Cara Therapeutics Announces Presentation at American Society of Nephrology Kidney Week 2020

October 21, 2020

- Results from global KALM-2 pivotal Phase 3 trial of KORSUVA ™Injection in hemodialysis patients with pruritus to be presented –

- NDA submission for KORSUVA Injection on track for fourth quarter 2020 -

STAMFORD, Conn., Oct. 21, 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, today announced that results from its KALM-2 pivotal Phase 3 trial of KORSUVA™ (CR845/difelikefalin) Injection in hemodialysis patients with moderate-to-severe chronic kidney disease-associated pruritus (CKD-aP) will be presented at the American Society of Nephrology (ASN) Kidney Week 2020 annual meeting, which is being held virtually from October 22-25, 2020.

Details for the oral presentation are as follows:

Title: Efficacy and Safety of Difelikefalin for Moderate-to-Severe CKD-Associated Pruritus: A Global Phase 3 Study in Hemodialysis Patients (KALM-2)
Abstract Number: FR-OR24
Date and Time: Friday, October 23, 5 to 7 p.m. ET
Presenter: Thomas D. Wooldridge, M.D., Nephrology and Hypertension Associates, Ltd., Tupelo, MS

In April 2020, the Company announced positive top-line results from KALM-2. The trial met the primary endpoint, with a statistically significant proportion of patients on KORSUVA Injection achieving a three-point or greater improvement from baseline in the weekly mean Worst Itching Intensity Numeric Rating Scale (NRS) versus placebo (p=0.02) at week 12. The trial also met the key secondary endpoint, with a statistically significant proportion of patients on KORSUVA Injection achieving a four-point or greater improvement from baseline in the weekly mean Worst Itching Intensity NRS versus placebo (p=0.01) at week 12. KORSUVA Injection was generally well-tolerated through 12 weeks of treatment with a safety profile consistent with prior clinical trials.

The Company remains on track to submit a New Drug Application for KORSUVA Injection to the U.S. Food and Drug Administration in the fourth quarter of 2020.

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). Cara has successfully completed its Phase 2 trial of Oral KORSUVA for the treatment of pruritus in patients with CKD and is currently conducting Phase 2 trials of Oral KORSUVA 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 expected timing for the submission of the Company's NDA for KORSUVA Injection for CKD-aP, the Company's ability to commercialize KORSUVA Injection and the Company's potential future growth and success. 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 most recent Quarterly Report on Form 10-Q 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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Source: Cara Therapeutics, Inc.