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Cara Therapeutics Reports Continuation of Phase 3 Trial of I.V. CR845 in Postoperative Pain Following Interim Assessment

- Trial will continue to test two doses of CR845 and aims to enroll up to 450 patients -

- Both doses of CR845 well tolerated -

- Trial completion expected in the fourth quarter of 2017 -

STAMFORD, Conn., June 21, 2017 (GLOBE NEWSWIRE) -- Cara Therapeutics, Inc. (Nasdaq:CARA), a biopharmaceutical company focused on developing and commercializing new chemical entities designed to alleviate pain and pruritus by selectively targeting peripheral kappa opioid receptors, today announced the completion of a prespecified interim conditional power analysis of its adaptive Phase 3 trial of I.V. CR845. Based on the guidance of the Independent Data Monitoring Committee (IDMC), the trial will continue to test two doses of CR845 (1.0, and 0.5 µg/kg I.V.) versus placebo in up to 450 patients undergoing abdominal surgery. The IDMC also reviewed the available safety information, including serum sodium levels, and confirmed that both doses of CR845 were well tolerated with no significant changes in the monitored safety parameters.

"We look forward to continuing to test both doses of I.V. CR845 in our ongoing adaptive Phase 3 trial following the IDMC's interim assessment analysis, and are encouraged by the overall clinical safety profile of CR845 for use in the postoperative setting," said Joseph Stauffer, D.O., M.B.A., Chief Medical Officer of Cara Therapeutics. "There remains a clear unmet need for effective analgesic agents that lack the serious safety risks inherent in current opioids. We anticipate completing enrollment of this trial later this year."

About the Ongoing CLIN3001 Postoperative Pain Trial

The CLIN3001 Phase 3 trial is a multi-center, randomized, double-blind, placebo-controlled, parallel-group adaptive design trial with repeated doses of I.V. CR845 or placebo administered both prior to and following abdominal surgery in male and female patients. The trial is enrolling up to 450 patients at 30 clinical trial sites within the United States. Two doses of I.V. CR845 (1.0, and 0.5µ g/kg I.V.) are being compared to placebo. The primary efficacy measure is the Change in Pain Intensity over the 24-hour postoperative period (AUC-24) using the patient-reported Numeric Rating Scale (NRS) score collected at prespecified time points through 24 hours. Postoperative nausea and vomiting (PONV) will be evaluated as a secondary efficacy measure.

About CR845

CR845 is a peripherally acting kappa opioid receptor agonist currently in development for the treatment of acute and chronic pain and pruritus. In multiple randomized, double-blind, placebo-controlled Phase 2 trials in patients undergoing laparoscopic hysterectomy or bunionectomy procedures, I.V. CR845 treatment resulted in statistically significant reductions in pain intensity and opioid-related side effects. In more than 1200 subjects dosed to date, CR845 was observed to be well tolerated, without incurring the dysphoric and psychotomimetic side effects that have been reported with centrally acting (CNS-active) kappa opioid receptor agonists, and lacking the respiratory depression and abuse liability of mu opioid receptor agonists. Top-line data from a Phase 2b trial of Oral CR845 in chronic pain associated with osteoarthritis are expected in the second quarter of 2017.

About Cara Therapeutics

Cara Therapeutics is a clinical-stage biopharmaceutical company focused on developing and commercializing new chemical entities designed to alleviate pain and pruritus by selectively targeting peripheral kappa opioid receptors. Cara is developing a novel and proprietary class of product candidates, led by CR845, that target the body's peripheral nervous system and have demonstrated initial efficacy in patients with moderate-to-severe pain without inducing many of the undesirable side effects typically associated with currently available opioid pain therapeutics.

Forward-looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Examples of these forward-looking statements include statements concerning the expected timing of the completion of the ongoing CLIN3001 postoperative pain trial of I.V. CR845 and the safety and efficacy results of the ongoing CLIN3001 clinical trial. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Risks are described more fully in Cara's filings with the Securities and Exchange Commission, including the "Risk Factors" section of Cara's Annual Report on Form 10-K for the year ended December 31, 2016 and its other documents subsequently filed with or furnished to the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. Except to the extent required by law, Cara undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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