

iron4u Aps
Dronninggaards Alle 136
DK-2840 Holte
Denmark

Odd Vaage-Nilsen
+45 4089 0208
ovn@iron4u.com

IRON4U COMPLETED CLINICAL PHASE II AND GRANTED PIP BY EMA FOR NEW HUMAN IV IRON

Further milestones reached as iron4u concludes clinical phase II study and the European Medicines Agency grants an agreement for a pediatric investigation plan.

The Danish pharmaceutical company, dedicated to developing treatments for patients suffering from iron deficiency or iron deficiency anemia, just concluded an important phase II clinical trial. After trial conclusion, the Medical Director at iron4u, Stig Waldorff, MD, says: "The results from phase II clinical trials are promising. Ferric bepectate demonstrated an attractive product profile and we are thrilled by the prospect of having results¹ published soon".

Besides the clinical trial, another milestone was reached as the European Medicines Agency granted an agreement for a pediatric investigation plan for ferric bepectate for pediatric patients 6 months to 18 years of age.

The milestones underscores iron4u's current momentum and Stig Waldorff concludes by saying: "The unique concept of ferric bepectate is basically iron nanoparticles encapsulated in a way that forms a stronger and bigger complex than seen with other IV iron product. These characteristics secures 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".

On the future market perspectives for ferric bepectate President and CEO at iron4u, Mr. Odd Vaage-Nilsen says:

"There is an enormous potential for an effective and well tolerated IV iron treatment which clinicians would be comfortable using. We have thoroughly analyzed the market possibilities, especially on the US market where sales of IV iron within a few years will reach USD 1bn. The total potential in the US market may well exceed USD 5bn. We will not push for partnerships as we have divested an asset enabling us to invest in the necessary clinical phase III studies with own resources. We will wait until it is evident for possible partners, that ferric bepectate is a product that will reach markets with a significant positive impact for patients globally and therefore willing to enter into a fair licensing agreement".

For further information – please visit our [website](#) or contact us:
Mr. Odd Vaage-Nilsen
President and CEO
Mobile: +45 4089 0208
E-mail: ovn@iron4u.com

¹ The results have since been published and can be found here:
<https://onlinelibrary.wiley.com/doi/pdf/10.1111/bcpt.13219>