



Rockwell Medical Announces Completion of Patient Enrollment Ahead of Schedule in Pivotal Phase 3 Clinical Trial of Triferic® in China

April 25, 2022

Trial with over 400 Patients Conducted by Partner Wanbang Pharmaceuticals, a Subsidiary of Fosun Pharma



Over 600,000 Patients receive Hemodialysis in China

WIXOM, Mich., April 25, 2022 /PRNewswire/ -- [Rockwell Medical](#), Inc. (Nasdaq: RMTI), a biopharmaceutical company dedicated to transforming the treatment of iron deficiency and anemia management, today announced that its partner, [Wanbang Biopharmaceuticals](#) enrolled the final patient, ahead of schedule, in its pivotal Phase 3 clinical trial for [Triferic®](#) (ferric pyrophosphate citrate) Dialysate to support a new drug application for regulatory approval in China. Wanbang Biopharmaceuticals is a subsidiary of Shanghai Fosun Pharmaceutical (Group) Co., Ltd. ("[Fosun Pharma](#)"), which is on the [Forbes Global 2000](#) list of the world's largest publicly-traded companies.

"This is a major milestone toward approval of Triferic Dialysate in China," commented Russell Ellison, M.D., M.Sc., President and CEO of Rockwell Medical. "[Initiated in January of last year](#), the trial has now enrolled a total of 442 patients at sites across the country. With over 600,000 patients receiving hemodialysis, China represents an enormous potential market opportunity for Rockwell, as we execute on our strategic plan to expand global access to Triferic."

Fosun Pharma is targeting submitting a New Drug Approval (NDA) submission to China's National Medical Products Administration ([NMPA](#)) in the third quarter of 2023.

Yongchun Zhou, Vice President at Wanbang Biopharmaceuticals stated, "The study was discussed with regulators from the Center for Drug Evaluation (CDE), part of the NMPA, at a very early stage, and was designed with feedback from those initial meetings top-of-mind. We congratulate our clinical trial team at Wanbang Biopharmaceuticals for executing a project plan for a complex study under challenging circumstances, and we look forward to completion of the trial in 2023."

The Phase 3 trial ("RMFPC-13") is a prospective, randomized, single-blind (patient), parallel two-arm, placebo-controlled, multicenter, study of Triferic administered via hemodialysate in Chinese CKD-5HD (hemodialysis) patients. The objective of the study is to confirm the efficacy and safety of Triferic administered at each hemodialysis treatment via hemodialysate in maintaining hemoglobin in Chinese CKD-5HD patients. Rockwell Medical signed exclusive licensing and manufacturing supply agreements with Wanbang Biopharmaceuticals for the rights to commercialize Triferic in China in 2016.

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. Rockwell Medical is also advancing its FPC platform by developing FPC for the treatment of iron deficiency anemia in patients outside of dialysis, who are receiving intravenous medications in the home infusion setting. 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.

Forward-Looking Statements

Certain statements in this press release may constitute "forward-looking statements" within the meaning of the federal securities laws. Words such as, "may," "might," "will," "should," "believe," "expect," "anticipate," "estimate," "continue," "could," "can," "would," "develop," "plan," "potential," "predict," "forecast," "project," "intend," "look forward to" or the negative of these terms, and 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), many of which are beyond our control and subject to change. Actual results could be materially different. Risks and uncertainties include, but are not limited to those risks more fully discussed in the "Risk Factors" section of our Annual Report on Form 10-K for the year ended December 31, 2021, as such description may be amended or updated in any future reports we file with the SEC. Rockwell Medical expressly disclaims any obligation to update our forward-looking statements, except as may be required by law.

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