

## **PRESS RELEASE**

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Subject Patiromer submitted to EMA to seek approval in the EU

### **Vifor Fresenius Medical Care Renal Pharma submits marketing authorisation application requesting European approval of Patiromer for treatment of hyperkalemia**

**Vifor Fresenius Medical Care Renal Pharma has submitted a marketing authorisation application (MAA) to the European Medicines Agency (EMA) for Patiromer. The company is seeking approval of Patiromer for the treatment of hyperkalemia, or elevated blood potassium levels, in the European Union (EU) through the EU centralized procedure.**

In August 2015, Vifor Fresenius Medical Care Renal Pharma (VFMCRP), a common company of Galenica and Fresenius Medical Care, and Relypsa, Inc. entered into an exclusive partnership to commercialise the potassium binder Patiromer in Europe and additional territories.

Patiromer is an investigational drug of Relypsa for the treatment of hyperkalemia that occurs most frequently in chronic kidney disease and heart failure patients. It represents an ideal complement to the existing product portfolio of VFMCRP for nephrology patients.

The drug was approved by the US Food and Drug Administration (FDA) for the treatment of hyperkalemia in the US in October 2015 under the name Veltassa<sup>®</sup>, becoming the first new medicine in more than 50 years for people with elevated serum potassium. The European submission will undergo a formal acceptance and validation phase during May 2016 by the EMA. After this period, an official regulatory review will be undertaken.

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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](http://www.galenica.com).***

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**Fresenius Medical Care** is the world's largest provider of products and services for individuals with renal diseases of which about 2.8 million patients worldwide regularly undergo dialysis treatment. Through its network of 3,418 dialysis clinics, Fresenius Medical Care provides dialysis treatments for 294,381 patients around the globe. Fresenius Medical Care is also the leading provider of dialysis products such as dialysis machines or dialyzers. Along with the core business, the company focuses on expanding the range of additional medical services in the field of care coordination. For more information about Fresenius Medical Care, visit the company's website at [www.freseniusmedicalcare.com](http://www.freseniusmedicalcare.com).

**Vifor Fresenius Medical Care Renal Pharma Ltd.**, a common company of Galenica 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 Galenica and 45% by Fresenius Medical Care.

**Relypsa, Inc.** 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<sup>®</sup> (Patiromer) for oral suspension, was developed based on Relypsa's rich legacy in polymer science. Veltassa<sup>®</sup> is approved in the United States for the treatment of hyperkalemia. Veltassa<sup>®</sup> 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 the VFMCRP and Relypsa Partnership**

In August 2015, VFMCRP and Relypsa announced that the companies had entered into an exclusive collaboration and license agreement for the development and commercialisation of Patiromer (US brand name: Veltassa<sup>®</sup>) outside the United States. Under the terms of the agreement, VFMCRP obtained an exclusive marketing right for Patiromer from Relypsa in worldwide territories except the United States and Japan, where Relypsa retains all commercial rights. Relypsa and VFMCRP are currently collaborating on ongoing development of Patiromer.

**Patiromer powder for oral suspension** (US brand name: Veltassa<sup>®</sup>) is an oral potassium binder approved in the US for the treatment of hyperkalemia, a potentially life-threatening condition defined as abnormally elevated serum potassium. This investigational medicine has been studied in both treatment and prevention studies, primarily 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.

**Hyperkalemia**, 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. 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. It is frequently prevalent in patients who suffer from CKD, hypertension, diabetes and/or heart failure. Patients with CKD or heart failure are at particular risk for developing hyperkalemia, especially those treated with renin-angiotensin-aldosterone-system (RAAS) inhibitors, which can increase blood potassium levels in patients taking these medicines.