Cara Therapeutics Reports Second Quarter 2021 Financial Results

August 9, 2021

– New Drug Application (NDA) Filing for KORSUVA™ Injection in CKD-aP under Priority Review by U.S. Food and Drug Administration (FDA); PDUFA Target Action Date August 23, 2021 –

– Conference call today at 4:30 p.m. ET –

STAMFORD, Conn., Aug. 09, 2021 (GLOBE NEWSWIRE) -- Cara Therapeutics, Inc. (Nasdaq: CARA), a biopharmaceutical company focused on developing and commercializing new chemical entities designed to alleviate pruritus by selectively targeting peripheral kappa opioid receptors (KORs), today announced financial results and operational highlights for the second quarter ended June 30, 2021.

"Having completed the late-cycle review of our NDA for our lead asset KORSUVA™ Injection with the FDA during the second quarter of the year, we remain on track for an expected Prescription Drug User Fee Act (PDUFA) target action date of August 23, 2021 and continue to be focused, along with our commercial partner, Vifor Pharma, on preparation for the U.S. launch of KORSUVA Injection in the second half of 2021, if approved," said Derek Chalmers, Ph.D., D.Sc., President and Chief Executive Officer of Cara Therapeutics. "We also continue to make good progress in our Oral KORSUVA programs across a range of patient populations where pruritus treatment remains a significant unmet need and, pending the outcome of our scheduled End-of-Phase 2 meeting with the FDA, aim to initiate our first Oral KORSUVA Phase 3 program in mild-to-moderate atopic dermatitis patients by year-end of 2021."

Second Quarter and Recent Developments:

KORSUVA Injection: Chronic Kidney Disease-Associated Pruritus (CKD-aP): Hemodialysis

In February 2021, the FDA accepted the filing of the NDA for KORSUVA Injection for the treatment of moderate-to-severe pruritus in hemodialysis patients. Shortly after this decision, the FDA granted Priority Review for the NDA filing of KORSUVA Injection in March 2021 with an expected PDUFA target action date of August 23, 2021. Following these decisions, the potential FDA approval and subsequent U.S. commercial launch of KORSUVA Injection could take place in the second half of 2021. If approved, KORSUVA Injection would be the first treatment for CKD-aP in hemodialysis patients.

In March 2021, the Company and Vifor Fresenius Medical Care Renal Pharma Ltd. (VFMCRP) announced that the European Medicines Agency (EMA) accepted to review the Marketing Authorization Application (MAA) for difelikefalin injection for the treatment of pruritus associated with chronic kidney disease in hemodialysis patients. The EMA will review the application under the centralized marketing authorization procedure. If approved, difelikefalin injection would receive marketing authorization in all member states of the European Union (EU), as well as in Iceland, Liechtenstein, and Norway. The EMA is expected to render a decision on the EU MAA in the second quarter of 2022.

The Company is party to a license agreement with Vifor (International) Ltd. (Vifor) dated October 2020 under which it granted Vifor an exclusive license to commercialize KORSUVA Injection for the treatment of pruritus in hemodialysis patients in the United States under a Cara 60%, Vifor 40% profit-sharing arrangement. Under the terms of the agreement, upon U.S. regulatory approval of KORSUVA Injection, the Company will be eligible to receive a $50.0 million common stock investment at a 20% premium to the 30-day trailing average price of the Company's common stock as of such date. In addition, the Company is eligible to receive payments of up to $240.0 million upon the achievement of certain sales-based milestones.

Oral KORSUVA: Atopic Dermatitis (AD)

In April 2021, the Company announced top-line results from its Phase 2 KARE dose-ranging clinical trial of Oral KORSUVA for the treatment of moderate-to-severe pruritus in mild-to-severe atopic dermatitis patients. The study did not meet its primary endpoint of Worst Itch – Numeric Rating Scale (WI-NRS) change from baseline at week 12 or secondary endpoint of 4-point responder analysis in the intent to treat (ITT) patient population. However, in a pre-specified analysis of mild-to-moderate (BSA <10%) AD patients (64% of ITT patient population), the study met its primary endpoint of WI-NRS change and secondary endpoint of 4-point responder analysis in this patient population. Additionally, a statistically significant improvement was demonstrated in the 4-point responder analysis, which we expect will be the Phase 3 registrational endpoint, in mild-to-moderate AD patients, with 32% of KORSUVA-treated patients achieving a greater than 4-point reduction vs. 19% in placebo group (p=0.03). Oral KORSUVA was generally well-tolerated across all doses.

The Company is scheduled to conduct an End of Phase 2 Meeting with the FDA in the third quarter of 2021 and, subject to discussions with the FDA, plans to initiate a Phase 3 program in mild-to-moderate AD patients by year-end 2021.

Oral KORSUVA: Non-Dialysis Dependent (NDD) CKD-aP

In April 2021, the Company held an End of Phase 2 Meeting with the FDA to discuss the results of the Phase 2 trial of Oral KORSUVA in NDD CKD-aP and the potential Phase 3 program. The FDA indicated the acceptability of Stage 5 pre-dialysis CKD patients as a viable patient population for a Phase 3 trial. The FDA also indicated the potential to use data from the Company's previous trials of KORSUVA Injection in dialysis patients to support an approval based on a single Phase 3 clinical trial of Oral KORSUVA in the Stage 5 pre-dialysis population. The Company plans to meet with the FDA in the fourth quarter of 2021, to discuss the potential inclusion of earlier stage CKD patients in a Phase 3 program.

Oral KORSUVA: Chronic Liver Disease-Associated Pruritus (CLD-aP): Primary Biliary Cholangitis (PBC)

The Company is currently conducting a Phase 2 trial of Oral KORSUVA for the treatment of pruritus in patients with hepatic impairment due to PBC. The trial is evaluating the safety and efficacy of Oral KORSUVA (1.0 mg tablet, twice daily) versus placebo for 16 weeks. The Company continues to screen patients in this ongoing Phase 2 trial, and primarily due to the ongoing effects of the COVID-19 pandemic on patient enrollment, currently expects to report top-line data in the first half of 2022.

Oral KORSUVA: Notalgia Paresthetica (NP)

The Company initiated a Phase 2 trial of Oral KORSUVA for the treatment of moderate-to-severe pruritus in patients suffering from NP, a nerve disorder characterized by chronic pruritus of the upper back, in early 2021. Currently, the Phase 2 trial has exceeded 50% patient enrollment and is expected to be fully enrolled by year-end 2021.

The Phase 2 multicenter, randomized, double-blind, placebo-controlled 8-week study is designed to evaluate the efficacy and safety of Oral KORSUVA for moderate-to-severe pruritus in approximately 120 subjects with NP. Subjects will be randomized to receive Oral KORSUVA 2.0 mg twice daily versus placebo for 8 weeks, followed by a 4-week active extension period. The primary efficacy endpoint is the change from baseline in the weekly mean of the daily 24-hour WI-NRS score at week 8 of the treatment period. Secondary endpoints include change from baseline in itch-related quality of life scores and a change from baseline in itch-related sleep disturbance subscale at the end of week 8.

COVID-19 Impacts and Business Operations

Due to the ongoing COVID-19 pandemic and in accordance with the FDA's updated guidance for conducting clinical trials, the Company has implemented numerous clinical and operational measures to prioritize the health and safety of patients, employees and study investigators and minimize potential disruptions to its ongoing clinical studies. The Company is working closely with its clinical and commercial manufacturing partners to continue to ensure sufficient supply of KORSUVA is available for its ongoing and planned clinical trials.

Based on guidelines from the Centers for Disease Control and Prevention and the State of Connecticut, all Cara employees continue to work remotely, and business travel has been restricted.

Upcoming Meeting Activities

The Company expects to make presentations at the following upcoming conferences:

- Cantor Fitzgerald Global Healthcare Conference, September 27-30, 2021
- Stifel Healthcare Conference, November 16-17, 2021
- Jefferies Global Healthcare Conference, November 16-18, 2021

- Piper Sandler Health Care Conference, November 30-December 2, 2021

Second Quarter 2021 Financial Results

Cash, cash equivalents and marketable securities at June 30, 2021 totaled $207.4 million compared to $251.5 million at December 31, 2020. The decrease in the balance primarily resulted from cash used in operating activities of $44.7 million, partially offset by proceeds of $1.0 million from the exercise of stock options.

For the three months ended June 30, 2021, net loss was $30.7 million, or $0.61 per basic and diluted share, compared to a net loss of $25.1 million, or $0.54 per basic and diluted share, for the same period in 2020.

Revenues: There was no revenue for the three months ended June 30, 2021, compared to $5.6 million during the same period of 2020. The Company recognized $5.1 million of license and milestone fees revenue during the three months ended June 30, 2020, $4.5 million of which related to its license agreement with VFMCRP and $0.6 million of which related to the achievement of a development milestone related to its license agreement with Chong Kun Dang Pharmaceutical Corp. The Company also recognized $0.5 million of clinical compound revenue from the sales of clinical compound for the three months ended June 30, 2020 to Maruishi Pharmaceutical Company Ltd. and VFMCRP.

Research and Development (R&D) Expenses: R&D expenses were $25.2 million for the three months ended June 30, 2021 compared to $26.1 million in the same period of 2020. The lower R&D expenses in 2021 were principally due to a net decrease in costs associated with clinical trials, stock compensation expense and cost of compound sales, partially offset by a $10.0 million milestone earned by Enteris Biopharma, Inc. during the three months ended June 30, 2021, increases in payroll and related costs, and increases in travel and related costs.

General and Administrative (G&A) Expenses: G&A expenses were $5.7 million for the three months ended June 30, 2021 compared to $5.4 million in the same period of 2020. The higher G&A expenses in 2021 were principally due to an increase in payroll and related costs, commercial costs and legal fees, partially offset by decreases in stock compensation expense and consultants' costs.

Other Income, net: Other income, net was $0.1 million for the three months ended June 30, 2021 compared to $0.6 million in the same period of 2020. The decrease in other income, net was primarily due to a decrease in interest income resulting from a lower yield on the Company's portfolio of investments in the 2021 period.

Financial Guidance

Based on timing expectations and projected costs for current clinical development plans, Cara expects that its existing unrestricted cash and cash equivalents and available-for-sale marketable securities as of June 30, 2021 will be sufficient to fund its currently anticipated operating expenses and capital expenditures into 2023, without giving effect to any potential milestone payments or potential product revenue under existing collaborations.

Conference Call

Cara management will host a conference call today at 4:30 p.m. ET to discuss second quarter 2021 financial results and provide a business update.

To participate in the conference call, please dial (855) 445-2816 (domestic) or (484) 756-4300 (international) and refer to conference ID 1568596. 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 Cara Therapeutics

Cara Therapeutics is a clinical-stage biopharmaceutical company focused on developing and commercializing new chemical entities designed to alleviate pruritus by selectively targeting peripheral 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 KORs located in the peripheral nervous system and on immune cells. In the Company's KALM™-1 and KALM-2 Phase 3 trials and two Phase 2 trials, KORSUVA Injection has demonstrated statistically significant reductions in itch intensity and concomitant improvement in pruritus-related quality of life measures in hemodialysis patients with moderate-to-severe CKD-aP. The FDA has accepted and granted Priority Review for the NDA for KORSUVA (difelikefalin) Injection for the treatment of moderate-to-severe pruritus in hemodialysis patients. The PDUFA target action date for KORSUVA is August 23, 2021. Oral KORSUVA has completed Phase 2 trials for the treatment of pruritus in patients with CKD and AD and is currently in Phase 2 trials in PBC and NP patients with moderate-to-severe pruritus.

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.

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 expected timing of the initiation, enrollment and data readouts from the Company's planned and ongoing clinical trials, the potential results of ongoing clinical trials, timing of future regulatory and development milestones for the Company's product candidates and potential commercialization of KORSUVA Injection for CKD-aP, the expected timeline for conducting meetings with the FDA concerning the Company's product candidates, including Oral KORSUVA for NDD CKD-aP and AD, the potential for the Company's product candidates to be alternatives in the therapeutic areas investigated, the Company's expected cash reach, and the potential impact of COVID-19 on the Company's clinical development and regulatory timelines and plans. 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 Therapeutics' filings with the Securities and Exchange Commission, including the "Risk Factors" section of the Company's most recent Annual Report on Form 10-K 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 Therapeutics undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

CARA THERAPEUTICS, INC.
CONDENSED STATEMENTS OF OPERATIONS
(amounts in thousands, except share and per share data)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenue:				
License and milestone fees	$ -	$ 5,099	$ 1,192	$ 13,120
Collaborative revenue	-	-	706	-
Clinical compound revenue	-	535	37	607
Total revenue	-	5,634	1,935	13,727
Operating expenses:				
Research and development	25,225	26,108	44,356	59,644
General and administrative	5,651	5,410	12,016	9,968
Total operating expenses	30,876	31,518	56,372	69,612
Operating loss	(30,876)	(25,884)	(54,437)	(55,885)
Other income, net	131	634	391	1,591
Loss before benefit from income taxes	(30,745)	(25,250)	(54,046)	(54,294)
Benefit from income taxes	-	182	-	304
Net loss	$ (30,745)	$ (25,068)	$ (54,046)	$ (53,990)
Net loss per share:				
Basic and Diluted	$ (0.61)	$ (0.54)	$ (1.08)	$ (1.15)
Weighted average shares:				
Basic and Diluted	50,059,984	46,799,703	49,989,379	46,762,327

CONDENSED BALANCE SHEETS
(in thousands)
(unaudited)

	June 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 22,335	$ 31,683
Marketable securities	132,841	149,242
Income tax receivable	697	1,507
Other receivables	305	557
Prepaid expenses	8,295	12,076
Total current assets	164,473	195,065
Operating lease right-of-use assets	3,641	4,279
Marketable securities, non-current	52,216	70,565
Property and equipment, net	716	840
Restricted cash	408	408
Total assets	$ 221,454	$ 271,157
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 13,493	$ 16,881
Operating lease liabilities, current	1,677	1,602
Total current liabilities	15,170	18,483
Operating lease liabilities, non-current	2,818	3,673
Commitments and contingencies	-	-
Stockholders' equity:		
Preferred stock	-	-
Common stock	50	50
Additional paid-in capital	649,784	641,195
Accumulated deficit	(446,363)	(392,317)
Accumulated other comprehensive (loss) income	(5)	73
Total stockholders' equity	203,466	249,001
Total liabilities and stockholders' equity	$ 221,454	$ 271,157

INVESTOR CONTACT:
Janhavi Mohite
Stern Investor Relations, Inc.
212-362-1200
Janhavi.Mohite@sternir.com

MEDIA CONTACT:
Claire LaCagnina
6 Degrees
315-765-1462
clacagnina@6degreespr.com

Source: Cara Therapeutics, Inc.