Cara Therapeutics Announces Initiation of Phase 2 Trial of Oral KORSUVA™ (CR845/difelikefalin) for Pruritus in Patients with Atopic Dermatitis

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STAMFORD, Conn., July 09, 2019 (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 (CR845/difelikefalin) for the treatment of pruritus in patients with atopic dermatitis (AD). AD is one of the most common chronic inflammatory diseases with prevalence rates of up to 5% in adults and approximately 25% in children.[1]

“Pruritus is a primary, defining feature of atopic dermatitis that significantly impacts patients’ quality of life and remains challenging to manage with current standard of care,” said Derek Chalmers, Ph.D., D.Sc., President and Chief Executive Officer of Cara Therapeutics. “We are excited to initiate this Phase 2 trial and evaluate Oral KORSUVA as a potential novel oral therapeutic option for the treatment of pruritus in patients with AD.”

Phase 2 Trial Design

The Phase 2 randomized, double-blind, placebo-controlled study is designed to evaluate the efficacy and safety of Oral KORSUVA for moderate-to-severe pruritus in approximately 240 adult subjects with AD. Subjects will be randomized to three tablet strengths of Oral KORSUVA: 0.25 mg, 0.5 mg and 1 mg taken twice daily (BID) vs. placebo for 12 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 Itch Numeric Rating Scale (I-NRS) score at Week 12 of the treatment period. Secondary endpoints include change from baseline in itch-related quality of life scores at the end of Week 12 as assessed by the total Skindex-10 and 5-D itch scales, as well as the proportion of patients achieving an improvement from baseline of ≥4 points with respect to the weekly mean of the daily 24-hour I-NRS score at Week 12.

About Pruritus Associated with Atopic Dermatitis

The point prevalence of chronic pruritus in AD ranges from 87% to 100%. Both quality of life and psychosocial well-being are known to negatively correlate with itch severity. The associated psychosocial co-morbidities of pruritus include sleep disruption, altered eating habits, reduced self-esteem, agitation, anxiety and depression.[2,3]

References:

1. Boguniewicz M. Immunol *Allergy Clin N Am*. 2005; 25(2):333–51; Eichenfeld L et al. *Am Acad Dermatol*. 2014; 70(2): 338–351; Barbarot S et al. *Allergy*. 2018; 73(6):1284-1293.
2. Mochizuki H, et al. *Allergol Int*: Official Journal of the Japanese Society of Allergology. 2017; 66(1):14-21.
3. Farmer WS, Marathe KS. *Adv Exp Med Biol*. 2017; 1027:161-177.

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 (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. In both Phase 3 and Phase 2 trials, KORSUVA Injection has demonstrated statistically significant reductions in itch intensity and concomitant improvement in quality of life measures in hemodialysis patients with moderate-to-severe chronic kidney disease-associated pruritus (CKD-aP). KORSUVA Injection is currently being investigated in Phase 3 trials in hemodialysis patients with CKD-aP. Oral KORSUVA is currently in Phase 2 trials for the treatment of pruritus in patients with CKD, as well as in patients with primary biliary cholangitis (PBC).

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 of Oral KORSUVA (CR845/difelikefalin) as a treatment for patients with AD, or the potential of Oral KORSUVA (CR845/difelikefalin) to be a treatment option for such 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, 2018, 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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