

PRESS RELEASE

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US FDA APPROVES USE OF VELTASSA[®] WITH OR WITHOUT FOOD

- **Updated label may allow for increased dosing flexibility for patients with hyperkalaemia**
- **Label update effective immediately in the US**

THE UNITED STATES (US) FOOD AND DRUG ADMINISTRATION (FDA) HAS APPROVED A SUPPLEMENTAL NEW DRUG APPLICATION (SNDAs) FOR VELTASSA[®] (PATIROMER) FOR ORAL SUSPENSION THAT WAS DEVELOPED BY US BIOTECH RELYPSA, SINCE 2016 A VIFOR PHARMA GROUP COMPANY, FOR THE TREATMENT OF HYPERKALAEMIA. HYPERKALAEMIA, OR ELEVATED BLOOD POTASSIUM LEVELS, OFTEN COEXIST WITH OTHER DISORDERS INCLUDING CHRONIC KIDNEY DISEASE, HEART FAILURE, DIABETES AND/OR HIGH BLOOD PRESSURE. THE LABEL UPDATE IS EFFECTIVE IMMEDIATELY IN THE US.

The label update is based on results from the phase-IV TOURMALINE study, which showed no statistically significant difference between the groups taking Veltassa[®] with or without food in achieving serum potassium levels within the target range (3.8 to 5.0 mEq/L).

“Since the US approval of Veltassa[®] two years ago, we have seen how the availability of this medicine has been able to raise awareness for a disease that is often asymptomatic and potentially fatal, to empower patients in managing their disease and to significantly transform how doctors treat it,” said Stefan Schulze, President of the Vifor Pharma Group Executive Committee and COO. “We are very pleased about this label update and believe that it will help patients to incorporate Veltassa[®] even more effectively into their daily treatment regimen.”

In the TOURMALINE study, 87.3% of the Veltassa[®] with food group and 82.5% of the Veltassa[®] without food group achieved potassium levels in the target range at either week three or week four. Patients with higher baseline potassium values generally had greater potassium reductions. Results were consistent when evaluated by baseline potassium, race, eGFR (an assessment of kidney function) and type-2 diabetes. Rates of adverse events were consistent with previous clinical trials of Veltassa[®] and were similar between study participants who took Veltassa[®] with food (48.2%) and those who took it without food (42.1%).

Veltassa[®] was approved by the US FDA for the treatment of hyperkalaemia in the US in October 2015 and has been available to patients in the US since December 2015. Veltassa[®] was approved in the EU, Norway, Iceland and Liechtenstein in July 2017, and in Switzerland and Australia in December 2017. Veltassa[®] is currently available to patients in Norway, the UK, Denmark and Germany. Other applications are planned in other markets worldwide.

FURTHER INFORMATION

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Vifor Pharma Group, formerly Galenica 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 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.

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.

The **TOURMALINE** study randomly assigned 114 patients with blood potassium levels greater than 5.0 mEq/L to receive Veltassa once-a-day at a starting dose of 8.4 g either with or without food. Patients were treated for four weeks and followed for two weeks after completing Veltassa[®] treatment. The primary endpoint was a comparison of the proportion of patients with blood potassium in the target range (3.8 to 5.0 mEq/L) at week three or week four between the two treatment groups. The study was conducted at 29 sites in the United States. Of the 112 patients evaluable for efficacy, 65% were male, 12.5% were African American, 56% were Hispanic/Latino, 65% were age 65 or older and 62% had stage 3b-5 (non-dialysis) chronic kidney disease.

Hyperkalaemia, or abnormally elevated levels of potassium in the blood, is a serious condition that can lead to life-threatening cardiac arrhythmia and sudden death. It is frequently prevalent in patients who suffer from chronic kidney disease (CKD), hypertension, diabetes and/or heart failure. Patients with CKD or heart failure are at particular risk for developing hyperkalaemia, especially those treated with renin-angiotensin-aldosterone-system (RAAS) inhibitors, which can increase blood potassium levels in patients taking these medicines. 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 can cause hyperkalaemia as a side effect. These include renin angiotensin aldosterone system (RAAS) inhibitors such as angiotensin receptor blockers (ARBs), aldosterone antagonists (AAs) and angiotensin-converting-enzyme (ACE) inhibitors.