Kapruvia® approved by European Commission for the treatment of moderate-to-severe pruritus in hemodialysis patients

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- **First approved therapy in Europe for the treatment of chronic kidney disease (CKD)-associated pruritus in hemodialysis patients**
- **First launches in Europe expected in H2 2022**

ST. GALLEN, Switzerland and STAMFORD, Conn., April 28, 2022 (GLOBE NEWSWIRE) -- Vifor Fresenius Medical Care Renal Pharma (VFMCRP) and Cara Therapeutics, Inc. (Nasdaq: CARA) today announced that the European Commission has granted marketing authorization to Kapruvia® (difelikefalin) for the treatment of moderate-to-severe pruritus associated with chronic kidney disease (CKD) in adult hemodialysis patients. The marketing authorization, which approves Kapruvia® for use in all member states of the European Union plus Iceland, Liechtenstein and Norway, follows the U.S. Food and Drug Administration (FDA) approval of KORSUVA™ (difelikefalin) injection in August 2021 for the same indication. Kapruvia® will be the first therapy available in Europe for the treatment of CKD-associated pruritus in hemodialysis patients.

"We are very excited about the European Commission's approval of Kapruvia ®, marking an important milestone on our journey to advance and fundamentally change the treatment paradigm for people living with the severe burden of pruritus associated with chronic kidney disease," said Dr. Klaus Henning Jensen, Chief Medical Officer of Vifor Pharma. "We look forward to bringing this first-in-class therapy to patients in Europe, with launch in first markets expected in the second half of 2022."

"The European Commission's approval of Kapruvia® provides a much-needed therapy to hemodialysis patients in Europe who suffer from pruritus," said Dr. Joana Goncalves, Chief Medical Officer of Cara Therapeutics. "We are excited to bring an innovative drug to physicians to help change the way pruritus is managed. We continue to work with our commercial partner VFMCRP, to fill a significant unmet medical need among CKD patients with pruritus in both the U.S. and Europe."

The approval in Europe is based on pivotal clinical data from two phase-III trials, KALM-1 and KALM-2, as well as supportive data from an additional 32 clinical studies. These studies showed that treatment with Kapruvia® resulted in clinically meaningful improvements in pruritus severity and in pruritus-related quality of life components and was found to be generally well tolerated in patients with moderate-to-severe CKD-associated pruritus.

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About Vifor Pharma Group

Vifor Pharma Group is a global pharmaceuticals company. It aims to become the global leader in iron deficiency and nephrology. The company is a partner of choice for pharmaceuticals and innovative patient-focused solutions across iron, dialysis, nephrology and rare conditions. Vifor Pharma Group strives to help patients around the world with severe, chronic and rare diseases lead better, healthier lives. It specializes in strategic global partnering, in-licensing and developing, manufacturing and marketing pharmaceutical products for precision patient care. Vifor Pharma Group holds a leading position in all its core business activities and includes the companies: Vifor Pharma, Sanifit Therapeutics, 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
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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 difelikefalin are ongoing in primary biliary cholangitis and notalgia paresthetica patients with moderate-to-severe pruritus. For more information, visit www.CaraTherapeutics.com and follow the company on Twitter, LinkedIn and Instagram.

About Chronic Kidney Disease-associated Pruritus
CKD-associated pruritus 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. The majority of dialysis patients (approximately 60 to 70%) report pruritus, with 30 to 40% reporting moderate or severe pruritus.[1,2,3] Data from the ITCH National Registry Study showed that among those with pruritus, approximately 59%[4] 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-associated pruritus is also an independent predictor of mortality and the risk for hospitalization among hemodialysis patients.

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 timeline for the launch of difelikefalin solution for injection in Europe and the potential of difelikefalin 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 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 undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

References:
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[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.

Source: Cara Therapeutics, Inc.