Kapruvia® receives positive CHMP opinion for the treatment of moderate-to-severe pruritus in hemodialysis patients

February 25, 2022

- **Committee for Medicinal Products for Human Use (CHMP) recommends approval of Kapruvia® (difelikefalin) as first therapy in Europe for the treatment of chronic kidney disease associated-pruritus (CKD-aP) in hemodialysis patients**
- **European Commission decision for EU Marketing Authorization is expected in Q2 2022**
- **Kapruvia® is approved in the U.S. under the trade name KORSUVA ™(difelikefalin) injection**

ST. GALLEN, Switzerland and STAMFORD, Conn., Feb. 25, 2022 (GLOBE NEWSWIRE) -- Vifor Fresenius Medical Care Renal Pharma (VFMCRP) and Cara Therapeutics, Inc. (Nasdaq: CARA) today announced that the European Medicines Agency's (EMA) CHMP has recommended approval of Kapruvia ® (difelikefalin) for the treatment of moderate-to-severe pruritus associated with chronic kidney disease in hemodialysis patients. The CHMP opinion is the basis for the European Commission's final decision regarding marketing authorization for Kapruvia ®. If approved, Kapruvia® will be the first therapy available in Europe for the treatment of chronic kidney disease-associated pruritus (CKD-aP) in hemodialysis patients.

"The positive CHMP recommendation is another major step forward on our mission to help kidney patients around the world lead better, healthier lives," said Dr. Klaus Henning Jensen, Chief Medical Officer of Vifor Pharma. "Kapruvia ® has demonstrated important clinical benefits to significantly relieve patients of the severe burden of chronic kidney disease-associated pruritus, a condition that has been historically underdiagnosed and undertreated. We look forward to the European Commission decision anticipated in Q2 2022, and to bringing a therapy with the potential to advance treatment of CKD-aP to patients in Europe."

"We are pleased to have received the positive CHMP opinion, which brings us one step closer to making a treatment option available to hemodialysis patients in Europe who suffer from pruritus," said Christopher Posner, President and Chief Executive Officer of Cara Therapeutics. "Together with our partner VFMCRP, we look forward to the European Commission decision in the second quarter of 2022 and to the commercial launch of KORSUVA™ (difelikefalin) injection inthe United States in April 2022. These are major milestones on Cara Therapeutics' path to being a category-defining leader in the treatment of pruritus."

The positive CHMP opinion 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-aP.

If approved, Kapruvia® would receive marketing authorization in all member states of the European Union (EU), as well as in Iceland, Liechtenstein and Norway.

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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 plans to initiate Phase 3 programs in the first quarter of 2022 for the treatment of pruritus in patients with atopic dermatitis and non-dialysis-dependent chronic kidney disease. 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-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. 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 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 regulatory approval of difelikefalin solution for injection and the potential timeline for EMA review and approval of the MAA 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 Quarterly Report on Form 10-Q for the quarter ended 30 September 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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Source: Cara Therapeutics, Inc.