Press Release

Vifor Pharma to revise DIAMOND study, readout expected in H2 2021

- **COVID-19 pandemic significantly impacted the DIAMOND study, leading to lower-than-anticipated enrolment and slower incidence of cardio-vascular events**
- **Independent study Executive Committee recommended new clinically relevant endpoints**
- **Data are expected to be published in H1 2022**
- **Vifor Pharma continues to drive evidence-based care using Veltassa® through multiple additional trial activities**

- Vifor Pharma will host a conference call today at 10:30 am CET -

St. Gallen, Switzerland, 24 June 2021 – Vifor Pharma Group today announced that the phase-IIIb DIAMOND study has been amended with new and clinically relevant endpoints, including a new primary endpoint of efficacy in potassium management in high-risk heart failure patients treated with guideline-recommended doses of renin-angiotensin aldosterone system inhibitor (RAASi). This decision has been made on the recommendation from the independent study Executive Committee and following the significant impact of COVID-19 on recruitment.

Patients with heart failure and chronic kidney disease are among those at the highest risk of severe outcomes of COVID-19 infection. During the pandemic, treatment practices have been adapted to reduce risks of exposure to COVID-19 during hospital visits, disrupting clinical care and impacting the conduct of randomized clinical trials such as the DIAMOND study. This has led to fewer patients enrolled in the trial than anticipated and to a slower incidence of cardio-vascular events.

More than 1,000 patients with heart failure and with hyperkalemia or history of hyperkalemia have already been enrolled in DIAMOND. Following the change of endpoints, study read-out and remaining data collection is expected to be completed in 2021.

Prof. Javed Butler, Principal Investigator for the DIAMOND study, said: “Guidelines give strong recommendation to use RAASi to reduce mortality and morbidity in heart failure patients, but unfortunately patients are often treated with low doses, or not treated at all, because RAASi increase potassium levels, which can cause hyperkalemia. The new primary endpoint allows us to investigate the role of Veltassa® in controlling serum potassium and potentially preventing hyperkalemia in heart failure patients treated with RAASi. This will maximize the scientific utility of the data collected in DIAMOND.”

Dr. Klaus Henning Jensen, Chief Medical Officer of Vifor Pharma Group, commented: “We believe that this decision is a responsible approach towards the heart failure patients participating in the trial and towards the need of the medical community to learn from the outcomes of the DIAMOND study. A significant amount of evidence on the use of Veltassa® in combination with RAASi medication has been recorded in DIAMOND. We expect these data to support an effective management of hyperkalemia in patients on RAASi therapy with Veltassa® and look forward to sharing this data during spring 2022 at a major conference.”

Vifor Pharma continues to support several data generation programs with the ongoing phase-IV PLATINUM study and the CARE-HK global study platform to drive evidence-based care using Veltassa® in chronic kidney disease and heart failure patients.

Conference call:

Vifor Pharma will host a conference call today, 24 June 2021 at 10:30 am (CET).

Access to conference call → link

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About Vifor Pharma Group
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 DIAMOND
This global, multicenter, double-blind, placebo controlled DIAMOND study was designed to evaluate the potential role of Veltassa® in enabling patients with, or at high risk of, hyperkalemia to remain on RAASi therapy. The previous primary endpoint of the study was the time to first occurrence of cardiovascular death or cardiovascular hospitalization. On recommendation of the independent study Executive Committee and due to COVID-19 impact on recruitment, the primary endpoint has been changed to investigate the role of Veltassa® in controlling serum potassium and potentially prevent hyperkalemia in heart failure patients treated with RAASi. More than 1,000 patients with hyperkalemia or history of hyperkalemia, who are therefore not able to use guideline-recommended doses of RAASi, were enrolled in the study.

About hyperkalemia
Hyperkalemia is a serious condition characterized by elevated levels of potassium in the blood. Patients with chronic kidney disease and heart failure, especially those treated with RAASi, are at particular risk of developing the condition. Studies have shown Veltassa® enables patients to remain on RAASi therapy by effectively managing their chronic hyperkalemia.