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New data Support That Ferric Bepectate Will Be The Next-Generation IV-Iron Treatment

by

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According to the World Health Organization (WHO), around two billion people in total, or more than 30% of the global population, are anemic. In many cases due to iron deficiency.

In developing countries an estimated 50% of pregnant woman and 40% of preschool children are anemic. Iron deficiency in the developing world is often aggravated by worm infections, malaria and other infectious diseases such as tuberculosis, HIV/AIDS or schistosomiasis.

The consequences of failing to maintain healthy iron levels can be critical. For example, anemia contributes to 20% of all maternal deaths worldwide. It is also responsible for impaired physical and cognitive development, increased risk of child morbidity, and reduced productivity in adults. Timely and effective treatment of iron deficiency can restore personal health and raise national productivity levels by as much as 20%, the WHO says.

Worse With Age

All of these problems will only get worse as populations around the world age rapidly over the next decades. Iron deficiency or iron-deficiency anemia are typically associated with malnutrition, major surgery, pregnancy and menstruation, but they are also frequently

diagnosed in people aged 70 years or over, and in age-related conditions such as chronic renal disease, cancer or inflammatory bowel disease.

Treatment of iron deficiency may seem easy achievable with oral iron, but iron is poorly absorbed in the gastrointestinal (GI) tract and GI side effects is a frequent complicating factor. In addition, when patients have symptoms caused by iron deficiency the iron stores in the body are typically depleted, requiring treatment for several months if attempts were made to relieve it by the oral route. Treatment of iron deficiency is therefore complicated by the need to deliver not just enough iron to restore health and productivity, but also the right levels to restore the iron stores in the body – and in the right way – to avoid any potentially severe adverse effects.

Iron is a crucial element of human life, both in the production of oxygen-carrying hemoglobin and as a core component of enzymes and proteins involved in key metabolic processes within the body. At the same time, though, too much free iron in the body may cause potentially fatal damage to human organs.

Benefit And Risk

Striking an acceptable balance between benefit and risk is fundamental to optimizing the effectiveness of iron treatment. Although IV-iron treatment has improved in some countries, high levels of iron deficiency still exist, as treatment strategies around the world remained essentially unaltered for decades. Most patients either do not receive treatment or are given oral iron formulations, exposing them to problematic gastrointestinal side-effects, such as nausea or constipation. Where intravenous (IV) iron therapy is available, there is still a risk of patients reacting adversely to free iron in plasma especially with compounds containing loosely bound iron.

Next-generation Solution

Iron4u is responsible for the clinical development of Ferric Bepectate. Iron4u has a team of specialists in the iv-iron market and associated treatments. The company will also be responsible for manufacturing of the finished product, and for worldwide commercialization outside Germany.

New data from clinical trials with Ferric Bepectate, an injectable total-dosage iron therapy based on modified starch rather than dextran, suggest that a next-generation solution to these issues is within reach. The clinical Phase-II trials showed that Ferric Bepectate can transport high-dose iron effectively and conveniently into the human body, with minimal risk of free iron in plasma.

Ferric Bepectate is the product of a development and marketing partnership between Germany's

Serumwerk Bernburg AG and Iron4u ApS, a pharmaceutical company founded in 2012 by investors from five European countries and based just outside Copenhagen, Denmark. Serumwerk Bernburg discovered and created Ferric Bepectate, securing patent coverage on the product until 2032. The German company will also manufacture the active pharmaceutical ingredient for future commercialization.

Iron4u holds sales and marketing rights to Ferric Bepectate worldwide except in Germany, where they stay with Serumwerk Bernburg. Iron4u is responsible for the clinical development of Ferric Bepectate, for manufacturing the finished product, and for worldwide commercialization outside Germany. Once Ferric Bepectate is approved and launched, it is expected to play a significant role in the IV iron market for treatments that can provide high dose iron repletion in one dose, yet without compromising patient safety.

Phase II Results

In Phase II trials, Ferric Bepectate was characterized by a rapid removal of iron from plasma; a low risk of free iron-related anaphylactoid adverse reactions; a slow physiological release of iron, with no serum ferritin peak; and the absence of iron in trial participants' urine, indicating that no free iron was circulating in plasma.

“The unique concept of Ferric Bepectate is basically iron nanoparticles encapsulated in a structure that forms a stronger and bigger complex than seen with other IV iron products,” explained Stig Waldorff, Medical Director at Iron4u. These characteristics make for “an ideal pharmacokinetic profile of an IV iron which is quickly cleared from plasma with minimal exposure to free iron,” he added.

With the global market for IV iron dominated by older products, and with interest shifting to higher-dose formulations, the Phase-II results with Ferric Bepectate indicate “an optimal iron carrier with convenient and easy administration and an efficacy and safety profile highly relevant to both patients and healthcare professionals,” Waldorff said.

Phase III trials

Ferric Bepectate is now in Phase III clinical trials involving 800 patients in three European countries (England, Austria and Germany). Two clinical Phase-III studies in, respectively, pre- and post-surgery are underway in collaboration with Germany's Fraunhofer Institute, the largest research organization in Europe. The principal investigators, Professor Kai Zacharowski and Professor Patrick Meybohm, believe these studies will make a significant contribution to our knowledge on the advantages of using IV iron before and after operations.

Commercial potential

Iron4U is also looking for partners to support further development and commercialization of Ferric Bepectate, with a particular emphasis on the US market but ultimately aiming at worldwide distribution. “The potential for an effective and well tolerated IV iron treatment which clinicians are comfortable using is enormous,” commented Iron4U’s CEO, Odd Vaage-Nilsen. “We expect US market sales of IV iron to reach US\$1 billion within two to three years.”

The full potential in the US market alone “may well exceed US\$ 5 billion”, Vaage-Nilsen added. “We are confident that ongoing clinical Phase-III trials with Ferric Bepectate will bring new knowledge to the medical world that might raise iron treatment to a new level.”