

Kidney treatment breakthrough boosts Wixom firm

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Salwa Sayah, Rockwell Medical quality control manager, measuring the amount of glucose in the product, in the lab at Rockwell Medical in Wixom on Feb. 13.(Photo: Daniel Mears / The Detroit News)

A Michigan-made drug recently approved by the Food and Drug Administration promises a safer, more-effective treatment for anemia in patients with chronic kidney disease and end-stage renal failure.

The compound, called Triferic, has put a national spotlight on Rockwell Medical Technologies Inc. — a small, by industry standards, pharmaceutical company that started in a Ferndale garage and now employs 300 people nationwide with headquarters in Wixom.

Triferic is the first iron maintenance drug approved by the FDA to replace iron and maintain hemoglobin in dialysis-dependent patients with chronic kidney disease. The generic name is ferric pyrophosphate citrate.

"We do think it's a very important advance for the treatment of patients on dialysis," said Dr. Steven Fishbane, a professor of medicine at Hofstra North Shore-LIJ School of Medicine, in Great Neck, N.Y., and a co-principal investigator in clinical trials of Triferic, with Harvard Medical School Professor Ajay Singh. "It's kind of exciting. I think it's looking very promising."

In 2013, the United States had about 452,000 people with end-stage renal disease receiving dialysis, according to research by IMS Midas, a health information services firm. About 2.52 million people worldwide require treatment for iron-deficiency anemia, a number that is growing 6 percent to 8 percent annually.

Iron-deficiency anemia is a frequent side effect of hemodialysis, the common treatment for people with chronic kidney disease and end-stage renal failure. Three to five times a week their blood is filtered through a dialysis machine that removes wastes, extra salt and fluids — the job normally done by the kidneys.

The process helps control blood pressure and restores blood to proper pH or acidity levels — but patients lose about 5 milligrams to 7 milligrams of iron with every dialysis treatment. Normal iron levels are between 34.9 and 44.5 percent for adult women and 38.8 to 50 percent for adult men, according to the Mayo Clinic.

Iron is needed for the body to produce red blood cells and hemoglobin, the protein that transports oxygen throughout the body. This essential element also functions as a seat belt for oxygen molecules, binding them to the hemoglobin for transport.

Iron-deficiency anemia causes fatigue, weakness, decreased physical and mental function, and even heart failure. The most common treatment is intravenous iron infusion, but it has lots of side effects. The IV iron can overload the body, mainly in the liver, which is toxic and causes inflammation and increased risks of infection, anaphylactic shock and death.

"Over the last couple of years, there are increasing concerns about infections and other safety risks" associated with IV iron infusion, said Fishbane, who tested "hundreds" of patients with Triferic during a 52-week clinical trial. "(Triferic) was most importantly both effective and very well tolerated and safe."

Triferic was tested in clinical trials involving more than 100,000 hemodialysis patients.

The hundreds of thousands of people with end-stage renal failure or who need iron-deficiency anemia treatment are a big potential market for Rockwell, which founder and CEO Robert Chioini started in 1995 in a 10-foot by 10-foot space commandeered from his father's commercial cleaning business off Livernois in Ferndale. The Michigan State University advertising graduate worked in sales for a medical products company and a dialysis products company before deciding to start his own business.

"I just kind of set up shop in there," Chioini said. "I took what I had learned in both those companies and squarely moved into dialysis products."

"I started out with (sterile dialysis) kits and would go out and sell them. My mom and my older brother would package them, and my dad would go out and deliver them."

Chioini soon began manufacturing dialysis concentrates, marketed as RenalPure Liquid Acid. He moved to Wixom and hired a chemist, plant manager, customer service personnel and transportation staff. His products were delivered by the drum in his own fleet of trucks. Then he developed dry dialysis products, called the Dri-Sate Dry Acid Mixing System.

"The thought was I wanted to get rid of the drums so I came up with a dry product. We were able to grow with a lot more trucks and drivers," Chioini said.

In 2001, Chioini was contacted by Dr. Ajay Gupta, a nephrologist or kidney doctor then working at Henry Ford Health System. Gupta now is the chief scientific officer for Rockwell Medical.

"Ajay saw our dialysate product at his clinic and was looking for a company to commercialize his invention of delivering iron through dialysate (the liquid used in hemodialysis for cleaning blood)," Chioini recalled. "The iron was a water-soluble salt so it could be delivered through the dialysate.

"We ended up licensing the technology in 2002."

The FDA approved intravenous iron as a rescue therapy for patients whose ferritin or iron stores levels are low due to iron deficiency, he said. The approval on Jan. 26 made Triferic the first and only iron maintenance therapy, meaning it can be used routinely with every dialysis treatment to replace iron and maintain hemoglobin — preventing iron-deficiency anemia.

According to Chioini, Triferic is more convenient and less costly than IV iron because it's added to the dialysis solution, rather than being administered by a separate IV line. The drug is slowly infused into the patient's bloodstream during the four-hour hemodialysis session. There is no chance of overloading the liver with iron, because the delivery method bypasses that vital organ.

"What makes Triferic special is that as soon as it enters the blood it immediately binds to transferrin (the natural binding site for iron in the human body) and goes to the bone marrow," Chioini said. "It's very similar to how healthy people get iron through food in their diet.

"Our expectation is that 450,000 patients in the U.S. today will all use this, and this will become the standard of care," Chioini added. "The technology, formulation and method of delivery is patented. It's probably the biggest thing to hit dialysis in 25 years."

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