Press Release

First patient treated in DIAMOND study to evaluate if Veltassa® (patiromer) improves outcomes by enabling long-term use of essential RAASi therapy

ZURICH, 21 May 2019 – Vifor Pharma today announced that treatment of the first patient in their global phase-IIIb DIAMOND study has begun. The study will evaluate the potential of Veltassa® to improve outcomes by enabling heart failure (HF) patients, with or without chronic kidney disease (CKD), to be treated with renin-angiotensin-aldosterone system inhibitors (RAASi) therapy in accordance with HF treatment guidelines[1,2]. Presently, RAASi treatment is frequently discontinued due to the risk of hyperkalaemia (elevated blood potassium levels).

The DIAMOND study is designed to further support the use of Veltassa® to effectively control high blood potassium levels, thereby enabling optimal RAASi therapy in HF patients. It is a global, multicentre, double-blind, placebo-controlled trial aiming to study approximately 2,400 patients in over 400 sites. Eligible patients will have HF (with or without CKD) with either current hyperkalaemia at screening or a history of hyperkalaemia in the past year that led to a reduction or discontinuation of RAASi therapy. The primary endpoint of the study is the time to first occurrence of cardiovascular death or cardiovascular hospitalisation. Top-line results are expected in 2022.

Hyperkalaemia can cause life-threatening abnormal heart rhythms and even sudden death[3]. There are often no warning signs, meaning a person can unknowingly experience recurring spikes in potassium levels and be at risk of cardiac events. The risk of hyperkalaemia can be a barrier to initiating and maintaining HF and CKD patients on guideline-recommended therapies such as RAASi treatment[1,2].

RAASi therapy has been shown to improve cardiovascular and renal outcomes and is proven to prolong survival and reduce hospitalisation. Its use is strongly recommended in clinical guidelines for the treatment of HF with reduced ejection fraction, and CKD[1,2]. Across the Veltassa® clinical trial program, over 99 percent of participants were also taking RAASi therapy. However, these therapies can increase blood potassium levels, which can lead to hyperkalaemia.

“Guidelines give their strongest recommendation to use RAASi therapy to improve mortality and morbidity in patients with heart failure and with kidney disease, but unfortunately they are often discontinued because they can cause hyperkalaemia,” said Professor Javed Butler, primary investigator of the DIAMOND study and chairman of the Department of Medicine, University of Mississippi Medical Center, US. “DIAMOND is a very important study that will help the medical community better understand the value of Veltassa® in treating hyperkalaemia and enabling patients to stay on these life-saving medicines.”

Additional details on the study are available on www.clinicaltrials.gov.

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About Hyperkalaemia

Approximately 73 percent of advanced CKD and 40 percent of chronic HF patients may be at risk of elevated blood potassium levels[4]. Hyperkalaemia can cause abnormal heart rhythms and even sudden death[3]. There are often no warning signs, meaning a person can unknowingly experience spikes in potassium levels recurrently and be at risk for these cardiac events. Some medicines that are often prescribed to people with CKD and heart failure to help delay progression of their underlying disease and reduce mortality can cause hyperkalaemia as a side effect. These may include RAASi such as angiotensin receptor blockers (ARBs), aldosterone antagonists (AAs) and angiotensin-converting-enzyme (ACE) inhibitors as well as angiotensin II receptor/neprilysin inhibitors (ARNI).

About Veltassa®

Veltassa® is a sodium-free potassium binder approved for the treatment of hyperkalaemia. Veltassa® should not replace emergency treatment for life-threatening hyperkalaemia. Made in powder form consisting of smooth, spherical beads, Veltassa® is mixed with water and taken once a day with food. Veltassa® is not absorbed and acts within the gastrointestinal tract. It binds to potassium in exchange for calcium, primarily in the colon. The potassium is then excreted from the body through the normal excretion process.

Important Safety Information about Veltassa® in the United States

Contraindications

Veltassa® is contraindicated in patients with a history of a hypersensitivity reaction to Veltassa® or any of its components.

Worsening of Gastrointestinal Motility

Use of Veltassa® should be avoided in patients with severe constipation, bowel obstruction or impaction, including abnormal post-operative bowel motility disorders, because Veltassa® may be ineffective and may worsen gastrointestinal conditions. Patients with a history of bowel obstruction or major gastrointestinal surgery, severe gastrointestinal disorders, or swallowing disorders were not included in clinical studies.

Hypomagnesemia

Veltassa® binds to magnesium in the colon, which can lead to hypomagnesemia. In clinical studies, hypomagnesemia was reported as an adverse reaction in 5.3 percent of patients treated with Veltassa®. Approximately 9 percent of patients in clinical trials developed hypomagnesemia with a serum magnesium value <1.4 mg/dL. Doctors should monitor serum magnesium and consider magnesium supplementation in patients who develop low serum magnesium levels.

Adverse Reactions

The most common adverse reactions (incidence ≥2 percent) are constipation, hypomagnesemia, diarrhea, nausea, abdominal discomfort and flatulence. Mild to moderate hypersensitivity reactions were reported in 0.3 percent of patients treated with Veltassa® and included edema of the lips.

For Veltassa®'s full Prescribing Information, please visit https://www.veltassa.com/pi.pdf.

Vifor Pharma Group is a global pharmaceuticals company headquartered in Switzerland. 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); Relypsa; and OM Pharma. Vifor Pharma Group is listed on the Swiss Stock Exchange (SIX Swiss Exchange, VIFN, ISIN: CH0364749348). For more information, please visit www.viforpharma.com.

Relypsa, Inc., a Vifor Pharma Group company, is a biopharmaceutical company focused on the development and commercialisation of late-stage medicines in the iron deficiency, nephrology and cardio-renal therapeutic areas. Relypsa is committed to delivering innovative therapies and improving the lives of patients with serious and life-threatening conditions that are often overlooked and undertreated. The company's first medicine, Veltassa® (patiromer) for oral suspension, was approved by the U.S. FDA in October 2015, making it the first approved medicine for the treatment of hyperkalaemia in more than 50 years. More information is available at www.relypsa.com.

References

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[3] Rastegar A, Soleimani M. Hypokalaemia and hyperkalaemia. Postgrad Med J. 2001;77:759-764.
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