# Cara Therapeutics Announces Completion of Interim Statistical Assessment for KARE Phase 2 Trial of Oral KORSUVA™ in Atopic Dermatitis Patients with Moderate-to-Severe Pruritus

June 17, 2020

***- Patient enrollment increased approximately 28% to maintain >80% statistical power for primary endpoint and key registration endpoint of >4-point improvement responder analysis -***

***- Full trial enrollment expected in fourth quarter of 2020 -***

STAMFORD, Conn., June 17, 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 the completion of a planned sample size re-estimation of its KARE Phase 2 dose-ranging trial of Oral KORSUVA for the treatment of moderate-to-severe pruritus in atopic dermatitis patients.

Based on the Independent Data Monitoring Committee's (IDMC) recommendation, KARE's trial size will be increased by approximately 28%, from an original enrollment target of 320 patients to 410 patients, to maintain the prespecified statistical power of 80 percent or greater on the trial's primary endpoint of change from baseline in the weekly mean of the daily 24-hour Itch Numeric Rating Scale (Itch NRS) and key secondary endpoint of proportion of patients achieving a >4 point improvement in Itch NRS score at week 12. The IDMC's recommendation was based on the results of a prespecified interim conditional power assessment conducted after approximately 50% of the originally targeted patient number completed the designated 12-week treatment period.

"We are pleased with this IDMC recommendation that, with a modest increase in target patient enrollment, keeps us on track for our trial's conservative statistical power goals for the key secondary >4-point responder endpoint, which is the accepted clinically meaningful endpoint for regulatory approval of therapeutics for pruritic dermatological indications," 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 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 410 adult subjects with atopic dermatitis. Subjects are randomized to three tablet strengths of Oral KORSUVA: 0.25mg, 0.5mg and 1mg taken twice daily (BID) versus placebo for 12 weeks followed by 4 weeks of an active extension phase.

KARE's primary efficacy endpoint is the 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 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.

**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 and 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 March 31, 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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