**Press Release**

# Full results from AFFIRM-AHF study show Ferinject® significantly reduces hospitalizations after acute heart failure in patients with iron deficiency

- **Ferinject® significantly reduced the incidence of heart failure hospitalizations in patients with iron deficiency after acute heart failure**
- **Results of the AFFIRM-AHF trial support the use of Ferinject® in patients after AHF with concomitant iron deficiency and with a LVEF[1] ≤ 50%**
- **Simultaneously the peer-reviewed AFFIRM-AHF study results have been published in The Lancet**

**St Gallen, November 13, 2020** – Vifor Pharma today presented the full results from the AFFIRM-AHF study at the 2020 American Heart Association (AHA) Scientific Sessions virtual congress. Simultaneously, results were published in the peer-reviewed medical journal The Lancet. The study evaluated the effect of Ferinject® (intravenous ferric carboxymaltose) on heart failure (HF) hospitalizations and cardiovascular (CV) mortality in iron deficient patients after hospital stabilization for acute heart failure (AHF).

The study demonstrated there were significantly fewer hospital readmissions due to HF among patients treated with Ferinject® compared to placebo. After 52 weeks, patients who received iron supplementation were 26% less likely to be re-admitted to the hospital for HF compared to placebo, after only one or two injections [RR 0.74; 95% CI 0.58-0.94; p=0.013].

“This is the first study demonstrating the benefits of iron supplementation initiated in stabilized patients hospitalized for AHF,” said **Prof Piotr Ponikowski, Principle Investigator and Head of the Department of Heart Diseases, Wroclaw Medical University in Wroclaw, Poland**. “The study showed that administration of Ferinject® in stabilized AHF patients with iron deficiency significantly reduces the risk of subsequent HF hospitalizations, and highlights the need for AHF patients to be more frequently screened for iron deficiency.”

“We are delighted to have presented full data from the AFFIRM-AHF study at the American Heart Association Scientific Sessions congress. This important data strengthens the evidence previously generated in large studies such as FAIR-HF and CONFIRM-HF,” said **Dr Klaus Henning Jensen, Chief Medical Officer Vifor Pharma**. “Iron deficiency is a frequent, yet often unrecognized co-morbidity in heart failure, and this trial makes a significant contribution to the growing body of evidence showing the importance of detecting and managing iron deficiency in patients after heart failure.”

On September 24, 2020 Vifor Pharma announced that overall AFFIRM-AHF narrowly missed the conventional 5% statistical significance on the primary composite endpoint, but numerically reduced total CV death and HF re-hospitalization events by 21% [RR 0.79; 95% CI 0.62-1.01; p=0.059]. Ferinject® was well tolerated and without unexpected safety findings. No increase in mortality was seen and death from cardiovascular (CV) causes was similar between groups [RR 0.96; 95% CI 0.70-1.32].

The outbreak of the COVID-19 pandemic resulted in significant disruption to the healthcare systems, with a 40% reduction in HF hospitalizations in Europe between March and June 2020[2]. HF patients are particularly at risk when

[1] Left ventricular ejection fraction (LVEF)

[2] Sokolski M, Gajewski P, Zymlinski R, et al. Impact of coronavirus disease 2019 (COVID-19) outbreak on acute admissions at the emergency and cardiology departments across Europe. Am J Med. 2020 Sep 30:S0002-9343(20)30825-1. doi:10.1016/j.amjmed.2020.08.043. Epub ahead of print. PMID: 33010226; PMCID: PMC7526639.

**Vifor Pharma Group**
Flughofstrasse 61
8152 Glattbrugg
Switzerland

Phone +41 58 851 8000
E-mail info@viforpharma.com
Web viforpharma.com

suffering COVID-19. Therefore prior to study completion, COVID-19 sensitivity analysis was pre-specified which excluded subjects reporting from the date of the outbreak in each country. Adjusted for COVID-19 impact the composite endpoint was more robust and significant [RR 0.75; 95% CI 0.59-0.96; p=0.024].

Additional significant results were seen with several secondary outcomes, including treatment benefits with Ferinject® observed seen on the time to first HF hospitalization or CV death (p=0.030) and days lost due to HF hospitalizations and CV death (p=0.035). These effects were more pronounced in the pre-COVID-19 analyses.

AFFIRM-AHF is the first of three ongoing mortality and morbidity trials including FAIR-HF2 and HEART-FID to understand the full potential of Ferinject® for those suffering from heart failure and iron deficiency. The study was a randomized, double-blind placebo-controlled trial with 1,108 patients in 15 countries, designed to evaluate the effect of Ferinject® or placebo administered prior to and subsequent to discharge in patients after AHF and iron deficiency on recurrent HF hospitalizations and CV death at 52 weeks after randomization.

Iron deficiency is present in approximately 80% of patients after AHF and indicates poor prognosis. It is associated with poor quality of life and increased risk for hospitalization and mortality, regardless of the presence or absence of anemia. Hospitalization due to AHF represents a growing health care problem that is associated with a higher risk of adverse clinical outcomes and huge economic burden.

Contact and further information:


**Media Relations**
Nathalie Ponnier
Global Head Corporate Communications
+41 79 957 96 73
media@viforpharma.com

**Investor Relations**
Julien Vignot
Head of Investor Relations
+41 58 851 66 90
investors@viforpharma.com


**Vifor Pharma Group** is a global pharmaceuticals company. It aims to become the global leader in iron deficiency, nephrology and cardio-renal therapies. The company is a partner of choice for pharmaceuticals and innovative patient-focused solutions. Vifor Pharma Group strives to help patients around the world with severe and chronic diseases lead better, healthier lives. The company develops, manufactures and markets pharmaceutical products for precision patient care. Vifor Pharma Group holds a leading position in all its core business activities and consists of the following companies: Vifor Pharma and Vifor Fresenius Medical Care Renal Pharma (a joint company with Fresenius Medical Care). Vifor Pharma Group is headquartered in Switzerland, and listed on the Swiss Stock Exchange (SIX Swiss Exchange, VIFN, ISIN: CH0364749348).
For more information, please visit viforpharma.com

**About AFFIRM-AHF**
The AFFIRM-AHF study is a multi-centre, randomised, double-blind, placebo-controlled trial, comparing the effect of Intravenous Ferric Carboxymaltose (FCM) on hospitalizations and mortality in iron deficient patients admitted for Acute Heart Failure (AHF). AFFIRM-AHF is the first study that evaluates the benefit of Ferinject® on hospitalizations and mortality in a very high risk population with iron deficiency and admitted in hospital for an episode of acute heart failure.