Cara Therapeutics Completes Full Enrollment in KARE Phase 2 Trial of Oral KORSUVA™ in Atopic Dermatitis Patients with Moderate-to-Severe Pruritus

December 2, 2020

- Topline data expected in first half of 2021 -

STAMFORD, Conn., Dec. 02, 2020 (GLOBE NEWSWIRE) -- Cara Therapeutics, Inc. (Nasdaq: CARA), a biopharmaceutical company focused on developing and commercializing new chemical entities designed to alleviate pruritus by selectively targeting peripheral kappa opioid receptors, or KORs, today announced that it has completed full enrollment of its KARE Phase 2 dose-ranging clinical trial of Oral KORSUVA™ (difelikefalin tablets) for the treatment of moderate-to-severe pruritus in atopic dermatitis patients. The trial has enrolled 400 patients at multiple clinical sites across the United States (US).

“Full enrollment of the KARE Phase 2 trial on schedule represents an important milestone for the clinical development of Oral KORSUVA. We look forward to reporting topline data from this trial in early 2021,” said Derek Chalmers, Ph.D., D.Sc., President and Chief Executive Officer of Cara Therapeutics. “Pruritus treatment continues to be a significant unmet need for patients with atopic dermatitis and we believe Oral KORSUVA has the potential to be a first-in-class oral anti-pruritic product with a favorable safety profile.”

KARE Phase 2 Trial Design

The KARE Phase 2 trial is a randomized, double-blind, placebo-controlled study that is designed to evaluate the efficacy and safety of Oral KORSUVA for moderate-to-severe pruritus in approximately 400 adult subjects with atopic dermatitis. Subjects were randomized to three tablet strengths of Oral KORSUVA: 0.25 mg, 0.5 mg and 1 mg taken twice daily (BID) versus placebo for 12 weeks followed by 4 weeks of an active extension phase.

KARE’s primary efficacy endpoint is change from baseline in the weekly mean of the daily 24-hour Itch NRS score at week 12 of the treatment period. The key secondary endpoint for KARE is the assessment of the proportion of patients achieving an improvement from baseline of ≥4 points with respect to the weekly mean of the daily 24-hour Itch NRS score at week 12. Itch-related quality of life scores at the end of week 12 are assessed by the total Skindex-10 and 5-D itch scales.

A prespecified interim conditional power assessment, conducted after approximately 50% of the originally targeted patient number completed the designated 12-week treatment period, was completed in the second quarter of this year. Based on the Independent Data Monitoring Committee’s (IDMC) recommendation, the size of the KARE trial was increased by approximately 28%, from an original enrollment target of 320 patients to approximately 400 patients, to maintain the prespecified statistical power of 80 percent or greater on the trial’s primary and key secondary endpoints of change from baseline in the weekly mean of the daily 24-hour Itch Numeric Rating Scale (Itch NRS) and proportion of patients achieving a >4 point improvement in Itch NRS score at week 12, respectively.

About Cara Therapeutics

Cara Therapeutics is a clinical-stage biopharmaceutical company focused on developing and commercializing new chemical entities designed to alleviate pruritus by selectively targeting peripheral kappa opioid receptors, or 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 two Phase 3 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). Oral KORSUVA has successfully completed a Phase 2 trial for the treatment of pruritus in patients with CKD and is currently in Phase 2 trials in atopic dermatitis and primary biliary cholangitis patients with moderate-to-severe pruritus.

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, including the timing for reporting topline data, future development of Oral KORSUVA for pruritus in patients with atopic dermatitis and the potential for Oral KORSUVA to be a first-in-class anti-pruritic product with a favorable safety profile for these patients. 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2020 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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