# Cara Initiates Phase 2 Trial of Oral KORSUVA™ for the Treatment of Pruritus in Patients with Notalgia Paresthetica

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**Expands clinical development of Oral KORSUVA™ into neuropathic pruritus**

STAMFORD, Conn., Jan. 11, 2021 (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 the initiation of a Phase 2 trial of Oral KORSUVA™ (difelikefalin) for the treatment of moderate-to-severe pruritus in patients suffering from notalgia paresthetica (NP), a nerve disorder characterized by chronic pruritus of the upper to middle back.

"We are excited to initiate this Phase 2 trial and further expand the potential of Oral KORSUVA™ in the treatment of moderate-to-severe pruritus in patients with notalgia paresthetica to help address the burden that these patients face," said Joana Goncalves, M.D., Chief Medical Officer of Cara Therapeutics. "Evaluating the ability to treat pruritus of a neuropathic origin, in addition to our current clinical development programs in systemic and dermatological chronic pruritus, will further support the potential of Oral KORSVUA™ as a broad anti-pruritic agent."

"Notalgia paresthetica is a common condition that is challenging to manage and impacts the quality of life of patients living with it," said Mark Lebwohl, M.D., Professor and Dean for Clinical Therapeutics and Chairman Emeritus of the Department of Dermatology at Icahn School of Medicine at Mount Sinai. "I am thrilled to be a part of this pioneering study that has the potential to generate a novel therapeutic option for this unmet need in patients with NP."

**Phase 2 Trial Design**

The Phase 2 multicenter, randomized, double-blind, placebo-controlled 8-week study is designed to evaluate the efficacy and safety of Oral KORSUVA™ for moderate-to-severe pruritus in approximately 120 subjects with NP. Subjects will be randomized to Oral KORSUVA™ 2 mg taker twice daily (BID) vs. placebo for 8 weeks, followed by a 4-week active extension phase.

The primary efficacy endpoint is the change from baseline in the weekly mean of the daily 24-hour Worst Itch-Numeric Rating Scale (WI-NRS) score at Week 8 of the treatment period. Secondary endpoints include change from baseline in itch-related quality of life scores at the end of Week 8 and safety assessments.

**About Pruritus Associated with Notalgia Paresthetica**

Notalgia paresthetica (NP) is a common, although under-recognized chronic, sensory neuropathy affecting the upper back.[1] It is estimated that chronic pruritus affects up to 13% of the United States population, and about 8% of these patients suffer from neuropathic itch , including NP.[2,3] One of the hallmark features of NP is chronic pruritus, which can be significantly burdensome and undermines the affected subject's quality of life and overall well-being.[3] The exact etiology of NP still has not been fully elucidated; however, it is widely accepted that NP is a sensory neuropathy caused by alteration and damage to thoracic spinal nerves.[3]

The management of NP is challenging and is often resistant to multiple therapies. There is currently no well-defined treatment for NP and conventional treatments for pruritus, such as antihistamines and topical steroids are largely ineffective.[4]

**References:**


1. Matthew Howard, Lukas Sahhar, Frank Andrews, Ralph Bergman and Douglas Gin. Notalgia paresthetica: a review for dermatologists. International J of Dermatology 2018,57, 388-392.
2. Manuel P. PEREIRA, Hannah LÜLING, Annette DIECKHÖFER, Sabine STEINKE, Claudia ZEIDLER and Sonja STÄNDER. Brachioradial Pruritus and Notalgia Paraesthetica: A Comparative Observational Study of Clinical Presentation and Morphological Pathologies. Acta DV 2018 ; 98:82-88.
3. Mollanazar, N.K., Koch, S.D. & Yosipovitch, G. Epidemiology of Chronic Pruritus: Where Have We Been and Where Are We Going?. *Curr Derm Rep* **4,** 20–29 (2015)Mirna Šitum, Maja Kolić, Nika Franceschi and Marko Pećina. Notalgia Paresthetica. Acta Clin Croat 2018; 57:721-725
4. Ahmed Ansari, David Weinstein & Naveed Sami. Notalgia paresthetica: treatment review and algorithmic approach. Journal of Dermatological Treatment 2019.


**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. The Company has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for KORSUVA™ Injection

(difelikefalin) for the treatment of moderate-to-severe pruritus in hemodialysis patients. KORSUVA Injection received Breakthrough Therapy Designation from the FDA for this indication. Cara has requested Priority Review for the NDA which, if granted, could result in a six-month review process. Oral KORSUVA has successfully completed a Phase 2 trial for the treatment of pruritus in patients with CKD and is currently in Phase 2 trials 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 potential for Oral KORSUVA to be a therapeutic option for pruritus related to NP, or other pruritus of a neuropathic origin, or in systemic and dermatological chronic 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's filings with the Securities and Exchange Commission, including the "Risk Factors" section of Cara's Quarterly Report on Form 10-Q for the quarter ended September 30, 2020 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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