Cara Therapeutics Doses First Patient in Phase 1 Trial of Oral KORSUVA™ (CR845/difelikefalin) in Chronic Liver Disease (CLD) Patients

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Data to inform dose selection for planned Phase 2 trial in CLD-associated pruritus

STAMFORD, Conn., Feb. 28, 2018 (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 the dosing of the first patient in a Phase 1 safety and pharmacokinetic (PK) trial of Oral KORSUVA™ (CR845/difelikefalin) in patients with chronic liver disease (CLD). Data from this trial will directly inform the design for the planned Phase 2 trial of Oral KORSUVA™ in patients suffering from moderate-to-severe CLD-associated pruritus, a condition for which there are currently no approved therapies in the United States.

“Based on its mechanism of action mediated by kappa receptors on peripheral sensory neurons and certain immune cells within the skin, we believe that KORSUVA™ has the potential to be an important symptomatic treatment for pruritus across a range of clinical conditions and we are pleased to begin dosing in the CLD population,” said Derek Chalmers, Ph.D., D.Sc., President and Chief Executive Officer of Cara Therapeutics. “The drug exposure data obtained in this Phase 1 trial of Oral KORSUVA™ will serve to define the dosing regimen for our planned Phase 2 trial in this patient population.”

Phase 1 Trial Design

The Phase 1 trial is an open-label study designed to evaluate the safety and PK profile of repeated doses of oral KORSUVA™ (twice daily) in up to 60 patients with chronic liver disease (CLD) and up to 12 matched healthy control subjects. KORSUVA™ (1.0 mg tablet strength) will be evaluated over an eight-day treatment period in patients with mild, moderate or severe CLD based on their Child-Pugh classification (i.e, Class A, B and C). In addition, PK and safety tolerability will be assessed with KORSUVA™ up to 5.0 mg tablet strength in mild and moderate CLD patients.

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.

About Chronic Liver Disease-Associated Pruritus (CLD-aP)

CLD-aP is an intense, intractable, debilitating condition that disrupts daily activities and sleep in patients with CLD, and consequently significantly impairs their quality of life. It leads to significant scratching and, in severe cases, results in excoriations and prurigo nodularis. Although the pathophysiology is not well understood, it is likely multi-factorial, involving immune system dysregulation (including elevated pro-inflammatory activity) and imbalance in the endogenous opioid system.[1] Based on annual prescriptions written for the symptomatic treatment of CLD-aP across liver conditions, it is estimated that approximately 2.5 million patients in the United States, or 30-40 percent of patients with CLD, suffer from CLD-aP.[2]

About Cara Therapeutics

Cara Therapeutics is a clinical-stage biopharmaceutical company focused on developing and commercializing new chemical entities designed to alleviate pruritus and pain by selectively targeting peripheral kappa opioid receptors (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. In Phase 2 trials, KORSUVA™ has demonstrated statistically significant reductions in itch intensity and concomitant improvement in quality of life measures in hemodialysis patients with moderate-to-severe CKD-associated pruritus (CKD-aP) and is currently being investigated in Phase 3 trials in hemodialysis patients with CKD-aP. Additionally, KORSUVA™ has demonstrated initial 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. Bergasa, N.: Medical Hypotheses; 86-89, 2018
2. 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 the potential of Oral Korsuva (CR845/difelikefalin) as a treatment for moderate-to-severe pruritus in CLD patients and statements concerning the initiation of the Company's planned Phase 2 trial of Oral Korsuva for the treatment of CLD patients suffering from moderate-to-severe associated pruritus. 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.

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