

PRESS RELEASE

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Subject FAIR-HF subanalysis results announced

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FAIR-HF subanalysis shows that Ferinject[®] improves kidney function in iron-deficient patients with chronic heart failure

Results of a subanalysis from the FAIR-HF (Ferinject[®] Assessment in patients with IRon deficiency and Chronic Heart Failure) study demonstrate that correcting iron deficiency with Ferinject[®] (ferric carboxymaltose) can improve renal function in chronic heart failure patients. Ferinject[®] is an intravenous (i.v.) iron product used to treat iron deficiency and iron deficiency anaemia. These results were presented on May 30th at the Heart Failure Association's Late Breaking Clinical Trials Session in Berlin, Germany, by Dr. Piotr Ponikowski, Professor of Cardiology from Wroclaw, Poland.

The authors of the FAIR-HF studied the effects of Ferinject[®] (ferric carboxymaltose) on renal function in iron deficient, anaemic or non-anaemic patients with chronic heart failure (CHF). Renal dysfunction commonly complicates the natural course of CHF as it makes patients susceptible to more severe symptoms and increases the risk of hospitalisation and death. Current CHF therapies appear to have little or no beneficial effect on declining renal function due to CHF.

"The results of the subanalysis are exciting for cardiologists and nephrologists and need to be investigated further," said Dr. Piotr Ponikowski, Professor of Cardiology at the Medical University in Wroclaw, Poland. "Many patients with CHF have renal dysfunction which is strongly related to poor health outcomes. None of the therapies used currently or recommended for CHF patients have a favourable effect on renal function. Thus, there is great interest in treatments which may protect the kidneys."

In total, 459 patients with CHF and iron deficiency were studied in 75 sites around the world. Two-thirds of the patients received Ferinject[®] weekly until the iron deficiency was reversed, with monthly treatment (maintenance phase) thereafter until week 24. The remaining patients received a placebo. Renal function was evaluated by assessing the estimated glomerular filtration rate (eGFR) at baseline and throughout the study. Increased eGFR corresponds to increased renal function, i.e. improvement.

At study weeks 4, 12 and 24, eGFR was found to be increased in patients receiving Ferinject[®], compared to a small decrease in renal function in the placebo group. At the end of the study, eGFR had increased by a mean of 3.2 ml/min/1.73m² from baseline in Ferinject[®]-treated patients, whereas in the placebo group, eGFR was reduced by 0.6 ml/min/1.73m². The difference between the Ferinject[®]

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and placebo groups was statistically significant ($p=0.017$ at week 24). These improvements in eGFR were seen as early as week 4 of the study. The response to Ferinject[®] was independent of the level of renal function at the start of the study, age, sex, CHF severity, or the presence of anaemia.

Dr. Iain Macdougall, of King's College Hospital, London, United Kingdom, commented: "There has been increasing interest and collaboration among nephrologists and cardiologists in elucidating the causes and improving the management of the cardio-renal anaemia syndrome. He added: "The data presented here show that intravenous iron therapy may be able to improve the function of both organs simultaneously. Further understanding of the mechanisms involved is required."

About FAIR-HF

FAIR-HF is a large, multi-centre, randomised, double-blind, placebo-controlled, phase III study of patients with CHF and iron deficiency (with or without anaemia). It was designed to test the potential benefits of correcting iron deficiency with Ferinject[®] in symptomatic CHF patients regardless of whether they had anaemia or not. FAIR-HF met both of its primary endpoints: improvements in quality of life (measured using the self-reported Patient Global Assessment [PGA]) and CHF symptoms (defined by the New York Heart Association (NYHA) class) at the end of the study compared with placebo. Both endpoints were statistically highly significant in favour of Ferinject[®]. The results were published in the *New England Journal of Medicine* in November 2009.

About the Heart Failure Association (HFA):

The HFA is the section of the European Society of Cardiology (ESC) dedicated to heart failure. Its mission is to "improve quality of life and longevity, through better prevention, diagnosis and treatment of heart failure, including the establishment of networks for its management, education and research." The Heart Failure Congress is the annual meeting of the HFA, and is dedicated to all professionals interested in the broad spectrum of problems relating to heart failure. Heart Failure Congress Late Breaking Clinical Trials sessions are innovative and provide the latest breakthroughs in clinical science. More information about the HFA can be found under the following link:

<http://www.escardio.org/communities/HFA/Pages/welcome.aspx>

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Galenica is a diversified group active throughout the healthcare market which, among other things, develops, manufactures and markets pharmaceutical products, runs pharmacies, provides logistical and database services and sets up networks. The Galenica Group enjoys a leading position in all of its business sectors – Pharma, Logistics and Retail. A large part of the Group's income is generated by international operations.

Additional information on the Galenica Group can be found at www.galenica.com.

Vifor Pharma, the Pharma business sector of the Galenica Group, researches, develops, manufactures and markets pharmaceutical products, with focus on the treatment of iron deficiency, where Vifor Pharma is one of the leading companies. It also conducts clinical studies for the application of medications for the treatment of various autoimmune diseases. Furthermore, Vifor Pharma manufactures prescription and over-the-counter (OTC) products developed within the company or produced or sold under license, and markets them on international markets. Vifor Pharma is headquartered in Switzerland (Zurich).

Additional information about Vifor Pharma can be found at www.viforpharma.com

About Ferinject®

Ferinject® is an innovative intravenous iron replacement product discovered and developed by Vifor Pharma. Ferric carboxymaltose, the active pharmaceutical ingredient of **Ferinject®**, overcomes the unmet clinical needs of i.v. iron therapy as **Ferinject®** is not associated with dextran-induced hypersensitivity reactions and has a low potential for iron toxicity. **Ferinject®**, in doses up to 1000mg iron, can be administered in a 15 minute drip infusion in patients with iron deficiency associated with a variety of clinical conditions.

So far, **Ferinject®** gained marketing authorisation in 20 European countries and Switzerland for the treatment of iron deficiency where oral iron is ineffective or cannot be used. In many countries, intravenous iron replacement products are primarily used to treat dialysis patients. However, iron deficiency is also part of many other illnesses representing a great market potential for Vifor Pharma's iron product. Ongoing development of scientific evidence supporting the use of **Ferinject®** outside of dialysis therefore has top priority. Vifor Pharma is evaluating new opportunities in the treatment of iron deficiency with **Ferinject®** in different therapeutic areas. Trials with **Ferinject®** in chronic kidney disease (CKD), oncology (anaemia in cancer patients), gastroenterology (inflammatory bowel diseases), and gynaecology are ongoing or planned.

References :

Ponikowski P. et al.

The impact of intravenous ferric carboxymaltose on renal function: An analysis of the FAIR-HF study. Abstract presented at Late Breaking Trial Session, HFA 2010

Anker SD, Colet JC, Filippatos G., et al.

Ferric Carboxymaltose in the treatment of iron deficient chronic heart failure patients with or without anaemia.

N Engl J of Med 2009; 361:2436-48

Ferinject® Summary of Product Characteristics