December 15, 2014

Relypsa Announces FDA Acceptance of New Drug Application for Patiromer for Oral Suspension to Treat Hyperkalemia

REDWOOD CITY, Calif., Dec. 15, 2014 (GLOBE NEWSWIRE) -- Relypsa, Inc. (Nasdaq:RLYP), today announced that the U.S. Food and Drug Administration (FDA) has accepted for filing the New Drug Application (NDA) for Patiromer for Oral Suspension (Patiromer FOS) for the treatment of hyperkalemia, a serious condition defined as abnormally elevated levels of potassium in the blood. Relypsa expects written notification of NDA acceptance along with the Prescription Drug User Fee Act (PDUFA) date (the expected date for completion of FDA review of the NDA), as well as a preliminary indication regarding the need for an Advisory Committee meeting, in the day-74 letter from the FDA in early January 2015.

The NDA is supported by eight clinical trials, including a Phase 3 program that was conducted under a Special Protocol Assessment, a long-term treatment trial that evaluated the safety and efficacy of Patiromer FOS in patients for up to one year, and an onset-of-action study that evaluated the time to potassium lowering action.

"Acceptance of our NDA is a significant milestone that triggers greater intensification of our steps toward commercial readiness," said John A. Orwin, president and chief executive officer. "If approved, we believe Patiromer FOS may be the first new therapeutic innovation available to treat patients with hyperkalemia in both acute and chronic settings in over 50 years. We also believe there is a significant unmet medical need for patients, particularly as it relates to chronic therapy, and we are planning for broad access to the drug. Based on the robust data which demonstrated the early onset of action and favorable safety profile for up to one year, we believe that Patiromer FOS, if approved, will become an important new treatment option for patients with hyperkalemia."

Last month, the company announced that results from the pivotal Phase 3 program of Patiromer for Oral Suspension were published in the *New England Journal of Medicine.*

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 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 study, a 12-month Phase 2 trial and a 48-hour Phase 1 onset-of-action study. In all of those studies, Patiromer FOS met its efficacy endpoints and the treatment was well tolerated. The pivotal clinical study 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 expected written response from the U.S. Food and Drug Administration, or FDA, *the commercial plans for Patiromer for Oral Suspension, or Patiromer FOS, the potential FDA approval of the drug, the therapeutic potential of the drug, the belief that there is a significant unmet medical need, the plan for broad access to the drug and the commercial potential of the drug. 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 September 30, 2014.*

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