

## PRESS RELEASE

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# EUROPEAN COMMISSION APPROVES MARKETING AUTHORISATION FOR VELTASSA<sup>®</sup>

- Veltassa<sup>®</sup> approved for marketing in the EU for hyperkalaemia
- First launches planned from the end of 2017 or early 2018
- Veltassa<sup>®</sup> to be European brand name

THE EUROPEAN COMMISSION HAS APPROVED PATIROMER TO BE MARKETED AS VELTASSA<sup>®</sup> IN THE 28 EU COUNTRIES FOR THE TREATMENT OF ELEVATED SERUM POTASSIUM LEVELS (HYPERKALAEMIA) IN ADULT PATIENTS. THE APPROVAL IS ALSO ACCEPTED IN NORWAY, ICELAND AND LIECHTENSTEIN.

Veltassa<sup>®</sup> is a sodium-free potassium binder approved for the treatment of hyperkalaemia in adult patients. This therapy can also be made available to patients who develop hyperkalaemia while being treated with renin angiotensin aldosterone system (RAAS) inhibitor therapy. Nearly 100% of patients treated with Veltassa<sup>®</sup> in the phase II-III clinical program were on RAAS inhibitors (RAASi) at baseline. First launches within Europe are expected to take place from the end of 2017 or early 2018.

“We are delighted to be able to offer Veltassa<sup>®</sup> to hyperkalaemia patients, including those on RAASi therapy, in the EU and in Norway, Liechtenstein and Iceland. With Veltassa<sup>®</sup>, patients have an option that is easy to take, keeps potassium levels stable and makes their hyperkalaemia so much easier to manage. In particular, Veltassa<sup>®</sup> makes it possible for patients to continue with their optimal RAASi dose in order to get the maximum benefit from their life-saving RAASi treatment,” said Stefan Schulze, President of the Executive Committee and COO of Vifor Pharma. “With Veltassa<sup>®</sup> we are able to offer an effective medicine that is in line with our aim to deliver innovative, patient-focused solutions. This approval is also another milestone towards our vision of global leadership in cardio-renal therapies.”

Developed by Relypsa, Veltassa<sup>®</sup> was approved by the US Food and Drug Administration (FDA) for the treatment of hyperkalaemia in the US in October 2015 and has been available to patients in the US since December 2015. Marketing authorisation applications for Veltassa<sup>®</sup> have been submitted and are under review in Switzerland and Australia, and are planned in other markets worldwide.

## FURTHER INFORMATION

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**Vifor Pharma Group**, formerly Galenica Group, is a global specialty 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](http://www.viforpharma.com).

**Vifor Fresenius Medical Care Renal Pharma Ltd.**, a common company of Vifor Pharma Group and Fresenius Medical Care, develops and commercialises innovative and high quality therapies to improve the life of patients suffering from chronic kidney disease (CKD) worldwide. The company was founded at the end of 2010 and is owned 55% by Vifor Pharma Group and 45% by Fresenius Medical Care. For more information about Vifor Fresenius Medical Care Renal Pharma and its parent companies, please visit [www.viforpharma.com](http://www.viforpharma.com) and [www.freseniusmedicalcare.com](http://www.freseniusmedicalcare.com).

**Relypsa, Inc.**, a Vifor Pharma Group company, is a biopharmaceutical company focused on the discovery, development and commercialisation 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® (patiomer) for oral suspension, was developed based on Relypsa's rich legacy in polymer science. Veltassa® is approved in the United States for the treatment of hyperkalaemia. Veltassa® has intellectual property protection until 2030 in the United States and 2029 in the European Union. More information is available at [www.relypsa.com](http://www.relypsa.com).

### **About Hyperkalaemia**

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.

### **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.