

## Rockwell Looking to Start New Iron Age

**Keith Chartier**

06/05/2009

Iron management in dialysis patients today is largely done intravenously; however, in the next few years Wixom, [Mich.-based](#) Rockwell Medical Technologies hopes to have a new dialysate-delivered iron drug on the market that could improve iron care, as well as save money.

Robert Chioni, Rockwell president and CEO, formed the company in 1995 when it started making dialysis kits and other ancillary dialysis products. In the years since, the company has grown from four employees to more than 130, has its own fleet of delivery trucks and is one of four major concentrate manufacturers and distributors in the United States.

Today, Rockwell's top priority is to complete the development of its iron therapy called Soluble Ferric Pyrophosphate, or SFP. It is designed to be delivered in small amounts as part of the dialysate during a dialysis treatment.

Ajay Gupta, MD, said he hopes SFP will solve the biggest challenge in iron management today—to efficiently deliver iron to bone marrow. He added that getting the iron to the bone marrow effectively and efficiently can lead to healthier patients, as well as lower costs for renal care overall. Gupta is an associate professor of medicine at UCLA and Charles Drew University Schools of Medicine, Los Angeles, as well as the inventor of SFP as a parenteral iron supplement .

SFP is a simple iron salt comprising ferric iron tightly bound to pyrophosphate with the highest binding stability constant vs. other large polymeric iron-carbohydrate complexes used intravenously, according to Rockwell. SFP's pyrophosphate component physiologically already exists naturally in the human body and is the chelator used by the body to normally transport iron inside the cells.

The phase 2 study of SFP should be finished at the end of 2009, and a phase 3 study could start by the end of 2010. Chioni said he expects SFP to hit the market in 2011.

"SFP essentially bypasses the liver and the other iron stores, and delivers iron directly into the blood in very small amounts, so that the blood's carrying capacity for iron is not overrun," Gupta said. "It takes it directly to the bone marrow, completely bypassing the liver, lymph nodes, spleen, etc."

Gupta estimated that the SFP's iron delivery is close to 100 percent. "We are delivering it directly to the bone marrow—just as you do when you eat a steak," he added. "When you eat a steak, and you are iron deficient, then the iron that is absorbed goes directly to the bone marrow from the bloodstream."

More delivered iron could also reduce expensive erythropoietin use, said Gupta. When EPO is dosed, you need iron. One of the reasons so much EPO gets used is because EPO is dosed, but at that time iron isn't available. So for it to work effectively or efficiently, more EPO would have to be dosed. SFP has iron available all of the time.

"There should be a benefit of needing less EPO, which is nice," Chioni said. "But with the bundling environment coming our way in 2011, especially, it's a perfect timing for this product. By maintaining iron on a consistent basis and being able to have it there when EPO is dosed, we believe we'll see somewhere between 20 and 50 percent less EPO needing to be dosed."

In addition to potential cost saving from less EPO, Chioni said using SFP could also save money because delivering it through the dialysate eliminates a needle, a syringe and an RN, who has to spend between five and fifteen minutes per patient to deliver the IV iron. "There is a savings there," Chioni said.