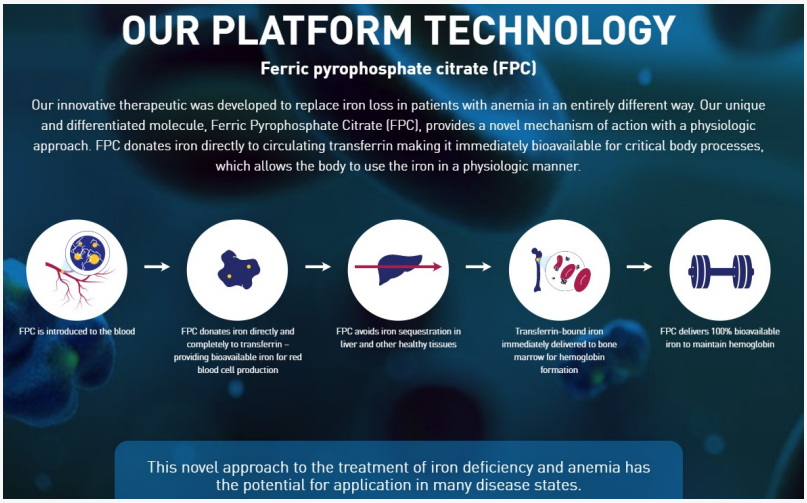
Next Generation BioPharma with Advanced Treatments for Anemia & FDA-Approved Therapies: Rockwell Medical (NASDAQ: RMTI)

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

RMTI Logo



RMTI Technology

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.

- Pre-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 Drogsan 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 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.

RMTI Triferic

RMTI Triferic AVNU

THE ROLE OF IRON IN MAINTAINING HEALTH

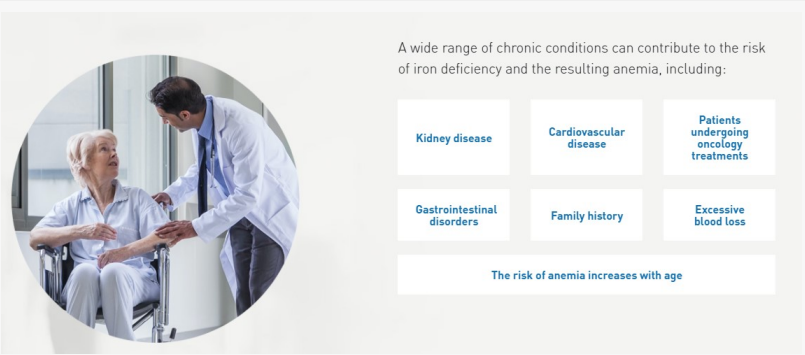
Iron is very important in maintaining many body functions, including the production of hemoglobin, the molecule in the blood that carries oxygen. If the body doesn't have sufficient hemoglobin, tissues and muscles don't get enough oxygen to function effectively. This leads to a condition called anemia.

> 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*

Iron deficiency is very common, and approximately 10 million people are iron deficient in the United States. Inadequate iron intake due to poor diet or restrictive diets can lead to iron deficiency, as well as numerous other underlying diseases and risk factors.

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



RMTI Pipeline

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 28thRMTI 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 11thRMTI 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.

RTIM and Drogsan 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 8thRMTI and Drogsan 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, Drogsan will be the exclusive development and commercialization partner for Triferic in Turkey and RMTI will supply the product to Drogsan. The agreement also allows for Drogsan 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.

as research material. All readers are strongly urged to perform research and due diligence on their own and consult a licensed financial professional before considering any level of investing in stocks. All material included herein is republished content and details which were previously disseminated by the companies mentioned in this release or opinion of the writer. CAP/FPS/ CA is not liable for any investment decisions by its readers or subscribers. Investors are cautioned that they may lose all or a portion of their investment when investing in stocks. CAP/FPS/CA has been compensated $500 by a third party for dissemination of this article.

Disclaimer/Safe Harbor:

These news releases and postings may contain forward-looking statements within the meaning of the Securities Litigation Reform Act. The statements reflect the Company's current views with respect to future events that involve risks and uncertainties. Among others, these risks include the expectation that any of the companies mentioned herein will achieve significant sales, the failure to meet schedule or performance requirements of the companies' contracts, the companies' liquidity position, the companies' ability to obtain new contracts, the emergence of competitors with greater financial resources and the impact of competitive pricing. In the light of these uncertainties, the forward-looking events referred to in this release might not occur.

SOURCE: CorporateAds.com

Dr. Russell H. Ellison M.Sc., M.D., MSc.Bres, CEO & Directo
Rockwell Medical, Inc.
+1 248-960-9009
email us here
Visit us on social media:
Facebook
Twitter
LinkedIn