



## RECENT DATA SUGGEST RESEARCHERS HAVE FOUND NEW GENERATION IV-IRON TREATMENT

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***Iron deficiency is the most widespread nutritional disorder affecting one third of the world's population. Yet, current iron deficiency treatment is in many countries both inconsistent and old-school. New clinical phase-2 data, however, suggest that German researchers have discovered an IV-iron treatment capable of transporting iron into the human body with a minimum risk of free iron in plasma.***



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According to the [World Health Organisation](#) (WHO) 2 billion people – representing over 30% of the world's population – are affected by iron deficiency. In fact, it is the only nutrient deficiency significantly prevalent in industrialised countries.

Despite staggering numbers and its widespread prevalence iron deficiency treatment hasn't changed fundamentally for decades. Most patients are either not treated or exposed to troublesome gastrointestinal side effects caused by oral iron. An alternative to oral iron is

intravenous iron therapy. Currently used IV-iron products have a risk of exposing the patient to free iron which does not seem to be the case with this new product.

Iron is essential for life itself: In the plant kingdom for the function of the photosynthesis processes. In the animal kingdom for the function of haemoglobin in red blood cells, and as a central component in many critical enzymes in the body. Yet, excess free iron in the human body may cause potentially fatal damage to the patients' organs.

According to WHO, however, benefits from fighting iron deficiency are substantial. Timely treatment can restore personal health and raise national productivity levels by as much as 20% in third world countries.

Besides malnutrition, major surgery, pregnancy and menstruation iron deficiency or iron deficiency anaemia is often diagnosed in patients suffering from chronic renal disease, cancer, inflammatory bowel disease and in elderly people (+70 years). As the number of elderly people is expected to grow rapidly over the next decades, the need to diagnose and treat iron deficiency in the old age population will pose a gigantic challenge.

### **An ideal pharmacokinetic profile**

The research and development of *Ferric Bepectate* may constitute the game changer that scientists have been searching for in their efforts to fight iron deficiency and iron deficiency anaemia.

*Ferric Bepectate* is the result of a partnership between *Serumwerk Bernburg AG* (Germany) and *Iron4u ApS* (Denmark). *Serumwerk Bernburg AG* invented and patented the product and will be the future producer of the API (Active Pharmaceutical Ingredient). *Iron4u ApS* will be responsible for the clinical development of *Ferric Bepectate* as well as production of the finished pharmaceutical product and worldwide commercialisation of *Ferric Bepectate* outside Germany.

"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. These characteristics secure an ideal pharmacokinetic profile of an IV-iron which is quickly cleared from plasma with minimal exposure of free iron. We feel confident that *Ferric Bepectate* will set a new benchmark for IV-iron products," says Medical Director at Iron4u, Mr. Stig Waldorff.

"In a global perspective the IV-iron market is dominated by old products. We see a huge unmet need for improved IV-iron compounds that do not release potentially harmful free iron. We have identified a market-move towards larger doses. The results of the clinical phase-2 trial suggest *Ferric Bepectate* to be an optimal iron carrier with convenient and easy administration and an efficacy and safety profile highly relevant to both patients as well as healthcare professionals," says Stig Waldorff.

CEO at Iron4u, Mr. Odd Vaage-Nilsen, adds:

"We are currently seeking partners to support further development and commercialisation of *Ferric Bepectate*. The potential for an effective and well tolerated IV-iron treatment which clinicians are comfortable using is enormous. We expect the US market sales of IV-iron to reach USD 1bn within 2-3 years. The full potential in the US market alone may well exceed USD 5bn. We are confident that ongoing phase-3 clinical trials will bring *Ferric Bepectate* to a new level".

### **Two clinical phase-3 studies ongoing**

In cooperation with the largest research organisation in Europe, the German Fraunhofer Institute with 22.000 employees, two ongoing studies – a pre-surgery as well as a post-surgery study – will involve a total of 800 patients in clinical phase-3.

From Frankfurt Professor Kai Zacharowski and Professor Patrick Meybohm, the principal investigators of the studies, have expressed that these studies will significantly increase our knowledge about the advantages of using IV-iron before and after surgery.

Further information – please visit our [website](#) or feel free to contact us:

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### **Facts about *Ferric Bepectate* – an IV-iron game changer**

- *Phase-2 clinical trial results demonstrate that Ferric Bepectate is characterised by:*
  - *rapid removal of iron from plasma (short half-life)*
  - *low risk of free iron related anaphylactoid adverse reactions*
  - *slow physiological release of iron (no serum ferritin peak)*
  - *no iron in urine – indicating no free iron in plasma*
- *Worldwide sales and marketing rights are owned by Iron4u ApS, Copenhagen, Denmark (except for Germany owned by Serumwerk Bernburg AG)*
- *Ferric Bepectate is patented until 2032*
- *Ferric Bepectate is a patented injectable total dosage iron therapy, currently in clinical phase-3 development for human use as injection and infusion*
- *Phase-3 clinical trials are conducted in 3 European countries: England, Austria and Germany. The clinical phase-3 trials will include 800 patients and has been characterised as “one of the most interesting iron studies in many years”*