Press Release

Vifor Pharma's phase-II AMBER study meets primary endpoint

- Veltassa® (patiromer) enables spironolactone for blood pressure management in patients with resistant hypertension and chronic kidney disease by controlling blood potassium levels.

ZURICH, 10 May 2019 – Vifor Pharma today announced results from the phase-II AMBER study which demonstrated that a significantly higher proportion of patients with resistant hypertension (RHTN) and chronic kidney disease (CKD) taking Veltassa® (patiromer) remained on spironolactone therapy compared to patients taking placebo at week 12. Veltassa® was shown to enable persistent use of spironolactone by controlling blood potassium levels. The data were presented at the 2019 National Kidney Foundation (NKF) Congress in Boston, MA on 10 May 2019.

The study achieved statistical significance of its pre-specified primary endpoint by demonstrating that a significantly higher proportion of patients taking Veltassa® remained on spironolactone therapy through 12 weeks of treatment versus placebo with concomitant spironolactone in patients with RHTN and CKD (86% vs. 66%, $p < .0001$, respectively). Safety results are consistent with existing Veltassa® data, with no new safety issues identified.

"Despite the efficacy of spironolactone in patients with RHTN, its use has never been studied in those who also have CKD due to the occurrence or risk of developing hyperkalaemia," said Dr. Rajiv Agarwal, Professor of Medicine, Indiana University School of Medicine. "The AMBER data suggest that patients treated with patiromer may be more likely to stay on spironolactone therapy, a life-saving medicine for those with RHTN."

Spironolactone, a renin-angiotensin aldosterone system inhibitor (RAASi), is a key component in the recommended treatment guidelines for patients with resistant hypertension[1,2]. However, it is challenging for many patients to stay on spironolactone treatment because it can further increase the risk of hyperkalaemia (elevated blood potassium levels), a condition that can cause abnormal heart rhythms and even sudden death[3].

"We are pleased with the AMBER study results and hope these data will support better adherence to guideline-directed treatment for patients with resistant hypertension and chronic kidney disease," said Thierry Teil, Chief Medical Officer of Vifor Pharma. "We look forward to partnering with the community to further validate and explore the promise of Veltassa® in fulfilling a clear unmet need among a complex patient population."

AMBER is **A** Rando**M**ized, Double-Blind, Placebo-controlled, Parallel Group Study of Patiromer for the Enablement of Spironolactone Use for **B**lood Pr**E**ssure Control in Patients with **R**esistant Hypertension and Chronic Kidney Disease: Evaluation of Safety and Efficacy. Approximately 290 patients at 60 sites in the United States, South Africa, the United Kingdom, France, Germany, Croatia, Hungary, Georgia, and Ukraine were enrolled in the study. The primary endpoint was the percentage of subjects remaining on spironolactone at week 12 compared between treatment groups (spironolactone and patiromer versus spironolactone and placebo).

Contact and further information:

Media Relations (excl. US)
Heide Hauer
Head of Corporate Communications
+41 58 851 80 87
media@viforpharma.com

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

Media Relations (US)
Albert Liao
Director of U.S Communications Relypsa
Tel.: +1 650 421 9532
E-mail: media@relypsa.com

About Hyperkalaemia
Approximately 73 percent of advanced CKD and 40 percent of chronic heart failure (HF) patients may be at risk of elevated blood potassium levels[4]. Hyperkalaemia can cause abnormal heart rhythms and even sudden death. 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 HF 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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Vifor Pharma Group

Flughofstrasse 61
8152 Glattbrugg
Switzerland

Phone +41 58 851 80 00

E-mail info@viforpharma.com
Web viforpharma.com