Cara Therapeutics and Vifor Fresenius Medical Care Renal Pharma (VFMCRP) Enter into Ex-U.S. Licensing Agreement to Commercialize KORSUVA™ Injection in Dialysis Patients with Pruritus

May 23, 2018

Cara receives upfront payment of $50 million in cash and an equity investment of $20 million

Cara eligible for up to $470 million in regulatory and commercial milestones

VFMCRP to commercialize KORSUVA injection worldwide except in the U.S., Japan and South Korea

Cara to commercialize KORSUVA injection in the U.S & co-promote with VFMCRP in U.S. Fresenius Medical Care (FMC) North America Dialysis Clinics

Cara to Host Conference Call Today at 8:30 a.m. EDT

STAMFORD, Conn., May 23, 2018 (GLOBE NEWSWIRE) -- Cara Therapeutics, Inc. (Nasdaq:CARA), a U.S. biopharmaceutical company focused on developing and commercializing new chemical entities designed to alleviate pruritus and pain by selectively targeting peripheral kappa opioid receptors, today announced that it has licensed worldwide rights, except in the U.S., Japan and South Korea, to commercialize KORSUVA (CR845/difelikefalin) injection for the treatment of chronic kidney disease-associated pruritus (CKD-aP) in dialysis patients to Vifor Fresenius Medical Care Renal Pharma Ltd (VFMCRP), a joint company of Vifor Pharma Group (SIX:VIFN) and Fresenius Medical Care (NYSE:FMS) that specializes in treatments for CKD. The U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy Designation to KORSUVA injection for this indication, for which there are currently no approved therapies in the U.S. or E.U.

“As a global leader in providing treatment for chronic kidney disease patients, VFMCRP is an ideal partner to bring KORSUVA injection to dialysis patients across Europe and other licensed territories,” said Derek Chalmers, Ph.D., D.Sc., President and Chief Executive Officer of Cara Therapeutics. “Additionally, we believe the ability to leverage VFMCRP’s nephrology-focused commercial expertise in our co-promotion partnership for U.S. Fresenius Medical Care dialysis facilities will provide significant momentum for adoption of KORSUVA injection, if approved in the U.S. Importantly, we continue to retain all rights to KORSUVA/CR845 in other indications.”

“CR845 injection is a first-in-class, innovative investigational medicine for treating a highly debilitating disease. It is a natural fit to our leading product portfolio in nephrology, and we look forward to making it available to patients who urgently need better therapy,” said Stefan Schulze, Vifor Pharma President of the Executive Committee and COO. “Sixty to 70% of dialysis patients experience CKD-aP. Nearly 20% suffer from a very severe form, which is associated with much lower survival. And despite this clear unmet medical need, there is no approved treatment for CKD-aP in Europe or the U.S. CR845 does not penetrate the brain and so bypasses unwanted side-effects like opioid addiction. It has significant potential for setting new standards in providing relief, both from CKD- induced itching and post-operative pain.”

Summary of License Agreement

Under the terms of the Agreement, Cara will receive an upfront payment in the amount of $50 million in cash and an equity investment of $20 million to acquire Cara common stock at a price of approximately $17/share. Cara will also be eligible to receive additional payments of up to $470 million, which includes $30 million in regulatory and up to $440 million in tiered commercial milestones that are all sales related. Cara is also eligible to receive tiered royalties based on net sales of KORSUVA injection in the licensed territories. VFMCRP will have the exclusive rights to commercialize KORSUVA injection for the treatment of CKD-aP in dialysis patients ex-U.S. except in Japan and South Korea. Cara retains full development and commercialization rights for KORSUVA injection for the treatment of CKD-aP in the U.S. except in the dialysis clinics of Fresenius Medical Care North America (FMCNA), where VFMCRP and Cara will promote KORSUVA injection under a profit-sharing arrangement based on net FMCNA clinic sales recorded by Cara. FMCNA is the largest kidney dialysis provider in the U.S. and treated approximately 38% of U.S. dialysis patients in 2017. Cara will solely promote KORSUVA injection in all non-FMC clinics in the U.S. and retain all profits from those sales.

KORSUVA (CR845/difelikefalin) Injection for CKD-aP in Dialysis Patients

In January 2018, based on positive data from Phase 2 clinical trials[1] and after completion of the End-of-Phase 2 meeting with the FDA, Cara initiated the first pivotal Phase 3 trial of KORSUVA injection (KALM-1 trial) in hemodialysis patients suffering from moderate-to-severe CKD-aP in the United States (additional information about the study can be found at www.clinicaltrials.gov, ID: NCT03422653). Cara also expects to initiate a global Phase 3 clinical trial of KORSUVA injection for the treatment of CKD-aP in hemodialysis patients in multiple countries later this year. Data from these studies are expected to support filings for regulatory approvals in the U.S. and other markets.

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.

Conference Call

Cara management will host a conference call today at 8:30 a.m. EDT to discuss the licensing agreement. To participate in the conference call, please dial (855) 445-2816 (domestic) or (484) 756-4300 (international) and refer to conference ID 2694637. A live webcast of the call can be accessed under

"Events and Presentations" in the News & Investors section of the Company's website at www.CaraTherapeutics.com.

An archived webcast recording will be available on the Cara website beginning approximately two hours after the call.

About CKD-aP

CKD-aP is an intractable systemic itch condition that occurs with the high frequency and intensity in patients with chronic kidney disease undergoing hemodialysis and peritoneal 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 percent in patients with end-stage renal disease (ESRD), with approximately 25 percent of patients reporting severe pruritus. The majority of dialysis patients (approximately 60-70 percent) report pruritus, with 30 to 40 percent reporting moderate or severe pruritus[2,3]. Recent data from the ITCH National Registry Study showed that among those with pruritus, approximately 59 percent 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. Data presentation at 2017 American Society of Nephrology's Annual Meeting (Kidney Week 2017)
2. Pisoni RL, et al. Pruritus in haemodialysis patients: international results from the Dialysis Outcomes and Practice Patterns Study (DOPPS). Nephrol Dial Transplant. 2006; 21:3495-3505.
3. Ramakrishnan 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
4. Mathur V. et al. A longitudinal study of Uremic Pruritus in hemodialysis patients. Clin J Am Soc Nephrol. 2010; 5(8):1410-1419

About Cara Therapeutics

Cara Therapeutics is a clinical-stage biopharmaceutical company focused on developing and commercializing new chemical entities designed to alleviate pruritus and pain by selectively targeting peripheral kappa opioid receptors (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. In Phase 2 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 CKD-aP and KORSUVA is currently being investigated in Phase 3 trials in hemodialysis patients with CKD-aP. Additionally, CR845/difelikefalin has demonstrated statistically significant pain relief in Phase 2 clinical trials conducted in patients with moderate-to-severe pain, without inducing many of the undesirable side effects typically associated with currently available opioid pain therapeutics.

About Vifor Fresenius Medical Care Renal Pharma Ltd (VFMCRP)

VMCRP is a joint company of Vifor Pharma Group and Fresenius Medical Care, develops and commercialises innovative and high quality therapies to improve the life of patients suffering from chronic kidney disease (CKD) worldwide. The company was founded at the end of 2010 and is owned 55% by Vifor Pharma Group and 45% by Fresenius Medical Care. For more information about Vifor Fresenius Medical Care Renal Pharma and its parent companies, please visit www.vfmcrp.com, www.viforpharma.com and www.freseniusmedicalcare.com.

About Vifor Pharma Group

Vifor Pharma, formerly Galenica Group, is a global pharmaceuticals company. It aims to become the global leader in iron deficiency, nephrology and cardio-renal therapies. The company is the 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; Vifor Fresenius Medical Care Renal Pharma, a joint company with Fresenius Medical Care; Relypsa; and OM Pharma. 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 www.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 plans, strategies and expectations for the future, including statements concerning the potential commercialization of KORSUVA in the licensed territories, the potential benefits of marketing KORSUVA in the United States through the promotion and profit share arrangement announced today, the potential of CR845 to set new standards in relief from CKD-induced itching and post-operative pain, the potential milestone and royalty payments payable to Cara pursuant to the agreement and the expected timelines for Cara's planned clinical trials and regulatory submissions. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Some of these risks and uncertainties include, but are not limited to, those related to the initiation and conduct of clinical trials, the receipt of data sufficient to support regulatory submissions and required regulatory approvals of KORSUVA, and uncertainties regarding the rate and degree of market acceptance of KORSUVA, if approved for marketing, as well as those risks and uncertainties described more fully in Cara's filings with the Securities and Exchange Commission, including the "Risk Factors" section of the Company's Annual Report on Form 10-K for the year ended December 31, 2017 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. 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.

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