Kapruvia® approved in Switzerland with additional regulatory decisions expected in H2 2022

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Kapruvia® (difelikefalin) is the first and only therapy approved through consortium filing for the treatment of chronic kidney disease (CKD)-associated pruritus in hemodialysis patients

Therapy recently approved in Canada under the brand name KORSUVA®

Regulatory decisions in Australia and Singapore expected by the end of 2022

ST. GALLEN, Switzerland, and STAMFORD, Conn., Aug. 19, 2022 (GLOBE NEWSWIRE) -- Vifor Fresenius Medical Care Renal Pharma (VFMCRP) and Cara Therapeutics, Inc. (Nasdaq: CARA) today announced that they have received approval for Kapruvia® from the Swiss Agency for Therapeutic Products (Swissmedic). Kapruvia® will be the first therapy available for the treatment of moderate-to-severe pruritus associated with chronic kidney disease in adult hemodialysis patients. Swissmedic approval for Kapruvia® follows approvals by the U.S. Food and Drug Administration, by the European Medicines Agency, by the UK Medicines and Healthcare products Regulatory Agency, as well as by Health Canada.

“The approval of Kapruvia® in Switzerland is the next step on our journey to bring this breakthrough treatment to hemodialysis patients living with CKD-associated pruritus around the world,” said Dr. Klaus Henning Jensen, Chief Medical Officer of CSL Vifor. “There is a high unmet medical need for a targeted therapy to treat moderate-to-severe pruritus, and we are convinced that Kapruvia® can provide relief to many suffering from this heavy burden. We are very committed to making this therapy available to patients as soon as possible.”

“We are pleased that Kapruvia® is now approved in Switzerland for hemodialysis patients who are suffering from CKD-associated pruritus,” said Christopher Posner, President and Chief Executive Officer of Cara Therapeutics. “As Cara Therapeutics continues on the path toward becoming the leader in the treatment of chronic pruritus, we are working with our partner VFMCRP to ensure this first-of-its-kind therapy is available to healthcare providers and patients across the globe who greatly need a treatment option.”

Swissmedic approval was 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.

Kapruvia® has been submitted in Switzerland as part of an Access Consortium procedure together with Canada (approved in August 2022), as well as Australia and Singapore. Regulatory decisions in these two markets are expected in the second half of 2022.

About CSL Vifor

CSL Vifor is a global partner of choice for pharmaceuticals and innovative, leading therapies in iron deficiency, dialysis and nephrology & rare disease. 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 30,000 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 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. The Company has completed the placebo-controlled phase of a Phase 2 proof-of-concept trial of oral difelikefalin for the treatment of moderate-to-severe pruritus in patients with notalgia paresthetica. A Phase 2 proof-of-concept trial in primary biliary cholangitis patients with moderate-to-severe pruritus is ongoing. 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] 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-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 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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