Data from New Analyses of Studies with Veltassa® Presented at 53rd European Renal Association Congress

REDWOOD CITY, Calif., May 22, 2016 (GLOBE NEWSWIRE) -- Relypsa, Inc. (NASDAQ:RLYP), a biopharmaceutical company, today announced that data from new analyses of studies with Veltassa® (patiromer) for oral suspension were presented at the 53rd Congress of the European Renal Association - European Dialysis and Transplant Association (ERA-EDTA) in Vienna.

"Patients with heart failure and chronic kidney disease often have restricted fluid and sodium intake, as these may cause congestive symptoms. We presented new data suggesting Veltassa may bind and remove sodium as well as potassium in the gastrointestinal tract, which may be relevant for these patients," said Lance Berman, M.D., chief medical officer of Relypsa. "A separate analysis showed Veltassa controlled potassium levels for up to a year in hyperkalemic patients who were taking multiple blood pressure medicines. This is important because the use of certain types of blood pressure medicine is often limited due to the side effect of hyperkalemia."

Effect of the Potassium Binding Polymer Patiromer on Urine Sodium Excretion in Healthy Adults (#SO008)

Presented by David A. Bushinsky, M.D., John J. Kuiper Distinguished Professor of Medicine and of Pharmacology and Physiology at the University of Rochester School of Medicine, and chief of the Nephrology Division at the University of Rochester Medical Center

This analysis of the Phase 1 RLY5016-101 study examined the change in urine excretion of sodium in 32 healthy volunteers treated with Veltassa at doses up to 50.4 grams daily for eight days.

Results showed that:

- Daily administration of Veltassa resulted in a dose-related decrease in mean urine sodium compared with placebo (p=0.009 across Veltassa doses).
- The most common adverse events were gastrointestinal events that were mild or moderate in severity. No serious adverse events were reported, and no study participants discontinued treatment because of an adverse event.

Effect of Patiromer for Up to 52 Weeks in Patients with Diabetic Kidney Disease Receiving Combined RAAS Inhibitor Therapy (#SO010)

Presented by Alain Romero, Pharm.D., Ph.D., Vice President, Relypsa, Redwood City, California

The AMETHYST-DN study evaluated Veltassa over 52 weeks in hyperkalemic patients with chronic kidney disease (CKD) and type 2 diabetes who were taking renin angiotensin aldosterone system (RAAS) inhibitors, such as angiotensin-converting-enzyme (ACE) inhibitors, angiotensin receptor blockers (ARBs) and mineralocorticoid antagonists. This post-hoc analysis assessed the effect of Veltassa on blood potassium levels in a sub-group of 56 hyperkalemic patients who were receiving at least two RAAS inhibitors to treat their hypertension. Of these, 31 were taking two medicines (an ACE inhibitor and an ARB) and 25 were taking a combination of an ACE inhibitor and/or an ARB as well as a mineralocorticoid antagonist.

Results showed that:

- Mean blood potassium decreased significantly from baseline to day 3, the first post-baseline visit, in those with mild (p < 0.005) or moderate (p < 0.0001) hyperkalemia.
- Clinically significant decreases in mean blood potassium with Veltassa were sustained throughout 52 weeks.
- At week 52, the mean change from baseline in systolic blood pressure was -11±3 mmHg and the mean change in diastolic blood pressure was -6±2 mmHg.
- Veltassa was generally well tolerated in this subgroup of patients. Over 52 weeks, 23 percent of patients reported one or more adverse events related to Veltassa. The two most common related events were constipation (8.9 percent, none severe) and diarrhea (5.4%, none severe). The rate of discontinuations due to adverse events was 8.9 percent.

About Hyperkalemia
Approximately 3 million people in the United States with stage 3 or 4 CKD and/or heart failure have hyperkalemia, or elevated blood potassium levels. Hyperkalemia can cause abnormal heart rhythms 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. Some medicines that are frequently prescribed to people with CKD and heart failure to help delay progression of their underlying disease can cause hyperkalemia as a side effect. These include RAAS inhibitors, such as ARBs, AAs (aldosterone antagonists) and ACE inhibitors.

About Veltassa
Veltassa was approved by the U.S. Food and Drug Administration 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 serum potassium.

Veltassa is a potassium binder approved for the treatment of hyperkalemia. Veltassa should not be used as an emergency treatment for life-threatening hyperkalemia because of its delayed onset of action.

Made in powder form consisting of smooth, spherical beads, Veltassa is mixed with water (90 milliliters or 3 ounces) 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.

IMPORTANT SAFETY INFORMATION

The Prescribing Information for Veltassa includes a Boxed Warning that Veltassa binds to many other orally administered medications, which could decrease their absorption and reduce their effectiveness. Other oral medications should be administered at least 6 hours before or 6 hours after Veltassa. Doctors should choose Veltassa or the other oral medication if adequate dosing separation is not possible.

Contraindications
Veltassa is contraindicated in patients with a history of a hypersensitivity reaction to Veltassa or any of its components.

Worsening of Gastrointestinal Motility
Use of Veltassa should be avoided in patients with severe constipation, bowel obstruction or impaction, including abnormal post-operative bowel motility disorders, because Veltassa may be ineffective and may worsen gastrointestinal conditions. Patients with a history of bowel obstruction or major gastrointestinal surgery, severe gastrointestinal disorders, or swallowing disorders were not included in clinical studies.

Hypomagnesemia
Veltassa binds to magnesium in the colon, which can lead to hypomagnesemia. In clinical studies, hypomagnesemia was reported as an adverse reaction in 5.3 percent of patients treated with Veltassa. Approximately 9 percent of patients in clinical trials developed hypomagnesemia with a serum magnesium value < 1.4 mg/dL. Doctors should monitor serum magnesium and consider magnesium supplementation in patients who develop low serum magnesium levels.

Adverse Reactions
The most common adverse reactions (incidence ≥2 percent) were constipation, hypomagnesemia, diarrhea, nausea, abdominal discomfort and flatulence. Mild to moderate hypersensitivity reactions were reported in 0.3 percent of patients treated with Veltassa and included edema of the lips.

For additional Important Safety Information and Veltassa's full Prescribing Information, please visit www.relypsa.com/veltassa/prescribing-information.

About Relypsa, Inc.
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. Veltassa is approved in the United States for the treatment of hyperkalemia. 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.

Forward-Looking Statements
To the extent that statements contained in this press release are not descriptions of historical facts regarding Relypsa, they are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, including statements regarding the results suggested by the data from new analyses of studies with Veltassa and the potential relevance to patients of such data and the potential importance to patients of data from a separate analysis of Veltassa. Such forward-looking statements involve
substantial risks and uncertainties that could cause our clinical development program, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in the clinical drug development and commercialization process, including regulatory requirements, Relypsa’s substantial dependence on Veltassa, Relypsa’s commercialization plans and efforts and other matters that could affect the availability or commercial potential of Veltassa. Relypsa undertakes no obligation to update or revise any forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the business of Relypsa in general, see Relypsa’s current and future reports filed with the U.S. Securities and Exchange Commission, including its Annual Report on Form 10-K for the year ended December 31, 2015 and its Quarterly Report on Form 10-Q for the quarterly period ended March 30, 2016.