



## **Cara Therapeutics Presents Late-Breaking Results of KARE Phase 2 Trial of Oral Difelikefalin (Oral KORSUVA™) in Atopic Dermatitis Patients with Moderate-to-Severe Pruritus at the 2021 European Academy of Dermatology and Venereology (EADV) Virtual Congress**

October 4, 2021

STAMFORD, Conn., Oct. 04, 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, presented results from the KARE Phase 2 clinical trial of oral difelikefalin for the treatment of moderate-to-severe pruritus in mild-to-severe atopic dermatitis (AD) patients. Results were presented by Brian Kim, MD, Associate Professor of Dermatology and Co-Director of the Center for the Study of Itch and Sensory Disorders at Washington University School of Medicine, during the Late Breaking News session of the 2021 European Academy of Dermatology and Venereology (EADV) Virtual Congress on October 2, 2021.

The presentation summarized data from 401 subjects with AD and moderate-to-severe pruritus, who were randomized to receive oral difelikefalin at a dose of 0.25 mg, 0.5 mg or 1.0 mg, or placebo over a 12-week treatment period.

Subjects with mild-to-moderate AD were included in a prespecified analysis. Approximately 64% of subjects had BSA<10 and the results of this "Itch Dominant AD" subgroup were presented.

In addition, a mouse model of AD was used to test the effects of difelikefalin on itch and lesion severity.

Although the primary endpoint, change from baseline in Itch Numerical Rating Scale (I-NRS) score, was not met with any of the difelikefalin dose groups in the overall population, a significant improvement (p= 0.039) in itch was observed at week 12 in the combined difelikefalin dose group in subjects with BSA <10%. In this subpopulation of itch-dominant AD, significant reduction in itch with difelikefalin was evident as early as day 2. In addition, a significantly greater proportion of subjects (32% vs 19%; p<0.05) in the combined difelikefalin dose group versus placebo achieved a ≥4-point improvement in I-NRS at week 12 (the required regulatory primary endpoint for Phase 3 pruritus programs). Difelikefalin was well-tolerated, with most adverse events (~95%) being mild or moderate in severity. The most commonly reported adverse events included abdominal pain, nausea, dry mouth, headache, dizziness, and hypertension. In the mouse model of AD, a rapid and significant anti-pruritic effect of difelikefalin was observed independently of effects on skin inflammation.

"Patients with mild-to-moderate AD commonly exhibit moderate-to-severe pruritus which is inadequately addressed by available topical medications," said Dr. Kim. "Together, the results of the KARE clinical study and the AD mouse model support the role of difelikefalin as a potential novel, systemic antipruritic agent that may effectively address pruritus in patients with itch-dominant AD."

### **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. KORSUVA Injection was approved by the U.S. Food and Drug Administration (FDA) for the treatment of moderate-to-severe pruritus associated with chronic kidney disease (CKD-aP) in adults undergoing hemodialysis on August 23, 2021. Oral KORSUVA has completed Phase 2 trials for the treatment of pruritus in patients with CKD and atopic dermatitis and is currently in Phase 2 trials in primary biliary cholangitis and notalgia paresthetica patients with moderate-to-severe pruritus.

### **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 future development of Oral KORSUVA for pruritus in patients with mild-to-moderate atopic dermatitis and the potential for Oral KORSUVA to treat these 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's filings with the Securities and Exchange Commission, including the "Risk Factors" section of Cara Therapeutic's Annual Report on Form 10-K for the year ended December 31, 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 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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