Cara Therapeutics Reports Third Quarter 2020 Financial Results

November 9, 2020

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

STAMFORD, Conn., Nov. 09, 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 third quarter ended September 30, 2020.

"In the third quarter, we built on the progress of the first half of the year and have made significant advancements in our clinical development programs for both KORSUVA™ (CR845/difelikefalin) Injection and Oral KORSUVA. With our pivotal Phase 3 program for KORSUVA Injection for chronic kidney disease-associated pruritus (CKD-aP) in hemodialysis patients complete, we remain on track to submit a 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. "Furthermore, we were very pleased to recently enter into a commercial license agreement with Vifor (International) Ltd. (Vifor) which we believe will provide significant momentum for the launch and adoption of KORSUVA Injection in the U.S. dialysis market, if approved. Looking ahead, we anticipate significant progress for our Oral KORSUVA programs in the coming quarters, including the completion of an End of Phase 2 Meeting with the FDA for CKD-aP non-hemodialysis patients in early 2021 and top-line data readout for our KARE Phase 2 dose-ranging trial in atopic dermatitis patients, anticipated in the first half of 2021."

Third Quarter and Recent Developments:

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

In October 2020, the Company entered into a license agreement with Vifor 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, the Company received an upfront payment of $100.0 million from Vifor and an additional payment of $50.0 million for the purchase of the Company's common stock at a price of $17.0094 per share. Upon U.S. regulatory approval of KORSUVA Injection, the Company will also be eligible to receive an additional $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.

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

Following the announcement of 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 in December 2019, the Company plans to conduct an End of Phase 2 Meeting with the FDA in the first quarter of 2021. Additionally, the Company intends to initiate the safety portion of the Phase 3 program in the fourth quarter of 2020 prior to the meeting.

Oral KORSUVA: Atopic Dermatitis (AD)

The Company is currently conducting the ongoing KARE Phase 2 dose-ranging trial of Oral KORSUVA for the treatment of moderate-to-severe pruritus in AD patients. The study 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.

The Company continues to expect that the trial will be fully enrolled in the fourth quarter of 2020 and anticipates reporting top-line results in the first half of 2021, subject to any delays related to the effects of the ongoing COVID-19 pandemic.

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

Appointments

In October 2020, the Company appointed Thomas Reilly, M.B.A., as Chief Financial Officer of Cara Therapeutics. Mr. Reilly is responsible for overseeing the Company's financial strategy and activities related to accounting, capital markets, and business operations. Mr. Reilly previously served as the Finance Head for the U.S. General Medicine Commercial Business at Allergan, now part of AbbVie.

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 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 primarily work remotely and business travel has been restricted.

Upcoming Activities

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

- Stifel Healthcare Conference, November 16-18, 2020
- Jefferies Global Healthcare Conference, November 17-19, 2020
- Piper Sandler Healthcare Conference, December 1-3, 2020
- J.P. Morgan Healthcare Conference, January 11-14, 2021

Third Quarter 2020 Financial Results

Net Loss: Net loss was $16.5 million, or $0.35 per basic and diluted share, for the three months ended September 30, 2020, compared to a net loss of $32.8 million, or $0.74 per basic and diluted share, for the same period of 2019.

Revenues: Total revenue was $9.3 million for the three months ended September 30, 2020, compared to $5.8 million during the same period of 2019. Total revenue primarily consisted of:

- The Company recognized $9.3 million and $5.8 million of license and milestone fees revenue for the three months ended September 30, 2020 and 2019, respectively, related to license fees earned in connection with its license agreement with Vifor Fresenius Medical Care Renal Pharma Ltd. (VFMCRP).

Research and Development (R&D) Expenses: R&D expenses were $21.1 million for the three months ended September 30, 2020 compared to $36.0 million for the three months ended September 30, 2019. The lower R&D expenses in 2020 were primarily due to a net decrease in clinical trial costs, an $8.0 million upfront payment made upon entering the license agreement with Enteris BioPharma, Inc. (Enteris) in 2019, and a decrease in travel and related costs, partially offset by increases in stock-based compensation expense, payroll and related costs, and a $2.5 million milestone earned by Enteris in 2020.

General and Administrative (G&A) Expenses: G&A expenses were $5.2 million for the three months ended September 30, 2020 compared to $4.2 million for the three months ended September 30, 2019. The increase in 2020 was primarily due to increases in insurance costs, franchise taxes, payroll and related costs, and commercial costs, partially offset by decreases in consultants' costs.

Other Income, Net: Other income, net was $379,000 for the three months ended September 30, 2020 compared to $1.3 million for the three months ended September 30, 2019. The decrease in 2020 was due to a decrease in net accretion income and a decrease in interest income resulting from a lower yield on the Company's lower average balance of its portfolio of investments in the 2020 period.

Cash and Cash Equivalents and Marketable Securities Position: At September 30, 2020, cash and cash equivalents and marketable securities totaled $131.4 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 $87.6 million, partially offset by proceeds of $0.7 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 unrestricted cash and cash equivalents and available-for-sale marketable securities as of September 30, 2020, with the additional funding of $150.0 million from the license agreement with Vifor in October 2020, will be sufficient to fund its currently anticipated operating expenses and capital expenditures into 2023, 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 third 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 2192536. 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 and potential commercialization of 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 September 30,		Nine Months Ended September 30,	
	2020	**2019**	**2020**	**2019**
Revenue:				
License and milestone fees	$ 9,257	$ 5,785	$ 22,377	$ 15,235
Clinical compound revenue	9	-	616	140
Total revenue	9,266	5,785	22,993	15,375
Operating expenses:				
Research and development	21,067	35,992	80,711	83,956
General and administrative	5,219	4,226	15,187	13,128
Total operating expenses	26,286	40,218	95,898	97,084
Operating loss	(17,020)	(34,433)	(72,905)	(81,709)
Other income, net	379	1,261	1,970	3,297
Loss before benefit from income taxes	(16,641)	(33,172)	(70,935)	(78,412)
Benefit from income taxes	132	330	436	650
Net loss	$ (16,509)	$ (32,842)	$ (70,499)	$ (77,762)
Net loss per share:				
Basic and Diluted	$ (0.35)	$ (0.74)	$ (1.51)	$ (1.88)
Weighted average shares:				
Basic and Diluted	46,885,424	44,517,134	46,803,659	41,314,044

CARA THERAPEUTICS, INC.
CONDENSED BALANCE SHEETS

(in thousands)
(unaudited)

	September 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 75,281	$ 18,305
Marketable securities	45,588	136,701
Income tax receivable	1,252	816
Other receivables	462	971
Prepaid expenses	10,254	8,863
Total current assets	132,837	165,656
Operating lease right-of-use asset	2,654	3,036
Marketable securities, non-current	10,506	63,159
Property and equipment, net	731	700
Restricted cash	408	408
Total assets	$ 147,136	$ 232,959
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 15,057	$ 19,665
Operating lease liability, current	1,030	967
Current portion of deferred revenue	511	22,262
Total current liabilities	16,598	42,894
Operating lease liability, non-current	2,691	3,352
Commitments and contingencies	-	-
Stockholders' equity:		
Preferred stock	-	-
Common stock	47	47
Additional paid-in capital	598,663	587,223
Accumulated deficit	(471,226)	(400,727)
Accumulated other comprehensive income	363	170
Total stockholders' equity	127,847	186,713
Total liabilities and stockholders' equity	$ 147,136	$ 232,959

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

MEDIA CONTACT:
Annie Starr
6 Degrees
973-415-8838
astarr@6degreespr.com

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