Cara Therapeutics Submits New Drug Application to U.S. Food and Drug Administration for KORSUVA™ Injection in Hemodialysis Patients with Moderate-to-Severe Pruritus

December 28, 2020

- *First NDA submission for Company's lead program, KORSUVA™ Injection –*
- *NDA submission includes request for Priority Review under Breakthrough Therapy Designation for KORSUVA Injection –*

STAMFORD, Conn., Dec. 28, 2020 (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, or KORs, today announced that it 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. The FDA has a 60-day filing review period to determine whether the NDA is complete and acceptable for filing.

The NDA submission is supported by positive data from two pivotal Phase 3 trials of KORSUVA Injection, including the KALM-1 trial conducted in the U.S. (*New England Journal of Medicine* 2020; 382:222-232) and the global KALM-2 trial, as well as supportive data from an additional 32 clinical studies.

"The NDA submission for KORSUVA Injection marks a significant milestone for Cara and for hemodialysis patients who suffer from intractable pruritus," said Derek Chalmers, Ph.D., D.Sc., President and Chief Executive Officer of Cara Therapeutics. "I'd like to thank the entire Cara team for working tirelessly to bring this first-in-class therapeutic from in-house discovery, through development to the completion of NDA submission, as well as the patients, investigators and site personnel who participated in the clinical trials. We look forward to working with the FDA through the review process and, along with our commercial partner, Vifor Pharma, remain focused on preparation for the U.S. launch of KORSUVA Injection, if approved."

About Chronic Kidney Disease-Associated Pruritus (CKD-aP)

CKD-aP is an intractable systemic itch condition that occurs with high frequency and intensity in patients with chronic kidney disease undergoing dialysis. Pruritus has also been reported in patients with stage III-V CKD who are not on dialysis. Aggregate, longitudinal, multi-country studies estimate the weighted prevalence of CKD-aP to be approximately 40% in patients with end-stage renal disease (ESRD), with approximately 25% of patients reporting severe pruritus. The majority of dialysis patients (approximately 60 to 70%) report pruritus, with 30 to 40% reporting moderate or severe pruritus.[1,2] Recent data from the ITCH National Registry Study showed that among those with pruritus, approximately 59% experienced symptoms daily or nearly daily for more than a year. Given its association with CKD/ESRD, most afflicted patients will continue to have symptoms for months or years, with currently employed antipruritic treatments, such as antihistamines and corticosteroids, unable to provide consistent, adequate relief. Moderate-to-severe chronic pruritus has repeatedly been shown to directly decrease quality of life, contribute to symptoms that impair quality of life (such as poor sleep quality), and is associated with depression.[3] CKD-aP is also an independent predictor of mortality among hemodialysis patients, mainly related to increased risk of inflammation and infections.

References:

1. Pisoni RL, et al. Pruritus in hemodialysis patients: international results from the Dialysis Outcomes and Practice Patterns Study. Nephrol Dial Transplant. 2006; 21:3495-3505.
2. Ramakrishnan K, et al. Clinical characteristics and outcomes of end-stage renal disease patients with self-reported pruritus symptoms. International Journal of Nephrology and Renovascular Disease. 2014; 7: 1-12.
3. Mathur VS, et al. A longitudinal study of Uremic Pruritus in hemodialysis patients. Clin J Am Soc Nephrol. 2010; 5(8):1410-1419.

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. In two Phase 3 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). 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 regulatory approval of KORSUVA Injection, the potential for the receipt of Priority Review from the FDA, and the potential timeline for FDA review of the NDA. 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.

MEDIA CONTACT:
Annie Starr
6 Degrees
973-768-2170
astarr@6degreespr.com

INVESTOR CONTACT:
Janhavi Mohite
Stern Investor Relations, Inc.
janhavi.mohite@SternIR.com

Source: Cara Therapeutics, Inc.