



## PRESS RELEASE

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Subject Vifor Fresenius Medical Care Renal Pharma enters into partnership with Relypsa to commercialise Patiromer FOS

## Vifor Fresenius Medical Care Renal Pharma enters into partnership to commercialise Patiromer FOS

Vifor Fresenius Medical Care Renal Pharma (VFMCRP), a common company of Galenica and Fresenius Medical Care, and Relypsa, Inc. have entered into an exclusive partnership to commercialise the potassium binder Patiromer for Oral Suspension (Patiromer FOS) in Europe and additional territories. Patiromer FOS is an investigational drug of Relypsa for the treatment of hyperkalaemia 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 patients with chronic kidney disease and iron deficiency.

Patiromer FOS is an oral potassium binder developed for the treatment of hyperkalaemia, a potentially life-threatening condition defined as abnormally elevated levels of potassium in the blood. Hyperkalaemia occurs most frequently in chronic kidney disease patients (CKD), heart failure patients (HF) and patients who suffer from hypertension or diabetes.

A New Drug Application (NDA) for Patiromer FOS for the treatment of hyperkalaemia is under review by the U.S. Food and Drug Administration (FDA), with a Prescription Drug User Fee Act (PDUFA) date of October 21, 2015 for completion of the review of the NDA. A Marketing Authorisation Application (MAA) for Patiromer FOS is expected to be submitted with the European Medicines Agency (EMA) in the first half of 2016.

Patiromer FOS has the potential to become an important new treatment option for hyperkalemia. With its well-established commercial organization, proven track record in the cardio renal space and dedicated renal sales force in Europe, VFMCRP represents an ideal partner for Relypsa that will enable a strong market entry for Patiromer FOS.

VFMCRP will obtain an exclusive marketing right from Relypsa in worldwide territories except the United States and Japan, where Relypsa retains all commercial rights. Also under the terms of the agreement, Relypsa and VFMCRP will collaborate on ongoing development of Patiromer FOS, including submission of a Marketing Authorisation Application (MAA) with the European Medicines Agency (EMA).

Under the terms of the agreement, Relypsa will receive an upfront cash payment of USD 40 million and will be eligible to receive payments of up to USD 125 million upon achieving certain regulatory and sales based milestones. The sales based milestones are structured in tiers of annual net sales up to USD 500 million in the licensed territories. In addition, Relypsa will receive tiered lower double-digit percentage royalties on net sales of Patiromer FOS in the licensed territories.

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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). For more information, please visit the company's website at <u>www.galenica.com</u>.

**Fresenius Medical Care** is the world's largest integrated provider of products and services for individuals undergoing dialysis because of chronic kidney failure, a condition that affects more than 2.6 million individuals worldwide. Through its network of 3,396 dialysis clinics in North America, Europe, Latin America, Asia-Pacific and Africa, Fresenius Medical Care provides dialysis treatments for 286,768 patients around the globe. Fresenius Medical Care is also the world's leading provider of dialysis products such as hemodialysis machines, dialyzers and related disposable products. For more information, please visit the Company's website at 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 development and commercialization of non-absorbed polymeric drugs to treat disorders in the areas of renal, cardiovascular and metabolic diseases. The company's two-part pivotal Phase 3 trial of its lead product candidate, Patiromer for Oral Suspension, for the treatment of hyperkalaemia, a potentially life-threatening condition defined as abnormally elevated levels of potassium in the blood, has been completed and the primary and secondary endpoints were met. A New Drug Application for Patiromer for Oral Suspension for the treatment of hyperkalaemia was accepted by the U.S. Food and Drug Administration and is currently under review. Relypsa has global royalty-free commercialization rights to Patiromer for Oral Suspension, which has intellectual property protection until 2030 in the United States and 2029 in the European Union.

For more information, please visit the company's website at www.relypsa.com.

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**Patiromer FOS** is an oral potassium binder in development for the treatment of hyperkalaemia, a potentially life-threatening condition defined as abnormally elevated levels of potassium in the blood. The investigational medicine has been studied in both treatment and prevention studies, primarily in patients with chronic kidney disease (CKD), and/or heart failure (HF), as well as patients with diabetes and hypertension. The clinical program includes a two part pivotal Phase 3 program conducted under Special Protocol Assessment with the U.S. Food and Drug Administration (FDA), a 12-month Phase 2 trial and a 48-hour Phase 1 onset-of-action trial.

**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 CKD, hypertension, diabetes and/or HF. Patients with CKD or HF are at particular risk for developing hyperkalaemia, especially those treated with renin-angiotensin-aldosterone-system (RAAS) inhibitors, which can increase levels of serum potassium in patients taking these medicines.