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Relypsa Announces Key Data Presented at ASN on Long-Term Chronic Treatment and Early Onset of Action With Patiromer for Oral Suspension

- Pre-Specified Sub-Analysis of Patients With Type II Diabetes From Phase 3 Trial Also Presented -

REDWOOD CITY, Calif., Nov. 17, 2014 (GLOBE NEWSWIRE) -- Relypsa, Inc. (Nasdaq:RLYP), a biopharmaceutical company, today announced that data from clinical trials of the company's lead product candidate, Patiromer for Oral Suspension (Patiromer FOS), were presented at the American Society of Nephrology (ASN) Annual Meeting held last week in Philadelphia. Among the data presented were two key posters related to long-term chronic treatment of hyperkalemia (HK) as well as data on the early onset of action of Patiromer FOS. Last month, the company announced that it had submitted a New Drug Application to the FDA for Patiromer FOS for the treatment of HK, a serious condition defined as abnormally elevated levels of potassium in the blood.

The long-term, 12-month trial results were presented by George Bakris, MD, professor of Medicine at the University of Chicago. The multi-center, randomized, open-label trial included 304 patients with chronic kidney disease (CKD) and diabetic nephropathy who were all receiving renin-angiotensin-aldosterone system (RAAS) inhibitor therapy and who received treatment with Patiromer FOS for up to one year. Patients were assigned to one of two groups based on their serum potassium level / degree of hyperkalemia at baseline (mild or moderate HK) and, within each group, were randomized to one of three Patiromer FOS starting doses. Patiromer FOS was taken twice daily and the dose was adjusted if necessary to maintain serum potassium in a target range. The baseline average serum potassium level in the mild HK group was 5.2 mEq/L and for the moderate group was 5.7 mEq/L. All endpoints were met in the study with statistically significant reduction in serum potassium observed at 48 hours in both mild and moderate HK groups ($p < 0.001$), which was maintained for 52 weeks.

The percent of patients maintained in the normal range (serum potassium at 3.8 to 5.0 mEq/L) during the 44 week maintenance period ranged from 77% to 95% for mild and moderate HK patients. Additionally, patients were found to have measurements of renal function that remained stable over the 52 week study period of the trial, a key finding in a patient population that historically would have experienced declining renal function. Of note, after treatment with Patiromer FOS was discontinued, mean serum potassium values increased at each subsequent visit. The most common side effect with Patiromer FOS in this study was mild constipation which occurred in 6 percent of patients, and with no severe cases. Patiromer FOS appeared to be well tolerated with 211 patients completing the 52 week trial, with a low rate of adverse event-related withdrawals (6% and 7%, respectively in the mild and moderate HK groups).

"This trial is an important contribution to our field in not only investigating Patiromer FOS as a long-term treatment for hyperkalemia, but also providing data on the recurrence of elevated potassium levels when treatment with Patiromer FOS is stopped," said George Bakris, MD, professor of Medicine at the University of Chicago. "If the drug is approved, I believe it will be a welcomed addition to our armamentarium to treat our patients with hyperkalemia."

Lance Berman, M.D., chief medical officer of Relypsa added, "To our knowledge, the 12-month trial of Patiromer FOS is the first such study ever completed to evaluate long-term, chronic treatment of hyperkalemia, a condition in chronic kidney disease patients that often limits use of kidney- and heart-protective RAAS inhibitors."

In a separate poster presentation, David Bushinsky, M.D., John J. Kuiper Distinguished Professor of Medicine, University of Rochester School of Medicine, presented detailed results from the company's Phase 1 Onset-of-Action trial which evaluated the timeliness of the potassium-lowering action of Patiromer FOS. The open-label, single-arm trial was designed to evaluate the time-to-onset of the potassium-lowering action in CKD patients with hyperkalemia who were taking at least one RAAS inhibitor. Following a 3-day restricted diet run-in period to control and stabilize dietary intake of potassium, the study enrolled 25 patients with baseline serum potassium levels of 5.5 to less than 6.5 mEq/L. Patients were treated twice daily with 8.4 g patiromer per dose and observed over a 48-hour treatment period, followed by a 7-day post-treatment safety follow-up period.

Following the first dose of Patiromer FOS, a numerical reduction in mean serum potassium was observed at the first time point of 4 hours, with statistical significance first demonstrated at the second measurement (7 hours post treatment initiation) as well as at all subsequent evaluations up to 48 hours ($p < 0.001$ at 48 hours). The trial met its primary endpoint in which an early potassium lowering action was observed. During the trial, mean serum potassium was reduced from 5.93 mEq/L at baseline by a maximum mean reduction of 0.83 mEq/L. Within 24 hours of treatment with Patiromer FOS, 80 percent of patients had serum potassium levels < 5.5 mEq/L, a clinically meaningful drop in potassium. Over the 48-hour treatment period, the potassium-

lowering effect was sustained with a steady decline in mean serum potassium, with no loss of effect or rebound in mean potassium levels during night-time periods. Patiromer FOS was well tolerated with no serious adverse events reported.

In another poster presentation, Matthew R. Weir, M.D. Professor and Director, Division of Nephrology, University of Maryland School of Medicine presented data from a pre-specified analysis of Type II diabetic patients treated for hyperkalemia in the company's Phase 3 program in chronic kidney disease patients on RAAS inhibitors. The analysis showed consistent results in the ability of Patiromer FOS to reduce serum potassium levels and maintain normokalemia compared to placebo in the arguably tougher to treat chronic kidney disease patients with Type II diabetes. Similarly, the safety results seen in this subgroup were consistent with the overall patient population in the Phase 3 program.

About Patiromer FOS

Patiromer FOS is a high capacity, oral potassium binder being developed for the treatment of hyperkalemia. The compound has been evaluated in CKD patients with hyperkalemia, including a two part Phase 3 program, a 12-month Phase 2 trial and a 48-hour Phase 1 onset-of-action trial. In all of those trials, Patiromer FOS met its efficacy endpoints and the treatment was well tolerated. The pivotal clinical trial for Patiromer FOS was conducted under a Special Protocol Assessment with the FDA.

About Relypsa, Inc.

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 has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration seeking approval to market Patiromer for Oral Suspension for the treatment of hyperkalemia, a serious condition defined as abnormally elevated levels of potassium in the blood. Relypsa has global royalty-free commercialization rights to Patiromer for Oral Suspension, which has intellectual property protection in the U.S. until at least 2030. 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 belief that the 12- month trial is an important contribution to the field in not only investigating Patiromer for Oral Suspension (Patiromer FOS) as a long-term treatment for hyperkalemia, but also providing data on the recurrence of elevated potassium levels when treatment is stopped, the belief that Patiromer FOS, if approved, will be a welcomed addition to our armamentarium to treat patients with hyperkalemia and the belief that the 12-month trial is the first such study ever completed to evaluate the long-term, chronic treatment of hyperkalemia. Such forward-looking statements involve substantial risks and uncertainties that relate to future events and the actual results could 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 process, including the regulatory approval process, the timing of the company's regulatory filings, the company's substantial dependence on Patiromer FOS, the company's commercialization plans and efforts and other matters that could affect the availability or commercial potential of Patiromer FOS. 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 the company in general, see Relypsa's current and future reports filed with the U.S. Securities and Exchange Commission, including its Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2014.

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