Press Release

Vifor Pharma announces outcome of AFFIRM-AHF topline data

- **The study narrowly missed statistical significance on the primary endpoint**
- **Pre-specified adjustment of COVID-19 impact, the study showed a statistically significant advantage**
- **The totality of evidence suggests that Ferinject® is clinically beneficial in high risk heart failure patients**

ST GALLEN, 24 SEPTEMBER 2020 – Vifor Pharma today announced topline data from its AFFIRM-AHF study evaluating the effect of Ferinject® (intravenous ferric carboxymaltose) on heart failure hospitalizations and cardiovascular mortality in iron-deficient patients hospitalized for acute heart failure (AHF), compared to placebo. The trial narrowly missed statistical significance on its composite primary endpoint of reducing the risk of total heart failure hospitalizations and cardiovascular death. A pre-specified sensitivity analysis considering the impact of the COVID-19 pandemic, revealed a statistically significant difference in favor of Ferinject® on cardiovascular mortality and hospitalization for heart failure. The study results will be presented at the American Heart Association (AHA) congress in November this year.

“This trial makes a significant contribution to the growing body of evidence showing the importance of detecting and managing iron deficiency in heart failure”, said Prof Piotr Ponikowski, Principle Investigator and Head of the Department of Heart Diseases, Wroclaw Medical University and Head of the Center for Heart Diseases at the University Hospital, Wroclaw, Poland. “The totality of evidence from the trial suggests that treatment with intravenous ferric carboxymaltose of patients’ hospitalized due to AHF with concomitant iron deficiency is clinically beneficial. We look forward to presenting the detailed data to the scientific community.”

“We are delighted with the completion of the AFFIRM-AHF trial and are very encouraged by the results,” said Dr Klaus Henning Jensen, Chief Medical Officer Vifor Pharma. “Iron deficiency is a frequent, yet often unrecognized, co-morbidity in heart failure, present in approximately 50% of patients. Ferinject® is the only iron therapy included in the ESC guidelines to improve clinical symptoms and quality of life in heart failure patients with iron deficiency.”

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® in prolonging and improving quality of life of those suffering from heart failure and iron deficiency. AFFIRM-AHF was a randomized, double-blind placebo-controlled trial with 1,132 patients who had heart failure with reduced and mid-range ejection fraction (LVEF<50%) and iron deficiency (serum ferritin <100ng/mL or serum ferritin 100-299 ng/mL with TSAT <20%). Patients were randomized to receive either Ferinject® or placebo before being discharged from the hospital following an episode of AHF and followed for 52 weeks. Ferinject® was generally well tolerated and without unexpected safety findings.

Hospitalization due to AHF is the leading cause for hospital admissions in patients above 65 years old. Post-discharge outcomes are still poor with readmission rates exceeding 30% during the first 6 months post discharge and 1-year mortality above 20%. Iron deficiency is present in the majority of these patients and unfavorably impacts the outcomes.

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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 the 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; Vifor Fresenius Medical Care Renal Pharma (a joint company with Fresenius Medical Care); and OM Pharma. 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 www.viforpharma.com

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