

PRESS RELEASE

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Subject FAIR-HF study results announced

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FAIR-HF study results show significant improvement in Chronic Heart Failure patients' lives and give a new therapeutic option to healthcare professionals

Results of the FAIR-HF study have demonstrated that Ferinject[®] – an intravenous iron treatment used to treat iron deficiency – significantly improves symptoms, exercise tolerance and quality of life and is well tolerated in Chronic Heart Failure patients with and without anaemia. The results have been unveiled today at the American Heart Association's Late-Breaking Clinical Trials Sessions 2009 in Orlando, USA, and posted on the website of the New England Journal of Medicine.

FAIR-HF (Ferinject[®] Assessment in patients with Iron deficiency and chronic Heart Failure) is a large, multi-centre, randomised, double-blind, placebo-controlled, phase III study of patients with Chronic Heart Failure (CHF) and iron deficiency (with or without anaemia). The study was designed to test whether correction of iron deficiency using intravenous (i.v.) iron (Ferinject[®], ferric carboxymaltose) confers a benefit in symptomatic CHF patients with and without anaemia. FAIR-HF met both of the two primary endpoints compared with placebo treatment: the self-reported Patient Global Assessment (PGA) at week 24, and the New York Heart Association (NYHA) class at week 24, adjusted for baseline NYHA class. Both endpoints were statistically significant in favour of Ferinject[®].

The details of the study results have been presented today at the American Heart Association's Late-Breaking Clinical Trials Sessions 2009 in Orlando, USA by the lead investigator of the FAIR-HF study, Stefan D. Anker, M.D., Ph.D., Professor of Cardiology and Cachexia Research, Department of Cardiology, Charité Medical School in Berlin, Germany. He comments: "Our study shows that treating iron deficiency for 24 weeks with iron in the form of i.v. ferric carboxymaltose improves symptoms in patients with Chronic Heart Failure with and without anaemia. This is remarkable as it is many years since a trial investigating a new drug has shown such a significant symptomatic improvement in the treatment of patients with CHF". Besides symptoms, Ferinject[®] also improved functional exercise capacity as measured by the six-minute walk test and quality of life and it was very well tolerated.

Study results

459 Chronic Heart Failure patients with iron deficiency (with or without anaemia) were studied in 75 study sites around the world. Two-thirds of the patients received weekly Ferinject[®] until the iron deficiency was reversed, with monthly treatment (maintenance phase) thereafter until week 24. The other one-third received a placebo.

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The trial results were significant: the group treated with Ferinject[®] showed significant improvements in both of the study's two primary endpoints. Measurements included 1) the quality of life of the patients using the self-reported Patient Global Assessment (PGA) score after 24 weeks ($P < 0.0001$) and 2) heart failure severity using the New York Heart Association (NYHA) class ($P < 0.0001$). For the PGA endpoint, 50% of patients assigned to ferric carboxymaltose were either "much improved" or "moderately improved" at week 24 compared to only 28% of patients in the placebo group. For NYHA class, 47% of patients assigned to ferric carboxymaltose were in NYHA class I or II at week 24, compared to only 30% on placebo therapy.

"Patients with Chronic Heart Failure are severely ill and have a poor quality of life. The positive results of the FAIR-HF study give physicians a new therapeutic option to improve the symptoms and quality of life of patients with Chronic Heart Failure and iron deficiency", specified David Ebsworth, CEO Vifor Pharma.

Furthermore, results showed significant progress in the secondary endpoints. After 24 weeks, patients receiving Ferinject[®] were able to walk 39 meters further than at baseline in the six-minute walk test, compared to approximately 9 meters in the placebo group ($P < 0.001$). The total difference between the patient group treated with Ferinject[®] and the placebo group was 35 meters at week 24. From as early as week 4 of the study, and throughout the study, i.v. iron improved quality of life assessments compared with placebo ($P < 0.001$).

Mortality and rates of adverse events including hospitalisations were similar in both trial groups.

"With the positive completion of the FAIR-HF study, Vifor Pharma has reached an important milestone in its clinical development program. Ongoing development of scientific evidence supporting the use of Ferinject[®] in key therapeutic areas is an important element within our strategy. We want to improve patient care for those suffering from iron deficiency, an affliction affecting millions around the world. The results of the FAIR-HF study demonstrate that we are heading in the right direction", stated Etienne Jornod, Chairman and CEO Galenica Group.

About AHA Congress:

With more than 18.000 visitors (4.500 alone coming from Europe), AHA is one of the most important congresses in cardiology. The congress is organised by the American Heart Association and is currently taking place in Orlando, Florida. The studies presented in the Late-Breaking Clinical Trials Sessions are novel, have an impact on research, feature rigorous design and methods, reach major clinical endpoints and base on a high quality statistical plan.

Additional information on: www.americanheart.org

About New England Journal of Medicine (NEJM):

The New England Journal of Medicine (NEJM) is a peer-reviewed medical journal published by the Massachusetts Medical Society. It is the oldest continuously published medical journal in the world, and is the most widely read, cited, and influential general medical periodical in the world.

The FAIR-HF online publication is available on the internet site of the New England Journal of Medicine under the following link: <http://content.nejm.org>. The print version will be published in the NEJM issue of 17 December 2009.

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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 – Vifor 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 worldwide pharmaceutical products, with focus on the treatment of iron deficiency, where Vifor Pharma is one of the leading companies. Vifor Pharma also conducts clinical studies for the application of medications for the treatment of various autoimmune diseases. Further, Vifor Pharma manufactures prescription and 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 on Vifor Pharma can be found at www.viforpharma.com

About Ferinject®

Ferinject® is an innovative intravenous iron replacement product from the research & development pipeline of 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. High doses of Ferinject® can be rapidly administered in a variety of indications.

So far, Ferinject® has gained marketing authorisation in 18 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 take top priority. Vifor Pharma will evaluate new opportunities in the treatment of iron deficiency with Ferinject® in different therapeutic areas. Trials with Ferinject® in CKD (Chronic Kidney Disease), Oncology (anaemia in cancer patients), Gastroenterology (inflammatory bowel diseases), Surgery (pre-operative anaemia), and Gynaecology are implemented or planned.