Cara Therapeutics Reports Second Quarter 2020 Financial Results

August 10, 2020

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

STAMFORD, Conn., Aug. 10, 2020 (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, 2020.

"In the second quarter, we continued to advance our clinical development programs for both KORSUVA™ Injection and Oral KORSUVA. Following positive top-line data from our KALM™-2 pivotal Phase 3 trial of KORSUVA Injection for chronic kidney disease-associated pruritus (CKD-aP) in hemodialysis patients, we remain on track to submit our first New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in the fourth quarter," said Derek Chalmers, Ph.D., D.Sc., President and Chief Executive Officer of Cara Therapeutics. "We also successfully completed a planned interim statistical analysis of our KARE Phase 2 dose-ranging trial of Oral KORSUVA for moderate-to-severe pruritus in atopic dermatitis (AD) patients and expect the trial to be fully enrolled by the fourth quarter."

Second Quarter and Recent Developments:

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

In April 2020, the Company announced positive top-line results from its KALM-2 global pivotal Phase 3 trial of KORSUVA Injection in hemodialysis patients with moderate-to-severe CKD-aP. The trial met the primary endpoint, with a statistically significant proportion of patients on KORSUVA Injection achieving a three-point or greater improvement from baseline in the weekly mean Worst Itching Intensity Numeric Rating Scale (NRS) versus placebo (p=0.02) at week 12. The trial also met the key secondary endpoint, with a statistically significant proportion of patients on KORSUVA Injection achieving a four-point or greater improvement from baseline in the weekly mean Worst Itching Intensity NRS versus placebo (p=0.01) at week 12. KORSUVA Injection was generally well-tolerated through 12 weeks of treatment with a safety profile consistent with prior clinical trials.

All safety databases are now closed with more than 1,500 total patient exposures achieved, including more than 700 patients completing at least six months of treatment and more than 400 patients completing one year of treatment.

The Company remains on track to submit an NDA for KORSUVA Injection to the FDA in the fourth quarter of 2020.

Oral KORSUVA: CKD-aP: Non-Hemodialysis

In December 2019, the Company announced positive top-line results from its Phase 2 dose-ranging trial of Oral KORSUVA for the treatment of pruritus in patients with stage III-V (moderate-to-severe) CKD. The Company plans to conduct an End of Phase 2 Meeting with the FDA in the first quarter of 2021. In advance of that meeting, the Company intends to initiate the safety portion of the Phase 3 program in the fourth quarter of 2020.

Oral KORSUVA: Atopic Dermatitis (AD)

In June 2020, the Company announced the completion of an interim conditional power assessment of its ongoing KARE Phase 2 dose-ranging trial of Oral KORSUVA for the treatment of moderate-to-severe pruritus in AD patients. The trial is evaluating the safety and efficacy of three tablet strengths (0.25 mg, 0.5 mg and 1.0 mg, twice daily) of Oral KORSUVA versus placebo for 12 weeks, followed by a 4-week active extension phase.

Based on the recommendation of the Independent Data Monitoring Committee, the size of the trial was increased from an original enrollment target of 320 patients to 410 patients, to maintain the prespecified statistical power of 80% or greater on the trial's primary endpoint of change from baseline in the weekly mean of the daily 24-hour Worst Itching Intensity NRS and key secondary endpoint of the proportion of patients achieving a four point or greater improvement in Worst Itching Intensity NRS score at week 12. The prespecified interim conditional power assessment was conducted after approximately 50% of the originally targeted patient number had completed the designated 12-week treatment period. The Company expects the trial to be fully enrolled in the fourth quarter of 2020 and aims to report top-line results in the first half of 2021, subject to any delays related to the ongoing COVID-19 pandemic.

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

The Company is 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 and aims to have top-line data in the first half of 2021, due in part to delays related to the ongoing COVID-19 pandemic.

Board of Directors Expansion and Appointment

In June 2020, the Company expanded its Board of Directors by appointing Susan Shiff, Ph.D., M.B.A., as a new Director. Dr. Shiff currently serves as Senior Vice President and Head of the Center for Observational and Real-World Evidence at Merck, known as MSD outside the United States and Canada.

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. Cara is working closely with its clinical and commercial manufacturing partners to continue to ensure sufficient supply of KORSUVA is available for its 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 Activities

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

- 40th Annual Canaccord Genuity Growth Conference, August 11-13, 2020
- Cantor Fitzgerald Global Healthcare Conference, September 15-17, 2020
- American Society of Nephrology Kidney Week, October 19-25, 2020
- Stifel Healthcare Conference, November 17-18, 2020
- Jefferies Global Healthcare Conference, November 17-19, 2020
- Piper Sandler Health Care Conference, December 1-3, 2020

Second Quarter 2020 Financial Results

Net Loss: Net loss was $25.1 million, or $0.54 per basic and diluted share, for the three months ended June 30, 2020, compared to a net loss of $23.0 million, or $0.58 per basic and diluted share, for the same period of 2019.

Revenues: Total revenue was $5.6 million for the three months ended June 30, 2020, compared to $5.2 million during the same period of 2019. Total revenue consisted of:

- The Company recognized $4.5 million and $5.2 million of license and milestone fees revenue for the three months ended June 30, 2020 and 2019, respectively, related to its license agreement with Vifor Fresenius Medical Care Renal Pharma Ltd. (VFMCRP).

- The Company recognized $0.6 million of license and milestone fees revenue for the three months ended June 30, 2020 related to the achievement of a milestone related to its license agreement with Chong Kun Dang Pharmaceutical Corp.

- The Company 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. There were no sales of clinical compound for the three months ended June 30, 2019.

Research and Development (R&D) Expenses: R&D expenses were $26.1 million for the three months ended June 30, 2020 compared to $24.4 million for the three months ended June 30, 2019. The higher R&D expenses in 2020 were primarily due to increases in stock-based compensation expense, payroll and related costs and cost of clinical compound sales, partially offset by a net decrease in clinical trial costs, conferences, and travel and related costs.

General and Administrative (G&A) Expenses: G&A expenses were $5.4 million for the three months ended June 30, 2020 compared to $5.0 million for the three months ended June 30, 2019. The increase in 2020 was primarily due to increases in consultants' costs, legal fees, and insurance costs, partially offset by decreases in stock-based compensation expense.

Other Income, Net: Other income, net was $634,000 for the three months ended June 30, 2020 compared to $947,000 for the three months ended June 30, 2019. The decrease in 2020 was due to a decrease in accretion and interest income resulting from a lower yield on our portfolio of investments in the 2020 period.

Cash and Cash Equivalents and Marketable Securities Position: At June 30, 2020, cash and cash equivalents and marketable securities totaled $153.0 million compared to $218.2 million at December 31, 2019. The decrease in the balance of cash and cash equivalents and marketable securities primarily resulted from cash used in operations of $66.0 million, partially offset by proceeds of $0.3 million from the exercise of stock options.

Financial Guidance

Based on timing expectations and projected costs for current clinical development plans, Cara expects that its existing cash and cash equivalents and available-for-sale marketable securities as of June 30, 2020 will be sufficient to fund its currently anticipated operating expenses and capital expenditures into the second half of 2021, without giving effect to any potential milestone payments under existing collaborations.

Conference Call

Cara management will host a conference call today at 4:30 p.m. ET to discuss second quarter 2020 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 7669087. A live webcast of the call can be accessed under "Events & 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. Cara has successfully completed its Phase 2 trial of Oral KORSUVA for the treatment of pruritus in patients with CKD and is currently conducting Phase 2 trials of Oral KORSUVA in AD and PBC 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 enrollment and data readouts from the Company's ongoing clinical trials, the potential results of ongoing clinical trials, timing of future regulatory and development milestones for the Company's product candidates, including the Company's projected timeline for the submission of its NDA for KORSUVA Injection for CKD-aP, the expected timeline for conducting meetings with the FDA concerning the Company's product candidates, 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 Quarterly Report on Form 10-Q 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.

Financial tables follow

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,	
	2020	**2019**	**2020**	**2019**
Revenue:				
License and milestone fees	$ 5,099	$ 5,208	$ 13,120	$ 9,450
Clinical compound revenue	535	-	607	140
Total revenue	5,634	5,208	13,727	9,590
Operating expenses:				
Research and development	26,108	24,356	59,644	47,964
General and administrative	5,410	4,994	9,968	8,902
Total operating expenses	31,518	29,350	69,612	56,866
Operating loss	(25,884)	(24,142)	(55,885)	(47,276)
Other income, net	634	947	1,591	2,036
Loss before benefit from income taxes	(25,250)	(23,195)	(54,294)	(45,240)
Benefit from income taxes	182	235	304	320
Net loss	$ (25,068)	$ (22,960)	$ (53,990)	$ (44,920)
Net loss per share:				
Basic and Diluted	$ (0.54)	$ (0.58)	$ (1.15)	$ (1.13)
Weighted average shares:				
Basic and Diluted	46,799,703	39,818,162	46,762,327	39,685,954

CARA THERAPEUTICS, INC.
CONDENSED BALANCE SHEETS
(in thousands)
(unaudited)

	June 30,	December 31,

	2020	2019
Assets		
Current assets:		
Cash and cash equivalents	$ 56,967	$ 18,305
Marketable securities	73,218	136,701
Income tax receivable	1,120	816
Other receivables	486	971
Prepaid expenses	10,124	8,863
Total current assets	141,915	165,656
Operating lease right-of-use asset	2,825	3,036
Marketable securities, non-current	22,861	63,159
Property and equipment, net	604	700
Restricted cash	408	408
Total assets	$ 168,613	$ 232,959
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 13,952	$ 19,665
Operating lease liability, current	1,006	967
Current portion of deferred revenue	9,768	22,262
Total current liabilities	24,726	42,894
Operating lease liability, non-current	2,959	3,352
Commitments and contingencies	-	-
Stockholders' equity:		
Preferred stock	-	-
Common stock	47	47
Additional paid-in capital	594,963	587,223
Accumulated deficit	(454,717)	(400,727)
Accumulated other comprehensive income	635	170
Total stockholders' equity	140,928	186,713
Total liabilities and stockholders' equity	$ 168,613	$ 232,959

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Source: Cara Therapeutics, Inc.