October 25, 2017

Cara Therapeutics Doses First Patient in Phase 1 Study of Oral CR845 in Non-Hemodialysis Chronic Kidney Disease Patients

Study to inform dose selection and design of Phase 2 trial in non-hemodialysis patients with chronic kidney disease-associated pruritus (CKD-aP)

STAMFORD, Conn., Oct. 25, 2017 (GLOBE NEWSWIRE) -- Cara Therapeutics, Inc. (Nasdaq:CARA), a biopharmaceutical company focused on developing and commercializing new chemical entities designed to alleviate pruritus and pain by selectively targeting peripheral kappa opioid receptors, today announced that it has dosed the first patient in its Phase 1 pharmacokinetic and safety trial of Oral CR845 tablets in patients with stage III-V chronic kidney disease (CKD) who are not on dialysis. According to estimates from the Centers for Disease Control and Prevention, approximately 15 percent of the adult population in the United States, or 30 million people, suffer from CKD, with an estimated 50 percent in stages III-V.[1] Of the patients diagnosed with stage III-V CKD, approximately 25 percent suffer from moderate-to-severe pruritus.[2,3]

"We are pleased to move Oral CR845 forward into non-hemodialysis patients with earlier-stage CKD," said Derek Chalmers, Ph.D., D.Sc., President and Chief Executive Officer of Cara Therapeutics. "Given the highly encouraging data we've achieved to date with I.V. CR845 in hemodialysis patients with moderate-to-severe pruritus, we believe Oral CR845 has the potential to substantially broaden our market potential in patients with CKD-aP."

Phase 1 Trial Design

The Phase 1 trial is designed to examine the pharmacokinetics and safety of three tablet strengths of Oral CR845 (0.25 mg, 0.5 mg and 1.0 mg), dosed daily over a one-week treatment period in up to 80 non-hemodialysis patients with stage III-V CKD. Data from this trial will inform dose selection and design of a planned placebo-controlled Phase 2 trial of Oral CR845 in non-hemodialysis stage III-V CKD-aP patients, which the Company plans to initiate in the first quarter of 2018. The U.S. Food and Drug Administration previously granted Breakthrough Therapy designation to I.V. CR845 for moderate-to-severe CKD-aP in hemodialysis patients.

About CKD-aP

CKD-aP is an intractable systemic itch condition that occurs with the greatest frequency and intensity in patients with chronic kidney disease undergoing hemodialysis and peritoneal dialysis. Pruritus has also been reported in patients with stage III-V CKD who are not on dialysis. Recent data from the ITCH National Registry Study showed that among those with pruritus, 59 percent 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 antipruritic treatments, such as antihistamines 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. CKD-aP is also an independent predictor of mortality among hemodialysis patients, mainly related to increased risk of inflammation and infections.

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 (KORs). Cara is developing a novel and proprietary class of product candidates, led by CR845, a first-in-class KOR agonist that targets the body's peripheral nervous system. In Phase 2 trials, CR845 has demonstrated statistically significant reductions in itch intensity and concomitant improvement in quality of life measures in patients with moderate-to-severe CKD-associated pruritus. Additionally, CR845 has also demonstrated initial signs of efficacy in patients with moderate-to-severe pain, without inducing many of the undesirable side effects typically associated with currently available opioid pain therapeutics.

References:

1. Center for Disease Control and Prevention: Chronic Kidney Disease (CKD) Surveillance Project. National Health and Nutrition Examination Survey. 2014.

2. Pruritus in Chronic Kidney Disease Patients: Early Results from CKDOPPS. Sukul, et. al, ERA-EDTA Abstract. December 2016
3. IMS Pruritus Market Landscape Analysis. September 2014

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 Oral CR845's potential as a treatment for CKD-aP in patients with stage III-V CKD and statements concerning the timing of the initiation of the Company's planned Phase 2 trial of Oral CR845 for the treatment of CKD-aP in stage III-V CKD 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 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, 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. 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

Source: Cara Therapeutics, Inc.