RELYPSA ANNOUNCES FDA APPROVAL OF VELTASSA(TM) (PATIROMER) FOR ORAL SUSPENSION FOR THE TREATMENT OF HYPERKALEMIA

- First new medicine for the treatment of hyperkalemia, or high blood potassium levels, in more than 50 years
- Approximately 3 million people with chronic kidney disease (CKD) and/or heart failure in the United States have hyperkalemia
- In clinical trials, Veltassa significantly reduced blood potassium and kept levels in the target range for up to a year in patients with hyperkalemia, allowing for chronic, daily treatment of hyperkalemia
- Company to hold conference call/webcast Thursday, October 22, 2015 at 8:00AM ET (5:00AM PT)

REDWOOD CITY, Calif., Oct. 21, 2015 (GLOBE NEWSWIRE) -- Relypsa, Inc. (NASDAQ:RLYP), a biopharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) has approved Veltassa™ (patiromer) for oral suspension, a new polymer medicine that binds potassium, for the treatment of hyperkalemia.

"We are very excited to bring people with hyperkalemia the first new medicine in more than 50 years," said John A. Orwin, president and chief executive officer of Relypsa. "The FDA approval of Veltassa represents approximately a decade of research by dedicated scientists and doctors, and underscores Relypsa’s commitment to developing polymer-based treatments for people with conditions that are often overlooked and undertreated. We would like to thank the many clinical trial investigators and patients who contributed to the development of this important medicine that may help the millions of people affected by hyperkalemia."

"As the number of people with CKD and heart failure continues to climb, hyperkalemia is a challenge doctors and patients need to be aware of," said Matthew R. Weir, M.D., professor and director, Division of Nephrology, University of Maryland School of Medicine and the lead investigator for the pivotal Phase 3 clinical trial of Veltassa. "Veltassa will provide doctors and patients a new medicine for daily treatment of hyperkalemia, which has been shown to be effective in correcting blood potassium and can be used chronically to keep levels in the target range."

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 renin angiotensin aldosterone system (RAAS) inhibitors such as ARBs (Angiotensin Receptor Blockers), AAs (Aldosterone Antagonists) and ACE (Angiotensin-Converting-Enzyme) inhibitors.

Veltassa Clinical Trial Data
The FDA approval of Veltassa was based on a clinical development program that studied patients who are representative of people who typically experience high blood potassium levels, including people who had CKD, heart failure, diabetes and hypertension.

- The pivotal Phase 3 OPAL-HK study showed Veltassa significantly decreased potassium levels in hyperkalemic CKD patients taking RAAS inhibitors (mean decrease of -1.01 ± 0.03 mEq/L from baseline; p<0.001). At four weeks, 76 percent of patients had potassium levels in the target range (3.8 to <5.1 mEq/L). During the second part of the trial, patients taking Veltassa had no change in median potassium from baseline (0.00 mEq/L), whereas potassium levels significantly increased in the placebo group (0.72 mEq/L; p<0.001).
- The Phase 2 AMETHYST-DN trial evaluated use of Veltassa over 52 weeks in hyperkalemic patients with CKD and type 2
diabetes who were taking RAAS inhibitors. Throughout the year-long study, the majority of patients had potassium levels in the target range (3.8-5.0 mEq/L).

- An open-label, uncontrolled, Phase 1 study evaluated Veltassa's onset-of-action in 25 hyperkalemic CKD patients. The mean baseline blood potassium level was 5.9 mEq/L. A statistically significant reduction in blood potassium levels was first observed at 7 hours after the first dose. Potassium levels continued to decline during the 48-hour treatment period of the study (-0.8 mEq/L at 48 hours after the first dose).

In the clinical trials, most adverse reactions were mild to moderate. The most common adverse reactions in all trials included constipation (7.2 percent: 5.4 percent mild and 1.8 percent moderate), hypomagnesemia (low magnesium levels; 5.3 percent), diarrhea (4.8 percent), nausea (2.3 percent), abdominal discomfort (2.0 percent) and flatulence (2.0 percent).

**Veltassa Availability**

Veltassa is expected to be available to patients in the United States by the first week of January 2016. Relypsa is committed to ensuring that people living with the burden of hyperkalemia have access to Veltassa. Veltassa KonnectSM is a centralized, comprehensive patient support center with a dedicated team of healthcare professionals and reimbursement specialists. Once Veltassa is available, this team will provide a variety of services to doctors and patients, including reimbursement support, co-pay assistance, a free drug program for eligible patients, and support to help patients take Veltassa as prescribed.

For more information regarding the availability of Veltassa and the patient support program, patients and doctors can call 1-844-870-7597.

**Conference Call Thursday, October 22, 2015 at 8:00AM ET (5:00AM PT)**

The Relypsa management team will host a conference call and webcast Thursday, October 22, 2015 to provide more information about Veltassa. The live call may be accessed by phone by calling (866) 410-4428 (domestic) or +1 (704) 908-0287 (international), conference code 60411469. The webcast can be accessed live on the investor relations section of the Relypsa website at http://investor.relypsa.com. It will be archived for 30 days following the call.

**About Veltassa**

Veltassa is the brand name for patiromer, 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, this new medicine 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 potential advantages of Veltassa, including the ability to be used chronically, the expected commercial availability of Veltassa and Relypsa's expected commercialization plans. 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, 2014 and its Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2015.

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