Kapruvia® (difelikefalin) recommended by England's NICE for the treatment of adults with moderate-to-severe CKD-associated pruritus

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Recommendation will enable eligible patients in England, Wales and Northern Ireland to access the first licensed treatment for moderate-to-severe chronic kidney disease (CKD)-associated pruritus in adult patients on haemodialysis

ST. GALLEN, Switzerland and STAMFORD, Conn., May 18, 2023 (GLOBE NEWSWIRE) -- Vifor Fresenius Medical Care Renal Pharma (VFMCRP) and Cara Therapeutics, Inc. (Nasdaq: CARA) today announced that England's National Institute for Health and Care Excellence (NICE) has recommended Kapruvia® for the treatment of moderate-to-severe CKD-associated pruritus in adult patients on haemodialysis. The decision follows authorisation from the UK's Medicines and Healthcare products Regulatory Agency (MHRA) in April 2022.

"The recommendation of Kapruvia® by NICE is a key step on our journey to bring this breakthrough treatment to in-centre haemodialysis patients living with moderate-to-severe CKD-associated pruritus in the UK," said Fabio Dorigotti, Head Global Medical Affairs of CSL Vifor. "We look forward to continue working with the National Health Service to ensure access to this important medicine for patients as quickly as possible."

"We are pleased that Kapruvia® will be available to CKD patients in England, Wales and Northern Ireland who are undergoing haemodialysis and suffering from moderate-to-severe CKD-associated pruritus," said Christopher Posner, President and Chief Executive Officer of Cara Therapeutics. "Together with VFMCRP, we are committed to bringing our first-of-its kind therapy to providers and patients around the world to help change the way pruritus is managed."

"Chronic kidney disease-related itch is common for people on haemodialysis and represents a significant unmet need; leading to poor sleep and reduced quality of life for patients," said Dr. Kieran McCafferty, Consultant Nephrologist, Barts Health NHS Trust. "We now have an option to help reduce the burden of CKD-related itch."

MHRA approval and the NICE recommendation were supported by positive data from two pivotal phase-III 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.

About CSL Vifor

CSL Vifor is a global partner of choice for pharmaceuticals and innovative, leading therapies in iron deficiency and nephrology. We specialize in strategic global partnering, in-licensing and developing, manufacturing and marketing pharmaceutical products for precision healthcare, aiming to help patients around the world lead better, healthier lives. Headquartered in St. Gallen, Switzerland, CSL Vifor also includes the joint company Vifor Fresenius Medical Care Renal Pharma (with Fresenius Medical Care).

The parent company, CSL (ASX:CSL; USOTC:CSLLY), headquartered in Melbourne, Australia, employs 32,000 people and delivers its lifesaving therapies to people in more than 100 countries. For more information about CSL Vifor visit, www.cslvifor.com.

About Cara Therapeutics

Cara Therapeutics is a commercial-stage biopharmaceutical company leading a new treatment paradigm to improve the lives of patients suffering from pruritus. The Company's Kapruvia ® (difelikefalin) injection is the first and only MHRA-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 Phase 3 programs ongoing for the treatment of pruritus in patients with non-dialysis dependent advanced chronic kidney disease and atopic dermatitis. In addition, the Company has initiated a Phase 2/3 program of oral difelikefalin for the treatment of moderate-to-severe pruritus in patients with notalgia paresthetica. 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.[1] The majority of dialysis patients in the UK (approximately 70%) report pruritus, with nearly half reporting moderate or severe pruritus.[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 gabapentinoids, 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]

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Source: Cara Therapeutics, Inc.