Relypsa to Present Multiple Posters at Upcoming Medical Meetings Highlighting Patiromer for Oral Suspension and Hyperkalemia Prevalence

REDWOOD CITY, Calif., May 15, 2015 (GLOBE NEWSWIRE) -- Relypsa, Inc. (Nasdaq:RLYP), a biopharmaceutical company, today announced multiple poster presentations at the 2015 Annual Scientific Meeting of the American Society of Hypertension (ASH), including a late-breaking poster highlighting new data on changes to aldosterone levels from the Phase 3 OPAL-HK study of Patiromer for Oral Suspension (Patiromer FOS). Elevated aldosterone, which regulates the balance of water and electrolytes in the body by forcing the kidney to excrete potassium into the urine, is associated with the progression of chronic kidney disease and cardiovascular complications. Additionally, Relypsa will present a poster at the 20th International Meeting of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) featuring new estimates of the prevalence of hyperkalemia in patients with advanced kidney and heart disease, as well two encore poster presentations on Patiromer FOS at the upcoming Heart Failure Association of the European Society of Cardiology Congress (HFA-ESC).

Data presented at ASH will include data from the two-part, Phase 3 OPAL-HK study, as well as data from the Phase 2 AMETHYST-DN study. Primary outcomes data from the Phase 3 OPAL-HK study were published in the New England Journal of Medicine in November 2014, and data from both trials were combined with results from Relypsa's broader clinical development program to support the Company's New Drug Application (NDA) for Patiromer FOS. The U.S. Food and Drug Administration (FDA) has assigned a Prescription Drug User Fee Act (PDUFA) action date of October 21, 2015, for completion of the review of the NDA.

"In an analysis of the Phase 3 OPAL-HK data, treatment with Patiromer FOS reduced aldosterone along with potassium levels during Part A of the study. During the Part B withdrawal phase of the study, aldosterone levels increased in placebo patients more than those treated with Patiromer FOS,” said Lance Berman, M.D., chief medical officer of Relypsa. "The data suggests that Patiromer FOS may have a further positive impact on key cardiorenal comorbidities of hyperkalemia beyond the regulation of potassium levels, which could be particularly important in the chronic use setting."

2015 Annual Scientific Meeting of the American Society of Hypertension Poster Presentations:

- Patiromer Decreases Aldosterone. With Decreases in Urine Albumin/Creatinine Ratio and Systolic Blood Pressure, in Patients with Chronic Kidney Disease and Hyperkalemia on RAAS Inhibitors: Results from OPAL-HK (Weir, et al. Late-breaking Poster #1; May 18, 2015)

- Reduction of Serum K+ with Patiromer for 1 Year in Patients with Diabetic CKD Who Developed Hyperkalemia While on Maximal Losartan and/or Spironolactone (Bakris, et al. Poster #126; May 17, 2015)

- Patiromer Increased Time to Renin-Angiotensin-Aldosterone System Inhibitor Discontinuation Compared with Placebo in Advanced Chronic Kidney Disease Patients with Hyperkalemia: Results from the Randomized Phase 3 OPAL-HK Study (Weir, et al. Poster #87; May 17, 2015)

- Treatment Gap Between Clinical Guidelines and the Utilization of Renin-Angiotensin-Aldosterone System Inhibitors in Patients with Chronic Kidney Disease and/or Diabetes: The Role of Hyperkalemia (Knispel, et al. Poster #9; May 16, 2015)

20th International Meeting of the International Society for Pharmacoeconomics and Outcomes Research Poster Presentation:

- Hyperkalemia Is Prevalent in Patients with Cardiorenal Comorbidities (Latts et al. Poster #PCV33, May 19, 2015)

Heart Failure Association of the European Society of Cardiology (HFA-ESC) Encore Poster Presentations:


- Patiromer lowers serum potassium and prevents recurrent hyperkalemia in patients with heart failure and CKD when treated with RAAS inhibitors: results from OPAL-HK (Pitt et al. Poster #P397, May 23, 2015)
About Hyperkalemia

Hyperkalemia, a serious condition defined as abnormally elevated levels of potassium in the blood, is frequently prevalent in patients who suffer from chronic kidney disease, hypertension, diabetes and/or heart failure. Hyperkalemia can lead to life-threatening cardiac arrhythmia and sudden death. Patients with chronic kidney disease or heart failure are at particular risk for developing hyperkalemia, especially those treated with renin-angiotensin-aldosterone-system (RAAS) inhibitors such as ARBs (Angiotensin Receptor Blockers), AAs (Aldosterone Antagonists), and ACE (Angiotensin-Converting-Enzyme) inhibitors. Although RAAS inhibition has been shown to protect kidney and cardiac function, many patients who could benefit from RAAS inhibitors are untreated or undertreated due to the undesirable side effect of increasing serum potassium.

About Patiromer FOS

Patiromer FOS is an 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's two-part pivotal Phase 3 trial of its lead product candidate, Patiromer for Oral Suspension, for the treatment of hyperkalemia, 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 hyperkalemia 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 in the United States 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 potential approval of Patiromer for Oral Suspension, or Patiromer FOS, and the potential of Patiromer FOS to have a positive impact on key cardiorenal comorbidities of hyperkalemia beyond the regulation of potassium levels. 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 process, including the regulatory approval process, the timing of Relypsa’s regulatory filings, Relypsa’s substantial dependence on Patiromer FOS, Relypsa’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 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 March 31, 2015.

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