Media Information

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Subject ESC guidelines strongly recommend Ferinject® as a treatment for iron deficiency in systolic heart failure patients

The 2016 ESC heart failure guidelines strongly recommend Ferinject® for the treatment of iron deficiency in patients with systolic heart failure

- **Iron deficiency is confirmed as an important comorbidity**
- **Screening and diagnosing iron deficiency is recommended in all newly diagnosed patients with systolic heart failure (HF)**
- **For the first time, the guidelines recommend that Ferinject® (ferric carboxymaltose) should be considered in symptomatic patients with systolic HF and iron deficiency in order to alleviate heart failure symptoms, improve exercise capacity and quality of life**

The 2016 European Society of Cardiology Guidelines for the diagnosis and treatment of acute and chronic heart failure (hereafter referred to as the ESC Guidelines HF 2016) include a strong recommendation for the treatment of iron deficiency with Ferinject® in patients with systolic heart failure (HF)[1].

Iron deficiency is a common comorbidity in HF associated with a worse prognosis[1]. Management of comorbidities is a key component of the holistic care of patients with HF[1]. In Europe, one in two patients with congestive heart failure (CHF) has iron deficiency[2]. Many studies have described iron deficiency, with or without anaemia, as an independent risk-factor for mortality[2], poor exercise capacity[3] and low quality of life[4].

Per ESC Guidelines HF 2016, ferritin and transferrin saturation (TSAT) are included in the recommended diagnostic tests for the initial assessment of a patient with newly diagnosed HF[1]. Treatment is recommended when ferritin is <100 µg/L, or ferritin is between 100–299 µg/L and TSAT <20%[1].

These treatment recommendations are based exclusively on the findings of two double-blind, placebo-controlled clinical trials of Ferinject® in patients with CHF and iron deficiency – FAIR-HF[5] and CONFIRM-HF[6]. The benefits of Ferinject® treatment in these studies demonstrated significant improvements in heart failure symptoms, exercise capacity and quality of life.

The ESC Guidelines HF 2016 also mention that treatment of these patients with Ferinject® for up to 52 weeks also showed reduced hospitalisation rates, based on the results of a meta-analysis[7].

Vifor Pharma welcomes the publication of the updated ESC Guidelines HF 2016, which were released at the 2016 Heart Failure Association meeting in Florence, Italy. “We are pleased that the ESC Heart Failure Guidelines 2016 continue to stress the importance of screening and diagnosing iron deficiency, and now includes, for the first time, a recommendation for the treatment of iron deficiency specifically with Ferinject®, in patients with HF,” said Maureen Cronin, Senior Medical Advisor, Vifor Pharma. “The guidelines reinforce the wealth of evidence showing Ferinject® can significantly improve HF symptoms, exercise capacity and quality of life for these patients, with the potential to reduce hospitalisation.”

Theresa McDonagh, Professor of Heart Failure and Consultant Cardiologist, Kings College London, UK, stated: “Iron deficiency is a debilitating condition which can place a huge burden on a patient’s

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day-to-day life. Approximately 1 out of 2 patients with chronic heart failure have iron deficiency, which is a condition associated with impaired functional capacity, reduced quality of life and a greater risk of mortality."

HF is one of the most cost-intensive chronic diseases, therefore, it is important that treatments for iron deficiency are both efficacious and cost-effective. Results from a recent German health-economic analysis of Ferinject® in patients with CHF and iron deficiency – also presented at the HFA 2016 congress in Florence – showed that, compared with no iron therapy, treatment with Ferinject® demonstrated a minimal net budget impact[8]. Treatment with Ferinject® also resulted in improved symptoms and New York Heart Association (NYHA) functional class, and reduced hospitalisation rates, in comparison with no iron therapy[8].

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About FAIR-HF and CONFIRM-HF
The FAIR-HF study was designed to evaluate the use of Ferinject® in patients with CHF and iron deficiency[5]. Over 6 months of treatment, Ferinject® was found to significantly improve patient global assessment, New York Heart Association (NYHA) functional class, 6-minute walk test distance and health-related quality of life, which, together, demonstrate the benefit of Ferinject® in CHF patients with iron deficiency.

The CONFIRM-HF study evaluated the longer-term efficacy and safety of Ferinject® in iron-deficient patients with CHF[6]. In this 12-month study, treatment of symptomatic, iron-deficient CHF patients with Ferinject® resulted in sustainable improvement in functional capacity, symptoms and quality of life, and were also found to be associated with a risk reduction of hospitalisation for worsening CHF.

***Vifor Pharma**, a company of the Galenica Group, is a world leader in the discovery, development, manufacturing and marketing of pharmaceutical products for the treatment of iron deficiency. The company also offers a diversified portfolio of prescription medicines as well as over-the-counter (OTC) products. Vifor Pharma, headquartered in Zurich, Switzerland, has an increasingly global presence and a broad network of affiliates and partners around the world.*
For more information about Vifor Pharma and its parent company Galenica, please visit www.viforpharma.com and www.galenica.com.

***Ferinject®** (US brand name: Injectafer®) is an innovative non-dextran-based intravenous (i.v.) iron replacement therapy discovered and developed by Vifor Pharma, a company of the Galenica Group. Ferric carboxymaltose is the active pharmaceutical ingredient of Ferinject®. To date, Ferinject® has gained marketing authorisation in 72 countries worldwide 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 a complication of many other diseases. Vifor Pharma is evaluating new opportunities in the treatment of iron deficiency with Ferinject® in different therapeutic areas. Further clinical trials with Ferinject® in chronic kidney disease (CKD), oncology (anaemia in cancer patients), cardiology (chronic heart failure), patient blood management and women's health are ongoing.*

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