



## Cara Therapeutics Announces Oral KORSUVA™ (difelikefalin) Improves Itch and Inflammatory Biomarkers in Atopic Dermatitis Patients with Moderate-To-Severe Pruritus

March 28, 2022

**Data presented in late-breaking session at the 2022 American Academy of Dermatology (AAD) Annual Meeting**

STAMFORD, Conn., March 28, 2022 (GLOBE NEWSWIRE) -- Cara Therapeutics, Inc. (Nasdaq: CARA), an early commercial-stage biopharmaceutical company leading a new treatment paradigm to improve the lives of patients suffering from pruritus, today announced data from a sub-study of the KARE Phase 2 clinical trial demonstrated Oral KORSUVA™ (difelikefalin) improved itch and inflammatory biomarkers in atopic dermatitis (AD) patients with moderate-to-severe pruritus. The biomarker data were presented during the Late-Breaking Research: Clinical Trials session at the 2022 American Academy of Dermatology (AAD) Annual Meeting.

The sub-study, which included 40 patients from the KARE trial, characterized the effect of Oral KORSUVA (difelikefalin) on pruritus- and AD-related gene expression using baseline and week 12 skin biopsies. Data pooled from all Oral KORSUVA (difelikefalin) treatment groups indicated treatment with Oral KORSUVA (difelikefalin) altered expression of multiple individual pruritus- and AD-related genes. Gene set variation analysis confirmed downregulation of pruritus-related genes and the Th2 pathway following 12 weeks of treatment with Oral KORSUVA (difelikefalin), but not placebo.

"Pruritus is extremely burdensome for patients with atopic dermatitis and new treatment options that effectively address pruritus and alleviate the itch-scratch cycle are greatly needed," said lead investigator Emma Guttman-Yassky, MD, PhD, Waldman Professor and System Chair of Dermatology and Immunology at the Icahn School of Medicine at Mount Sinai. "Results from our sub-study demonstrate oral difelikefalin downregulated the expression of key markers associated with pruritus and atopic dermatitis inflammation, indicating the potential of difelikefalin to provide an additional anti-inflammatory benefit in patients with atopic dermatitis-related pruritus."

In addition to the late-breaking oral presentation, quality of life data from a subgroup analysis of the KARE trial were presented in a poster at the 2022 AAD Annual Meeting. The poster, "Oral Difelikefalin Improves Itch and Quality of Life in Subjects With Itch-Dominant Atopic Dermatitis: Subgroup Analysis of a Randomized, Phase 2 Study," (#33993) is available at: <https://eposters.aad.org/>.

### About Cara Therapeutics

Cara Therapeutics is an early commercial-stage biopharmaceutical company leading a new treatment paradigm to improve the lives of patients suffering from pruritus. The Company's novel KORSUVA™ (difelikefalin) injection is the first and only FDA-approved treatment for moderate-to-severe pruritus associated with chronic kidney disease in adults undergoing hemodialysis. The Company is developing an oral formulation of difelikefalin and has initiated Phase 3 programs for the treatment of pruritus in patients with non-dialysis dependent advanced chronic kidney disease and atopic dermatitis. Phase 2 trials of Oral KORSUVA (difelikefalin) are ongoing in primary biliary cholangitis and notalgia paresthetica patients with moderate-to-severe pruritus. For more information, visit [www.CaraTherapeutics.com](http://www.CaraTherapeutics.com) and follow the company on [Twitter](#), [LinkedIn](#) and [Instagram](#).

### 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 KORSUVA's potential to provide a benefit, including an anti-inflammatory benefit, to patients suffering from atopic dermatitis-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 Cara Therapeutics' Annual Report on Form 10-K for the year ended December 31, 2021 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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