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Cara Receives Breakthrough Therapy Designation from FDA for I.V. CR845 for the Treatment of Chronic Kidney Disease-Associated Pruritus in Hemodialysis Patients

Phase 3 safety extension trial underway

STAMFORD, Conn., June 23, 2017 (GLOBE NEWSWIRE) -- Cara Therapeutics, Inc. (Nasdaq:CARA), a biopharmaceutical 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 the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy designation to I.V. CR845 for the treatment of moderate-to-severe uremic pruritus (UP) in chronic kidney disease (CKD) patients undergoing hemodialysis.

"The FDA's decision to grant Breakthrough Therapy designation is recognition of both the significant unmet medical need among CKD patients with UP and the potential of I.V. CR845 to address it," said Derek Chalmers, Ph.D., D.Sc., President and Chief Executive Officer of Cara Therapeutics. "We have already initiated our Phase 3 program and look forward to working closely with the FDA to bring this potential new treatment option to hemodialysis patients as quickly as possible."

Breakthrough Therapy designation is granted to expedite the development and review process for new therapies addressing serious or life-threatening conditions, where preliminary clinical evidence indicates that the drug candidate may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints.

This regulatory decision was supported primarily by positive top-line results from Part A of a Phase 2/3 clinical trial of I.V. CR845 in patients with UP. Part A of the trial met its primary endpoint, with a 68 percent reduction in worst itching scores versus placebo after an eight-week treatment period ($p < 0.0019$), and its secondary endpoint, with a 100 percent improvement in quality of life domains versus placebo ($p < 0.0007$). I.V. CR845 was well-tolerated in the trial.

About the Safety Trial of I.V. CR845 in Hemodialysis Patients

The 52-week Phase 3 study is enrolling up to 240 hemodialysis patients with CKD-associated pruritus who previously completed one of the Company's Phase 2/3 studies (CR845-CLIN2101 Part A or CR845-CLIN2005 Part B). This open-label trial will evaluate the long-term safety of I.V. CR845 at the dose of 0.5mcg/kg, a dose that met both primary and secondary efficacy endpoints (reduction of itch and improved quality of life, respectively) in patients with moderate-to-severe uremic pruritus (UP).

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 estimate 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 60-70 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, which are 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 CR845

CR845 is a peripherally acting kappa opioid receptor agonist currently in development for the treatment of acute and chronic pain and pruritus. In multiple randomized, double-blind, placebo-controlled Phase 2 trials in patients undergoing laparoscopic hysterectomy or bunionectomy procedures, I.V. CR845 treatment resulted in statistically significant reductions in pain intensity and opioid-related side effects. In more than 1200 subjects dosed to date, CR845 was observed to be well-tolerated, without incurring the dysphoric and psychotomimetic side effects that have been reported with centrally acting

(CNS-active) kappa opioid receptor agonists, and lacking the respiratory depression and abuse liability of mu opioid receptor agonists.

About Cara Therapeutics

Cara Therapeutics is a clinical-stage biopharmaceutical 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, led by CR845, 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 impact of breakthrough therapy designation on the development and potential commercialization of I.V. CR845 for the treatment of moderate to severe UP in CKD patients undergoing hemodialysis. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such risks include the risk that breakthrough designation may be rescinded if our clinical development program no longer meets the criteria for breakthrough designation, and fact that breakthrough therapy designation: does not guarantee marketing approval of I.V. CR845; does not improve the likelihood of the FDA's granting of marketing approval for I.V. CR845 compared to drugs considered for approval under conventional FDA procedures; and does not guarantee a faster development process or review determination by the FDA. Additional factors that could cause actual results to differ from those expressed or implied by forward-looking statements are described 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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