PRESS RELEASE

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Subject FDA Approves Supplemental New Drug Application for Veltassa® Removing Boxed Warning Regarding Drug-Drug Interactions

FDA Approves Supplemental New Drug Application for Veltassa® Removing Boxed Warning Regarding Drug-Drug Interactions

- **The updated US label for Veltassa® recommends patients take Veltassa® at least 3 hours before or 3 hours after other oral medications**
- **Change can provide doctors greater flexibility in prescribing Veltassa® to patients**
- **Approval reinforces potential of Veltassa® as a key platform of additional growth for Vifor Pharma**
- **Vifor Pharma to make necessary investments to achieve Veltassa's significant mid-term potential**

Galenica Group today announced that Relypsa, Inc., a Vifor Pharma Company, has received approval from the US Food and Drug Administration (FDA) for a supplemental New Drug Application (sNDA) with important updates to the US label of Veltassa® (patiromer) for oral suspension. The US label for Veltassa® no longer includes a Boxed Warning regarding the separation of Veltassa® and other oral medications.

The updated US label for Veltassa® recommends patients take Veltassa® at least 3 hours before or 3 hours after other oral medications. This information is now detailed in the dosage and administration section (Section 2) and the drug interactions section (Section 7) of the label. In addition, data from the Veltassa® drug-drug interaction program has been added to the Clinical Pharmacology section of the label (Section 12). The separation time between administration of Veltassa® and other oral medications has changed from at least 6 hours to at least 3 hours.

With the removal of the Boxed Warning doctors can have greater flexibility in prescribing Veltassa® in combination with other oral medications.

"In addition to the positive impact that this approval will have for patients, it also validates the decision of Vifor Pharma to acquire Relypsa," said Etienne Jornod, Executive Chairman of Galenica and Vifor Pharma. "With this approval, we will continue to build on the solid and consistent growth of Vifor Pharma and we will undertake the investments required to support the commercialization of Veltassa® to achieve its full potential. As a result of the Relypsa acquisition, Vifor Pharma has gained direct access to the key US market. This will enable us to maximise the potential of our compelling product portfolio and enhance our growing attraction as an international partner of choice."

The investment made in Relypsa underlines Vifor Pharma's strategy to grow both organically as well as through in-licensing deals and acquisitions to further support the company's emerging global leadership in nephrology, cardio-renal and gastroenterology therapies. With the combination of the assets and products of Vifor Pharma, Vifor Fresenius Medical Care Renal Pharma (VFMCRP), Relypsa and its partners, Vifor Pharma is positioned to become a major player in the US in its core therapy areas.

Mr. Jornod added: "Vifor Pharma is in a transformational phase and we are investing now to accelerate future revenue growth and to further reduce the manufacturing cost of Veltassa®."

Veltassa® was approved by the FDA for the treatment of hyperkalemia in the United States on October 21, 2015, becoming the first medicine in more than 50 years for people with elevated blood potassium levels and it is patent protected until 2030.

A Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) for Patiromer (powder for oral suspension) was submitted in April 2016 and is currently under review with a decision expected in the second half of 2017.

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Galenica *is a diversified Group active throughout the healthcare market which, among other activities, develops, manufactures and markets pharmaceutical products, runs pharmacies, provides logistical and database services and sets up networks. With its two Business units Vifor Pharma and Galenica Santé, the Galenica Group enjoys a leading position in all its core business activities. A large part of the Group's income is generated by international operations. Galenica is listed on the Swiss Stock Exchange (SIX Swiss Exchange, GALN, security number 1,553,646).*
Additional information concerning the Galenica Group can be found at www.galenica.com.

Vifor Pharma*, a company of the Galenica 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 medicines as well as over-the-counter (OTC) products. Vifor Pharma, headquartered in Zurich, Switzerland, 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.

Relypsa, Inc*., is a biopharmaceutical company focused on the discovery, development and commercialization of polymeric medicines for patients with conditions that are often overlooked and undertreated and can be addressed in the gastrointestinal tract. The Company's first medicine, Veltassa® (patiromer) for oral suspension, was developed based on Relypsa's rich legacy in polymer science. Relypsa was founded in 2007 and, in September 2016, became a Vifor Pharma company. More information is available at www.relypsa.com.*

Veltassa® *(patiromer for oral suspension) is an oral potassium binder approved in the US for the treatment of hyperkalaemia, a potentially life-threatening condition defined as abnormally elevated serum potassium. This medicine has been studied in patients with CKD, and/or heart failure, as well as patients with diabetes and hypertension. Patiromer 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.*

Hyperkalaemia*, or abnormally elevated levels of potassium in the blood, is a serious condition that can lead to life-threatening cardiac arrhythmia and even sudden death. Approximately 3 million people in the United States with stage 3 or 4 CKD and/or heart failure have hyperkalaemia. 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.

***Veltassa® Drug-Drug Interaction Program** tested 28 drugs to determine the potential for interaction with Veltassa®. Fourteen drugs showed no interaction with Veltassa® in in vitro drug-drug interaction tests (conducted in test tubes). Of the 14 drugs that did show an interaction in vitro, 12 were selected for further testing in Phase 1 studies in healthy volunteers to assess whether the results seen in vitro translated into an effect in people. These studies showed Veltassa® did not alter the absorption of nine of the 12 drugs when co-administered. Veltassa® reduced absorption of three drugs when co-administered, however, there was no interaction when Veltassa® and these three drugs were taken 3 hours apart.*