Cara Therapeutics Reports First Quarter 2020 Financial Results

May 11, 2020

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

STAMFORD, Conn., May 11, 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, or KORs, today announced financial results and operational highlights for the first quarter ended March 31, 2020.

"We are very excited by the recent success of our KALM™-2 pivotal Phase 3 trial of KORSUVA™ Injection in hemodialysis patients with moderate-to-severe chronic kidney disease-associated pruritus. With no approved therapies in the U.S. or Europe for this significant unmet need, we look forward to submitting our first New Drug Application (NDA) for KORSUVA Injection in the second half of 2020," said Derek Chalmers, Ph.D., D.Sc., President and Chief Executive Officer of Cara Therapeutics. "Given the challenges of operating under the current COVID-19 environment, I'd like to commend our entire team for their hard work and dedication in continuing to advance our clinical development programs and commercial preparations according to plan."

First 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 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). KORSUVA Injection was generally well-tolerated through 12 weeks of treatment with a safety profile consistent with prior clinical trials.

More than 1,500 total patient exposures have now been achieved, including all ongoing safety trials, with more than 600 patients completing at least six months of treatment and more than 300 patients completing one year of treatment.

The Company remains on track to submit an NDA to the U.S. Food and Drug Administration (FDA) for KORSUVA Injection in the second half 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 remains on track to conduct an End of Phase 2 Meeting with the FDA to enable initiation of a Phase 3 program in the second half of 2020.

Oral KORSUVA: Atopic Dermatitis (AD)

In January 2020, the Company expanded its ongoing Phase 2 trial of Oral KORSUVA for the treatment of pruritus in patients with AD from 240 adult patients to approximately 320 adult patients with moderate-to-severe pruritus. The ongoing Phase 2 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. Study sites remain open, although the rate of enrollment has been affected due to the COVID-19 pandemic.

The Company remains on track to complete an interim statistical analysis in the second quarter of 2020, after approximately 50% of the targeted number of patients complete the designated 12-week treatment period. The Company expects to report top-line results from this trial in 2020, subject to any delays related to the COVID-19 pandemic.

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

The Company continues to enroll patients in the ongoing 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 expects top-line results from this trial in 2020, subject to any delays related to the COVID-19 pandemic.

COVID-19 Impacts and Business Operations

Due to the 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 ensure sufficient supply of KORSUVA and the Company currently believes future supply will be uninterrupted.

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

Upcoming Activities

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

- BofA Securities 2020 Health Care Conference, May 12-14, 2020
- Jefferies Global Healthcare Conference, June 2-4, 2020

First Quarter 2020 Financial Results

Net Loss: Net loss was $28.9 million, or $0.62 per basic and diluted share for the three months ended March 31, 2020, compared to $22.0 million, or $0.56 per basic and diluted share, for the same period of 2019.

Revenues: Total revenue was $8.1 million for the three months ended March 31, 2020, compared to $4.4 million during the same period of 2019. Total revenue in 2020 consisted of:

- The Company recognized $8.0 million and $4.2 million of license and milestone fees revenue for the three months ended March 31, 2020 and 2019, respectively, related to its license agreement with Vifor Fresenius Medical Care Renal Pharma Ltd.

- The Company recognized $72,000 and $140,000 of revenue from the sales of clinical compound for the three months ended March 31, 2020 and 2019, respectively, in connection with the sale of clinical compound to Maruishi Pharmaceutical Co. Ltd.

Research and Development (R&D) Expenses: R&D expenses were $33.5 million for the three months ended March 31, 2020 compared to $23.6 million in the same period of 2019. The higher R&D expenses in 2020 were primarily due to a net increase in clinical trial costs, increases in stock compensation expense, payroll and related costs, conferences and travel and related costs.

General and Administrative (G&A) Expenses: G&A expenses were $4.6 million for the three months ended March 31, 2020 compared to $3.9 million in the same period of 2019. The increase in 2020 was primarily due to increases in legal and accounting fees, stock compensation expense, insurance costs, franchise taxes, and payroll and related costs. Those increases were partially offset by a decrease in travel and related costs.

Other Income, net: Other income, net was $1.0 million for the three months ended March 31, 2020 compared to $1.1 million in the same period of 2019. The decrease in 2020 was primarily due to a decrease in net accretion income partially offset by an increase in interest income resulting from a higher average balance of the Company's portfolio of investments as compared to the prior year period.

Cash and Cash Equivalents and Marketable Securities Position: At March 31, 2020, cash and cash equivalents and marketable securities totaled $179.8 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 $38.3 million of cash used in operating activities, partially offset by $0.1 million received 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 March 31, 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 first 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 3875739. 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. Oral KORSUVA is in Phase 2 trials for the treatment of pruritus in patients with CKD, AD and PBC.

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 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 first NDA, 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.

Financial tables follow

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

	Three Months Ended	
	March 31, 2020	**March 31, 2019**
Revenue:		
License and milestone fees	$ 8,021	$ 4,242
Clinical compound revenue	72	140
Total revenue	8,093	4,382
Operating expenses:		
Research and development	33,536	23,608
General and administrative	4,558	3,908
Total operating expenses	38,094	27,516
Operating loss	(30,001)	(23,134)
Other income, net	957	1,089
Loss before benefit from income taxes	(29,044)	(22,045)
Benefit from income taxes	122	85
Net loss	$ (28,922)	$ (21,960)
Net loss per share :		
Basic and Diluted	$ (0.62)	$ (0.56)
Weighted average shares:		
Basic and Diluted	46,724,951	39,552,277

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

	March 31, 2020	**December 31, 2019**
Assets		
Current assets:		
Cash and cash equivalents	$ 17,036	$ 18,305
Marketable securities	103,160	136,701
Income tax receivable	938	816
Other receivables	847	971
Prepaid expenses	10,688	8,863
Total current assets	132,669	165,656
Operating lease right-of-use asset	2,876	3,036
Marketable securities, non-current	59,568	63,159
Property and equipment, net	652	700
Restricted cash	408	408

Total assets	$ 196,173	$ 232,959
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 17,371	$ 19,665
Operating lease liability, current	991	967
Current portion of deferred revenue	14,241	22,262
Total current liabilities	32,603	42,894
Operating lease liability, non-current	3,096	3,352
Commitments and contingencies	-	-
Stockholders' equity:		
Preferred stock	-	-
Common stock	47	47
Additional paid-in capital	590,144	$ 587,223
Accumulated deficit	(429,649)	(400,727)
Accumulated other comprehensive income (loss)	(68)	170
Total stockholders' equity	160,474	186,713
Total liabilities and stockholders' equity	$ 196,173	$ 232,959

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Source: Cara Therapeutics, Inc.