October 22, 2014

Relypsa Submits New Drug Application to U.S. FDA Seeking Approval for Patiromer for Oral Suspension to Treat Hyperkalemia

Submission Based on Phase 3 Program Conducted Under Special Protocol Assessment and 12-Month Phase 2 Safety, Efficacy and Tolerability Data

REDWOOD CITY, Calif., Oct. 22, 2014 (GLOBE NEWSWIRE) — Relypsa, Inc. (Nasdaq:RLYP), today announced that the company has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) seeking approval to market Patiromer for Oral Suspension (Patiromer FOS) for the treatment of hyperkalemia, a serious condition defined as abnormally elevated levels of potassium in the blood.

The NDA is supported by eight clinical trials, including a Phase 3 program that was conducted under a Special Protocol Assessment as well as a Phase 2 trial that evaluated Patiromer FOS in patients for up to one year.

“Our submission of the NDA for Patiromer FOS is an important milestone, which sets the stage for NDA acceptance and regulatory review of our application and ultimately, potential approval of the drug and potentially marking the first new therapeutic innovation available to treat patients with hyperkalemia in over 50 years,” said John A. Orwin, president and chief executive officer of Relypsa. "We look forward to offering patients a potential treatment for hyperkalemia that can normalize their potassium levels in acute and chronic settings. Based on the efficacy and safety of twice daily dosing demonstrated in clinical studies, as well as the early onset of action and favorable safety profile for up to one year, we believe that Patiromer FOS has the potential to become a preferred treatment option for hyperkalemia."

Lance Berman, chief medical officer of Relypsa added, "We believe that the clinical development program for Patiromer FOS is the first to provide robust clinical data for the evaluation of efficacy of a therapy for the treatment of hyperkalemia. To our knowledge, Patiromer FOS is the first therapy to date that has successfully completed a prospective 12-month evaluation of safety, efficacy and tolerability in a long term, chronic treatment setting in hyperkalemic patients."

About Hyperkalemia and Patiromer

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.

Patiromer for Oral Suspension 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’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. 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 importance of the NDA submission for Patiromer FOS, the potential NDA acceptance and regulatory review, the potential approval of the drug, the potential of the drug to be the first new therapeutic innovation available to treat patients with hyperkalemia in over 50 years, the potential of the drug to treat hyperkalemia and normalize potassium levels in acute and chronic settings, the belief that the drug has the potential to become a preferred treatment option for hyperkalemia, the belief that the drug’s clinical development program is the first to provide robust data for the evaluation of efficacy of a therapy for the treatment of hyperkalemia and the belief that the drug is the first therapy to date that has successfully completed a prospective 12-month evaluation of safety, efficacy and tolerability in a long term, chronic treatment setting in hyperkalemic patients. 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, its 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 the company’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 June 30, 2014.

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Source: Relypsa, Inc.

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