Cara Therapeutics and Vifor Pharma announce U.S. FDA acceptance and Priority Review of NDA for KORSUVA™* injection in hemodialysis patients with moderate-to-severe pruritus

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- **FDA has set Prescription Drug User Fee Act (PDUFA) target action date of August 23, 2021**
- **If approved, KORSUVA™ injection would be first therapy for treatment of pruritus in hemodialysis patients**

STAMFORD, Conn, and ST. GALLEN, Switzerland, March 08, 2021 (GLOBE NEWSWIRE) -- Cara Therapeutics (Nasdaq:CARA) and Vifor Pharma today announced that the U.S. Food and Drug Administration (FDA) has accepted and granted Priority Review for the New Drug Application (NDA) for KORSUVA™ (difelikefalin) solution for injection for the treatment of moderate-to-severe pruritus in hemodialysis patients. The PDUFA target action date for KORSUVA is August 23, 2021. The FDA stated that currently it is not planning to hold an advisory committee meeting to discuss the application.

The FDA grants Priority Review to drug applications for potential therapies that, if approved, would be significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications. The NDA filing is supported by positive data from two pivotal Phase 3 trials – KALM-1, conducted in the U.S. (New England Journal of Medicine 2020; 382:222-232), and the global KALM-2, as well as supportive data from an additional 32 clinical studies.

“The FDA acceptance for filing and granting of Priority Review for the KORSUVA NDA marks a significant milestone for Cara and for the substantial number of hemodialysis patients with chronic intractable pruritus,” said Derek Chalmers, Ph.D., D.Sc., President and Chief Executive Officer of Cara Therapeutics. “The FDA’s agreement to expedite the timeline through Priority Review designation aligns with our understanding of the therapeutic potential of KORSUVA to fundamentally change the treatment paradigm for this serious unmet need. We look forward to working with the FDA through the review process and, along with our commercial partner, Vifor Pharma, remain focused on preparing for the U.S. launch of KORSUVA injection, if approved.”

“We are delighted that the FDA accepted and granted Priority Review for this breakthrough therapy. Pruritus in hemodialysis patients is a debilitating condition with a significant impact on quality of life and increased risk for hospitalization and mortality. It impacts up to 40% of dialysis patients around the world. If KORSUVA is approved, we will be able to offer a medicine that is in line with our aim to deliver innovative therapies to patients with high unmet medical needs. We are highly committed to bringing this important new treatment to patients in the U.S. as soon as possible following FDA approval, together with our partner Cara Therapeutics,” commented Stefan Schulze, CEO of Vifor Pharma Group.

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.[1,2,3] 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.[4] 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 haemodialysis 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] Sukul et al. Self-reported Pruritus and Clinical, Dialysis-Related, and Patient-Reported Outcomes in Hemodialysis Patients. Kidney Med. 2020 Nov 21;3(1):42-53.

[4] Mathur VS, et al. A longitudinal study of Uremic Pruritus in hemodialysis patients. Clin J Am Soc Nephrol. 2010; 5(8):1410-1419.

* 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.

Contacts and further information:

Media Contact
Claire LaCagnina
6 Degrees
315-765-1462
clacagnina@6degreespr.com

Investor Contact
Janhavi Mohite
Stern Investor Relations, Inc.
212-363-1200
janhavi.mohite@sternir.com

Vifor Pharma Group Contacts

Media Relations
Nathalie Ponnier
Global Head Corporate Communications
+41 79 957 96 73
media@viforpharma.com

Investor Relations
Julien Vignot
Head of Investor Relations
+41 58 851 66 90
investors@viforpharma.com

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, primary biliary cholangitis and notalgia paresthetica patients with moderate-to-severe pruritus.

About Vifor Pharma Group
Vifor Pharma Group is a global pharmaceuticals company. It aims to become the global leader in iron deficiency, nephrology and cardio-renal therapies. The company is a partner of choice for pharmaceuticals and innovative patient-focused solutions. Vifor Pharma Group strives to help patients around the world with severe and chronic diseases lead better, healthier lives. The company develops, manufactures and markets pharmaceutical products for precision patient care. Vifor Pharma Group holds a leading position in all its core business activities and consists of the following companies: Vifor Pharma and Vifor Fresenius Medical Care Renal Pharma (a joint company with Fresenius Medical Care). Vifor Pharma Group is headquartered in Switzerland, and listed on the Swiss Stock Exchange (SIX Swiss Exchange, VIFN, ISIN: CH0364749348).

For more information, please visit viforpharma.com.

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™ solution for injection and the potential timeline for FDA review of the NDA and the potential of KORSUVA™ solution for injection to be a therapeutic option for CKD-aP in dialysis dependent 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's filings with the Securities and Exchange Commission, including the "Risk Factors" section of Cara's Annual Report on Form 10-K for the year ended 31 December 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

Source: Cara Therapeutics, Inc.