



Cara Therapeutics Completes Enrollment of KALM-1 Pivotal Phase 3 Trial Of KORSUVA™ (CR845/difelikefalin) Injection in Hemodialysis Patients with Pruritus

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Top-line Data Readout Expected in Q2, 2019

STAMFORD, Conn., Jan. 07, 2019 (GLOBE NEWSWIRE) -- Cara Therapeutics, Inc. (Nasdaq:CARA), a biopharmaceutical company focused on developing and commercializing new chemical entities with a primary focus on the treatment of pruritus by selectively targeting peripheral kappa opioid receptors, today announced completion of enrollment in the KALM-1 Phase 3 trial of KORSUVA™ (CR845/difelikefalin) Injection in hemodialysis patients with moderate-to-severe chronic kidney disease-associated pruritus (CKD-aP). More than 350 hemodialysis patients with CKD-aP have now been randomized across approximately 60 clinical sites in the United States.

"Completion of enrollment in the first pivotal Phase 3 trial is an important milestone toward our goal of developing KORSUVA™ Injection as a first-in-class therapeutic for hemodialysis patients suffering from pruritus," said Derek Chalmers, Ph.D., D.Sc., President and Chief Executive Officer of Cara Therapeutics. "We are pleased that our development team was able to enroll the trial within our projected timelines, and we look forward to reporting top-line data in the second quarter of this year."

KORSUVA™ Injection Phase 3 Program Update

KALM-1 Phase 3 Trial

KALM-1 is a multicenter, randomized, double-blind, placebo-controlled 12-week treatment trial in the U.S. with a 52-week open label extension phase that is designed to evaluate the safety and efficacy of 0.5 mcg/kg KORSUVA CR845/difelikefalin injection in 350 hemodialysis patients with moderate-to-severe pruritus.

The primary efficacy endpoint is the proportion of patients achieving at least a 3-point improvement from baseline in the weekly mean of the daily 24-hour Worst Itch Numeric Rating Scale (NRS) score at week 12. In a completed Phase 2 trial, the proportion of patients with an improvement from baseline in the weekly mean Worst Itch NRS score of ≥ 3 points at week 8 was statistically significantly higher in the CR845/difelikefalin 0.5 mcg/kg group compared to the placebo group (64% vs. 29%; $p < 0.01$).¹

Secondary endpoints include assessment of itch-related quality of life changes measured using the validated self-assessment 5-D itch and Skindex-10 scales, as well as the proportion of patients achieving > 4 -point improvement from baseline in weekly mean of the daily 24-hour Worst Itch NRS score at week 12.

KALM-2 Phase 3 Trial

In August 2018, Cara announced the dosing of the first patient in its second Phase 3 efficacy trial (KALM-2), which is similar in design to the KALM-1 trial and will support regulatory filings for approvals worldwide. This global Phase 3 trial is designed to enroll hemodialysis patients with moderate-to-severe pruritus in the United States, as well as multiple countries in Europe and Asia Pacific. Based on the current patient enrollment rate and future projections, the Company expects to report top-line data from this trial in the second half of 2019.

Phase 3 Safety Trial

In 2017, the Company initiated a 52-week Phase 3 safety trial that is designed to enroll up to 240 hemodialysis patients with CKD-aP. This open-label trial is evaluating the long-term safety of KORSUVA (CR845/difelikefalin) Injection at the dose of 0.5mcg/kg and has enrolled more than 200 patients. Thus far, over 100 patients have completed at least six months of treatment, with approximately 40 percent of these through the one-year treatment period. To date, the safety and tolerability have been consistent with data reported in Phase 2 trials of KORSUVA Injection in hemodialysis patients with CKD-aP. Additionally, based on a recent Independent Data Safety Monitoring Board evaluation, no new safety signals have been observed.

References:

1. Data presentation at 2017 American Society of Nephrology's Annual Meeting (Kidney Week 2017).

About Cara Therapeutics

Cara Therapeutics is a clinical-stage biopharmaceutical company focused on developing and commercializing new chemical entities designed to alleviate pruritus and pain by selectively targeting peripheral kappa opioid receptors (KORs). Cara is developing a novel and proprietary class of product candidates, led by KORSUVA™ (CR845/difelikefalin), a first-in-class KOR agonist that targets the body's peripheral nervous system, as well as certain immune cells. In Phase 2 trials, KORSUVA Injection has demonstrated statistically significant reductions in itch intensity and concomitant improvement in quality of life measures in hemodialysis patients with moderate-to-severe chronic kidney disease-associated pruritus (CKD-aP), and is currently being investigated in Phase 3 trials in hemodialysis patients with CKD-aP. Additionally, in a recently completed Phase 2/3 trial in post-operative patients, I.V. CR845/difelikefalin demonstrated reduction in moderate-to-severe pain, while also reducing the incidence and intensity of nausea and vomiting throughout the post-operative period.

The FDA has conditionally accepted KORSUVA™ as the trade name for difelikefalin injection. CR845/difelikefalin is an investigational drug product and its safety and efficacy have not been fully evaluated by any regulatory authority.

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 ongoing trials and future development of the Company's product candidates, including the timing for completion of Cara's Phase 3 clinical trials, and the potential of CR845 to address medical needs in a range of pruritic conditions, including CKD-aP. 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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