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Cara Therapeutics Announces Top-line Results From Phase 2b Trial of Oral CR845 in Chronic Pain Patients With Osteoarthritis of the Hip or Knee

- Statistically significant 39 percent reduction in mean joint pain score in hip patients at eight weeks with 5.0 mg dose -

- 35 percent reduction in mean joint pain score for all patients at eight weeks with 5.0 mg dose -

- All tablet strengths well tolerated over eight-week treatment period -

- Conference call today at 4:30 p.m. ET -

STAMFORD, Conn., June 29, 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 top-line results from a Phase 2b trial of an oral tablet formulation of the Company's peripherally selective kappa opioid agonist, CR845, in patients with osteoarthritis (OA) of the knee or hip.

"Developing effective analgesics that lack the high abuse potential and serious side effects of currently available drug classes remains the most pressing need in chronic pain," said Dr. Ajay D. Wasan, M.D., M.Sc., Professor of Anesthesiology and Psychiatry, Vice Chair for Pain Medicine, Department of Anesthesiology, University of Pittsburgh Medical Center (UPMC). "The magnitude of the reduction in mean joint pain scores observed in all patients in this trial together with an encouraging safety profile underscores the significant potential of CR845 as a new therapeutic approach for the treatment of chronic inflammatory pain."

Oral CR845 Phase 2b Trial Design and Results

The Phase 2b trial was a randomized, double-blind, placebo-controlled trial of three tablet strengths of CR845, 1.0 mg, 2.5 mg and 5.0 mg, dosed twice a day (BID) over an eight-week treatment period in 476 patients with osteoarthritis of the hip or knee experiencing moderate-to-severe pain.

- The primary efficacy endpoint was the change from baseline at week eight, with respect to the weekly mean of the daily pain intensity score using a numerical rating scale (NRS).
- Secondary endpoints included overall Patient Global Assessment (PGA) score, mean reduction in rescue medication and overall improvement in WOMAC scores.
- The trial design incorporated a four-week titration period for a response, followed by a four-week maintenance period. Sixty-seven percent of CR845-treated patients in the maintenance period titrated to the 5.0 mg dose after the four-week titration period, based on change in the observed mean joint pain score (NRS).
- Patients with OA of the hip maintained on the 5.0 mg dose to the end of the eight-week treatment period exhibited a statistically significant 39 percent reduction in mean joint pain score ($p=0.043$ vs. placebo); all patients (OA of the knee or hip) maintained on the 5.0 mg dose to the end of the eight-week treatment period exhibited a 35 percent reduction in mean joint pain score ($p=0.111$ vs. placebo).
- Patients maintained on the 1.0 mg and 2.5 mg tablet strengths did not exhibit significant reductions in mean joint pain scores compared to placebo.
- For patients maintained on the 5.0 mg dose, there was a statistically significant increase in the proportion of patients whose OA was "very much improved" or "much improved" as indicated by Patient Global Assessment score in both the total patient group ($p < 0.005$ vs. placebo) and in patients with primary OA of the hip ($p < 0.006$ vs. placebo).
- The reduction in pain score in the 5.0 mg dose group in hip patients was accompanied by a reduction in mean rescue medication of 41 percent at week eight versus placebo.
- An overall improvement of 62 percent from baseline in WOMAC scores was observed over the eight-week treatment period for the 5.0 mg dose group in hip patients.
- All tablet strengths were generally well tolerated with no drug-related serious adverse events (SAEs). For the 5.0 mg dose, the most common adverse events reported at the > 5 percent incidence level were dry mouth (six percent) and constipation (12 percent). Importantly, there were no clinically significant changes in serum sodium levels observed during the eight-week treatment period for any dose group.

"We believe that the present trial of oral CR845 has highlighted the potential of a peripherally acting kappa agonist to provide clinical benefit in a chronic pain population and we're pleased that statistical significance was achieved for the 5.0 mg dose in patients with OA of the hip," said Joseph Stauffer, D.O., M.B.A., Chief Medical Officer of Cara Therapeutics. "The drug was observed to be well tolerated over the treatment period and this overall data set will inform both our dose selection and patient population in designing our next trial of oral CR845 in OA patients."

Conference Call

Cara management will host a conference call today at 4:30 p.m. ET to discuss the Oral CR845 OA trial results and next steps for the program. To participate in the conference call, please dial (855) 445-2816 (domestic) or (484) 756-4300 (international) and refer to conference ID 47802588. A live webcast of the call can be accessed under "Events and Presentations" in the News & Investors section of the Company's website at www.CaraTherapeutics.com.

An archived webcast recording will be available on the Cara website beginning approximately two hours after the call.

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.

About Cara Therapeutics

Cara Therapeutics is a clinical-stage biotechnology company focused on developing and commercializing new chemical entities designed to alleviate pain and pruritus by selectively targeting kappa opioid receptors. Cara is developing a novel and proprietary class of product candidates that target the body's peripheral nervous system and have demonstrated efficacy in patients with moderate-to-severe pain without inducing many of the undesirable side effects typically associated with currently available 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 oral CR845's potential to treat chronic pain patients and expand the potential clinical utility of CR845 beyond acute pain, the establishment of the clinical utility of Oral CR845 and the future clinical development of Oral CR845, including the expected timing and design of any additional clinical trial(s). 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 Therapeutics' filings with the Securities and Exchange Commission, including the "Risk Factors" section of the Company'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. Cara Therapeutics 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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