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Cara Therapeutics Completes Planned Enrollment of Eight-Week Multi-Dose Phase of Adaptive Trial of I.V. CR845 in Chronic Kidney Disease-Associated Pruritus

- Part A of the trial will evaluate three doses of I.V. CR845 versus placebo in 160 dialysis patients -
- Top-line data expected in first quarter of 2017 -

STAMFORD, Conn., Nov. 29, 2016 (GLOBE NEWSWIRE) -- Cara Therapeutics, Inc. (Nasdaq:CARA), a biotechnology company focused on developing and commercializing new chemical entities designed to alleviate pain and pruritus by selectively targeting peripheral kappa opioid receptors, today announced that it has completed patient enrollment for the multi-dose phase of its adaptive Phase 2/3 trial of I.V. CR845 in dialysis patients suffering from moderate-to-severe uremic pruritus (UP). UP is an intractable systemic itch condition in patients with chronic kidney disease (CKD), for which there are no approved therapies in the United States.

"We're very pleased to have completed enrollment as planned for Part A of the Phase 2/3 trial in pruritus associated with chronic kidney disease, as these eight-week data will determine the optimal dosing to carry forward into planned registration trials. In our previous Phase 2 trial, I.V. CR845 significantly reduced itch and improved the quality of life for dialysis patients with this condition over a two-week treatment period," said Derek Chalmers, Ph.D., D.Sc., President and Chief Executive Officer of Cara Therapeutics. "We look forward to reporting top-line data from Part A of this trial in the first quarter of 2017 and, based on the results, initiating the planned registration phase later in the year."

About the Phase 2/3 Adaptive Trial

The Phase 2/3 trial is being conducted in a two-part adaptive design:

- Part A is a randomized, double-blind, placebo-controlled trial of three doses of I.V. CR845 (0.5 mcg/kg, 1.0 mcg/kg, and 1.5 mcg/kg) administered three times per week after dialysis over an eight-week treatment period in 160 patients.
- Part B will be a randomized, double-blind, placebo-controlled trial of one optimized dose of I.V. CR845 administered three times per week after dialysis over a 12-week treatment period in up to 240 patients.

Primary and secondary endpoints will include itch intensity and quality of life measures associated with pruritus burden, using a series of previously validated self-assessment scales.

About the Prior Phase 2 Trial of I.V. CR845 in Uremic Pruritus

The previously conducted Phase 2 trial was a double-blind, randomized, placebo-controlled trial designed to evaluate the efficacy of I.V. CR845 (1.0 mcg/kg) compared to placebo in reducing the intensity of itch in dialysis patients over a two-week dosing period. The trial enrolled 65 dialysis patients at multiple sites in the U.S.

The primary endpoint of the Phase 2 trial was the change from baseline of the average worst itching during the second week of treatment, as recorded on a visual analog scale (VAS). Patients receiving I.V. CR845 experienced a 54 percent greater reduction in worst itch scores than those receiving placebo (p-value = 0.016), with an average reduction of -48 percent from baseline as measured by the VAS. I.V. CR845-treated patients also exhibited statistically significant reductions in both daytime (-51 percent, p=0.03) and nighttime (-75 percent, p=0.007) worst itch scores compared to placebo treatment.

Secondary endpoints focused on quality of life measures associated with pruritus using a series of previously validated self-assessment scales, including the Skindex 10 score. Patients receiving I.V. CR845 experienced a 71 percent greater reduction in the average total Skindex 10 score at the end of the two-week treatment period than those receiving placebo (p-value = 0.031). Another secondary measure, itch-related sleep disturbances based on the Itch MOS Sleep Problems Index II, showed a positive trend in patients receiving I.V. CR845, with a 62 percent improvement compared to placebo.

About Uremic Pruritus

Uremic pruritus (UP) is an intractable systemic itch condition that occurs with the greatest frequency and intensity in chronic kidney disease (CKD) patients under hemodialysis (HD) and peritoneal dialysis; however, pruritus has also been reported in

CKD patients who are not yet on dialysis. Aggregate, longitudinal, multi-country studies calculate the weighted prevalence of UP to be approximately 40 percent of patients with end-stage renal disease (ESRD), with approximately 24 percent of patients reporting severe pruritus. Similarly, the majority of dialysis patients (approximately 60 percent) report pruritus, with 30 to 40 percent reporting moderate or severe pruritus. Recent data from the ITCH National Registry Study showed that among those with pruritus, 59 percent had experienced symptoms daily or nearly daily for more than a year. Given its association with CKD/ESRD, most afflicted patients will continue to have symptoms for months or years with currently employed anti-pruritic treatments, such as anti-histamines and corticosteroids, unable to provide consistent adequate relief. Moderate-to-severe chronic pruritus has repeatedly been shown to directly decrease quality of life, contribute to symptoms that impair quality of life (such as poor sleep quality), and is associated with depression. UP is also an independent predictor of mortality among HD patients, mainly related to increased risk of inflammation and infections.

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 peripheral 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 initial 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 the expected timing of the reporting results of the trial, the expected timing of the initiation of Part B of the trial for I.V. CR845 for UP, the ability of the trial to demonstrate an extended patient benefit, and the potential for I.V. CR845 to be a therapeutic option for UP. 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, 2015 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.

MEDIA CONTACT:

Annie Starr

6 Degrees

973-415-8838

astarr@6degreespr.com

INVESTOR CONTACT:

Michael Schaffzin

Stern Investor Relations, Inc.

212-362-1200

michael@sternir.com

Primary Logo

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