICHIGAN, UNITED STATES, July 6, 2021 /EINPresswire.com/ -- [Next Generation BioPharma](#) with Advanced Treatments for Anemia & [FDA-Approved Therapies: Rockwell Medical \(NASDAQ: RMTI\)](#)

☐ Commercial Stage Developer of Advanced Treatments for Anemia.

☐ Major Supplier of Hemodialysis Concentrate Products to Kidney Dialysis Clinics in the United States.

☐ Bre-IND Meeting Request with FDA for Proposed Clinical Trial of Treatment for Iron Deficiency Anemia in Patients Receiving Home Infusion.

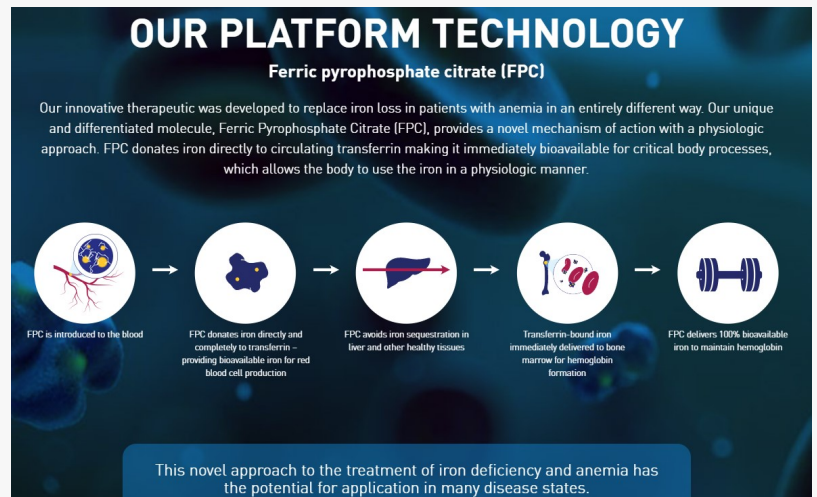
☐ Extension of Multi-Year Distribution Agreement with Nipro Medical Corporation for Dialysis Concentrates – Minimum Value \$11.4 Million.

☐ Exclusive License Agreement with Drogan Pharmaceuticals in Turkey.

Rockwell Medical (NASDAQ: RMTI) 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.



RMTI Logo



RMTI Technology

RMTI has two FDA-approved therapies indicated for patients undergoing hemodialysis, which are the first two products developed from the FPC platform. RMTI 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, RMTI is one of two major suppliers of life-saving hemodialysis concentrate products to kidney dialysis clinics in the United States.

THE ROLE OF IRON IN MAINTAINING HEALTH

Iron is very important in maintaining many body functions, including the production of hemoglobin, the molecule in the blood that carries oxygen. If the body doesn't have sufficient hemoglobin, tissues and muscles don't get enough oxygen to function effectively. This leads to a condition called anemia.





We expect to finalize our Phase 2 clinical study design and protocol with the advice and guidance of the FDA"

*Russell Ellison, M.D., RMTI
President and Chief Executive
Officer*

Anemia affects more than 1.6 billion people globally and over 3 million people in the U.S. Iron deficiency is the most common cause of anemia worldwide, afflicting several hundred million people. Severe iron-deficiency anemia may cause fatigue or tiredness, shortness of breath, or chest pain.

▣ RMTI Works to Manage Iron in a New Way





TRIFERIC is the first and only FDA-approved product indicated for the replacement of iron to maintain hemoglobin in adult patients with hemodialysis-dependent chronic kidney disease (HDD-CKD).

TRIFERIC is a novel physiologic approach to iron maintenance - delivering bioavailable iron to replace what is lost at every dialysis treatment, resulting in hemoglobin stability.^{1,2,3}


[LEARN MORE](#)

IMPORTANT SAFETY INFORMATION FOR TRIFERIC


INDICATION
TRIFERIC is indicated for the replacement of iron to maintain hemoglobin in adult patients with hemodialysis-dependent chronic kidney disease (HDD-CKD).

Limitations of Use
TRIFERIC is not intended for use in patients receiving peritoneal dialysis. TRIFERIC has not been studied in patients receiving home hemodialysis.


Warnings and Precautions




RMTI Triferic



OUR COMPANY
OUR THERAPEUTIC FOCUS
OUR TECHNOLOGY
HEMODIALYSIS CONCENTRATES
INVESTORS





Triferic AVNU is designed for direct intravenous infusion, which provides hemodialysis patients with greater access to the Triferic platform and expands administration options for clinicians.


Triferic AVNU can be administered regardless of a dialysis center's mode of bicarbonate delivery. Many dialysis centers in international markets and an increasing number of dialysis centers in the U.S. have converted to the use of dry bicarbonate cartridges or bags and on-line dialysate generation, which is not compatible with Triferic Dialysate.

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IMPORTANT SAFETY INFORMATION FOR TRIFERIC AVNU

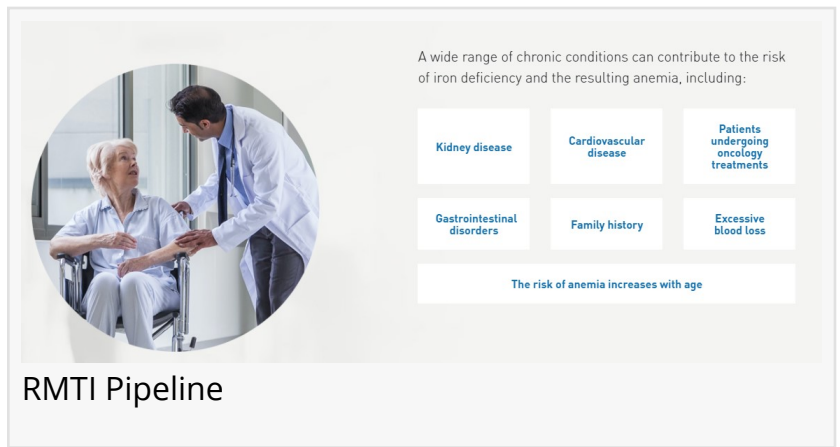
INDICATION
TRIFERIC AVNU (ferric pyrophosphate citrate for injection) is an iron-replacement product indicated for the replacement of iron to maintain hemoglobin in adult patients with hemodialysis-dependent chronic kidney disease (HDD-CKD).

Warnings and Precautions
Serious hypersensitivity reactions, including anaphylactic-type reactions, some of which have been life-threatening and fatal, have been reported in patients receiving parenteral iron products. Patients may present with shock, clinically



RMTI Triferic AVNU

The RMTI ferric pyrophosphate citrate (FPC) product is a novel complex iron salt, developed to replace iron losses in patients with anemia in an entirely new way. This unique and differentiated molecule consists of an iron atom complexed to one pyrophosphate and two citrate anions. This RMTI formulation has been shown to allow for rapid donation of iron to transferrin, protein in the blood that binds to iron and transports it through the body, including to the bone marrow. This mechanism uses the body's own means to transport iron safely to tissues that need iron (i.e. red blood cells and muscle).



The RMTI FPC product is a form of protected iron in which citrate and pyrophosphate are tightly complexed to the iron. The molecule is water soluble, making the iron completely bioavailable. FPC has the ability to deliver iron directly and completely to transferrin. This transferrin-bound iron is immediately delivered to the bone marrow to be incorporated into hemoglobin.

The structure of FPC minimizes the potential for the iron to be taken up into the body's storage cells, such as those present in the liver and other tissues. Iron release from body storage cells can be slowed or blocked when inflammation is present. Because of its Mechanism of Action, FPC increases bioavailable iron without excessively increasing body iron stores or causing inflammation, iron toxicity, or oxidative stress.

In addition, FPC iron is delivered regardless of other underlying conditions which might otherwise block the release of iron. Some of the challenges of managing iron in sick patients, including inflammation, hepcidin block, and functional iron deficiency, can be overcome with FPC due to its ability to provide bioavailable iron.

□ RMTI Files Pre-IND Meeting Request with FDA for its Proposed Clinical Trial of FPC as a Treatment for Iron Deficiency Anemia in Patients Receiving Home Infusion

On June 28th RMTI announced that it has submitted a pre-IND (Investigational New Drug) meeting request with the U.S. Food and Drug Administration (FDA) in support of its proposed Phase 2 clinical trial of Ferric Pyrophosphate Citrate (FPC), designed for the treatment of iron deficiency anemia and maintenance of hemoglobin in patients receiving infusion therapy in the home setting.

Home infusion represents a large and rapidly growing segment of healthcare. Many patient groups requiring home infusion therapies suffer from chronic diseases that are associated with a high incidence of iron deficiency and anemia. For example, it is estimated that 40%-55% of all

home parenteral nutrition patients are iron deficient. Current treatment patterns can be inadequate for patients on home infusion therapy with iron deficiency anemia, causing them to suffer extreme fatigue and can result in serious health risks, such as, poor immune function and heart failure.

□ Extension of Multi-Year Distribution Agreement with Nipro Medical Corporation for Dialysis Concentrates - Minimum of Approximately \$11.4M in Purchases Over 3-year Period

On June 11th RMTI announced that it extended its distribution agreement with its long-term distribution partner, Nipro Medical Corporation (NMC), for a period of three years through May 2024. The agreement was originally initiated in 2008. With the extension of the agreement, NMC will continue to distribute dialysis concentrates manufactured by RMTI to numerous countries in Latin America and the Caribbean. NMC is a leading renal, medical, surgical and interventional radiology products manufacturer and a major distributor of renal products in these regions.

□ RMTI and Drogosan Pharmaceuticals Enter into Exclusive License Agreement for the Rights to Commercialize TRIFERIC® in Turkey

- With approximately 65,000 patients receiving hemodialysis annually, Turkey represents a significant and expanding market opportunity -

On June 8th RMTI and Drogosan Pharmaceuticals, a leading pharmaceutical company in Turkey with an established presence in the nephrology space having launched the first locally manufactured biosimilar in 2014 and building it to be the leader in the Epoetin Alfa market in Turkey, announced that the Companies entered into an exclusive license agreement for the rights to commercialize the RMTI Triferic AVNU (ferric pyrophosphate citrate injection) product in Turkey.

Under the terms of the license agreement, Drogosan will be the exclusive development and commercialization partner for Triferic in Turkey and RMTI will supply the product to Drogosan. The agreement also allows for Drogosan to negotiate further geographic expansion into the surrounding region. In consideration for the license, RMTI will receive an upfront fee and will be eligible for milestone payments based on reimbursement price approval.

For more information on Rockwell Medical (RMTI) visit: <https://www.rockwellmed.com>.

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