PRESS RELEASE

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VIFOR PHARMA ANNOUNCES THREE OUTCOMES TRIALS IN HEART FAILURE AND IRON DEFICIENCY

- **Further analysis of existing data suggests that Ferinject® may have a positive impact on morbidity and mortality in patients with systolic heart failure.**
- **Three trials have been initiated to evaluate the efficacy of Ferinject® on morbidity and mortality outcomes in patients with systolic heart failure and iron deficiency.**
- **Based on the wealth of data supporting the use of Ferinject® in improving symptoms and quality of life, in patients with systolic chronic heart failure and iron deficiency, the European Society of Cardiology Heart Failure 2016 Guidelines recognise iron deficiency as a co-morbidity and recommend to consider Ferinject® as treatment.**

AS PART OF ITS CONTINUED COMMITMENT TO IMPROVING THE LIVES OF PATIENTS SUFFERING FROM HEART FAILURE AND IRON DEFICIENCY, VIFOR PHARMA ANNOUNCES THREE RECENTLY-INITIATED DOUBLE-BLIND, PLACEBO-CONTROLLED CLINICAL TRIALS, ENTITLED AFFIRM-AHF, FAIR-HF2 AND HEART-FID, WHICH WILL STUDY THE EFFECTS OF FERINJECT® (FERRIC CARBOXYMALTOSE) VERSUS PLACEBO ON MORBIDITY AND MORTALITY OUTCOMES.

These trials follow the FAIR-HF[1], CONFIRM-HF[2] and EFFECT-HF[3] trials, which showed statistically significantly beneficial effects of Ferinject® versus placebo or standard of care, on symptoms, functional capacity and oxygen consumption, respectively. Consideration of Ferinject® is now recommended in the European Society of Cardiology (ESC) Heart Failure 2016 Guidelines[4] for the treatment of symptomatic patients with systolic chronic heart failure (CHF) and iron deficiency. Ferinject® is the only intravenous (i.v.) iron treatment specifically mentioned in the ESC guidelines. Recently the American College of Cardiology/American Heart Association/Heart Failure Society of America (ACC/AHA/HFSA) issued a focused update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure (HF). This recent ACCF/AHA update included a new recommendation that intravenous repletion of iron, especially in the setting of concomitant hepcidin deficiency in HF, may improve exercise capacity and quality of life (QoL). Furthermore, the European Medical Agency approved in March 2017 the inclusion of the CONFIRM-HF results in the Ferinject® prescribing information.

The AFFIRM-AHF trial is the first study of Ferinject® in the acute heart failure patient population. In this trial, 1,100 patients will be randomised to receive either Ferinject® or placebo before being discharged from the hospital following an episode of acute heart failure. The rate of repeat hospitalisations and death will comprise the primary endpoint.

“We are encouraged by the results of an analysis from the CONFIRM-HF trial which showed a reduction in hospitalisation for worsening heart failure in patients with systolic chronic heart failure and iron deficiency who were treated with Ferinject®. This gives us reason to believe we may also be able to have a positive

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impact on vulnerable acute heart failure patients with iron deficiency and the AFFIRM-AHF trial sets out to prospectively study this," said Prof Piotr Ponikowski, Head of the Department of Heart Diseases, Wroclaw Medical University and Head of the Cardiology Department at the Center for Heart Diseases at 4th Military Hospital, Wroclaw, Poland, and principle investigator for both the CONFIRM-HF and the AFFIRM-AHF trials.

The FAIR-HF2 trial is an independent study sponsored by the University Medical Center Hamburg-Eppendorf (UKE), within the frame of the German Center for Cardiovascular Disease (DZHK) and in cooperation with the University of Göttingen, and the Charité in Berlin, Germany. In this trial, 1,200 patients with systolic CHF and iron deficiency will be randomised to Ferinject® or placebo. As in the AFFIRM-AHF trial, the rate of recurrent heart failure hospitalisations and cardiovascular death will comprise the primary endpoint.

"The earlier trials, specifically FAIR-HF and CONFIRM-HF, showed us that we can improve both symptoms and functional capacity in our systolic chronic heart failure patients with iron deficiency with Ferinject®. Importantly, a recently published meta-analysis reported significantly lower rates of recurrent cardiovascular hospitalisation and cardiovascular death for patients with iron deficiency and systolic chronic heart failure treated with Ferinject® versus placebo. The FAIR-HF2 trial will explore whether we can further advance the care of these patients by reducing the rate of recurrent hospitalisations for heart failure and death," said Prof Stefan Anker, Division of Cardiology and Metabolism; Department of Internal Medicine & Cardiology; DZHK (German Center for Cardiovascular Research); and Berlin-Brandenburg Center for Regenerative Therapies (BCRT), at Charité University Medicine, Berlin, Germany

The HEART-FID[5] trial, conducted by Vifor Pharma's US partner American Regent, a member of the Daiichi Sankyo Group, will assess the effects of Injectafer® (US brand name of Ferinject®) compared to placebo on the following outcome measures: the 12-month rate of death, hospitalisation for worsening heart failure, and the six-month change in six-minute walk for patients in heart failure with iron deficiency. The study is anticipated to enroll more than 3,000 adult patients across North America, and is one of the largest studies of intravenous iron in heart failure.

"Iron deficiency affects up to half of all heart failure patients and is associated with impaired exercise tolerance, and mortality in patients with or without anaemia[6]," said Prof Adrian F. Hernandez, MD, MHS, Duke Clinical Research Institute, Durham, North Carolina, USA, and HEART-FID study chair. "HEART-FID has the potential to provide a deeper understanding of how intravenous iron may help patients with heart failure with a low ejection fraction."

FURTHER INFORMATION

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Vifor Pharma Group, formerly Galenica Group, is a global specialty 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 specialty 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; Relypsa; 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.

Vifor Pharma, a company of the Vifor Pharma 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 and nonprescription medicines. Vifor Pharma's operational headquarters are in Zurich, Switzerland, and the company has an increasingly global presence and a broad network of affiliates and partners around the world. For more information about Vifor Pharma, please visit www.viforpharma.com.

American Regent is a leader in the development, manufacturing and sales of generic and branded IV iron medications. With a history of 50 years in generic specialty injectables, American Regent has sales approaching one billion dollars from products manufactured in our facilities in the United States. American Regent strives for continuous improvement to bring to market high quality innovative medications to meet unmet medical needs, and produces high quality accessible generic medications covering a wide array of therapeutic areas. American Regent is a member of the Daiichi Sankyo Group; and is headquartered in Shirley, NY. For more information, please visit www.americanregent.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 Vifor Pharma Group. Ferric carboxymaltose is the active pharmaceutical ingredient of Ferinject®. To date, Ferinject® has gained marketing authorisation in more than 70 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), cardiology (chronic heart failure), oncology (anaemia in cancer patients), patient blood management and women's health are ongoing. Ferinject® is celebrating in 2017 the 10th anniversary of its first marketing authorisation.

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