Cara Therapeutics Reports Fourth Quarter and Full Year 2019 Financial Results

February 27, 2020

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

STAMFORD, Conn., Feb. 27, 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 fourth quarter and full year ended December 31, 2019.

"During 2019, we reported significant advancements in both our KORSUVA ™ Injection and Oral KORSUVA late-stage clinical pruritus programs, including positive results from our first pivotal Phase 3 efficacy trial (KALM™-1) of KORSUVA Injection for the treatment of chronic kidney disease-associated pruritus in patients undergoing hemodialysis and our Phase 2 trial of Oral KORSUVA in pre-dialysis patients. Additionally, we broadened our clinical pruritus program for Oral KORSUVA with the initiation of Phase 2 trials in both atopic dermatitis and liver disease patients," said Derek Chalmers, Ph.D., D.Sc., President and Chief Executive Officer of Cara Therapeutics. "We expect 2020 to be an exciting year as our KALM-2 pivotal Phase 3 trial advances to top-line data in the second quarter and we aim to file our first NDA for KORSUVA Injection in the second half of the year."

Fourth Quarter and Recent Developments:

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

The Company expects top-line data for its pivotal KALM-2 Phase 3 global trial of KORSUVA Injection in the second quarter of 2020 and remains on track to file a New Drug Application, or NDA, to the U.S. Food and Drug Administration, or FDA, for KORSUVA Injection in the second half of 2020.

In October 2019, the Company announced the completion of an interim statistical assessment for its pivotal KALM-2 Phase 3 global trial of KORSUVA Injection. Based on the recommendation of the Independent Data Monitoring Committee, the size of the trial was increased from an original enrollment target of 350 patients to 430 patients.

Currently, more than 1,500 total patient exposures have 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.

In November 2019, the Company announced a publication in the *New England Journal of Medicine* of full results from the KALM-1 Phase 3 trial of KORSUVA Injection in patients undergoing hemodialysis with moderate-to-severe CKD-aP.

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. Oral KORSUVA met the primary endpoint with a statistically significant reduction in the weekly mean of the daily 24-hour worst itching intensity Numeric Rating Scale with the 1.0 mg tablet strength versus placebo after the 12-week treatment period (p=0.018). Oral KORSUVA was generally well-tolerated with a safety profile consistent with that seen in previous KORSUVA clinical trials. The Company aims to complete an End of Phase 2 Meeting with the FDA to enable initiation of a Phase 3 program of Oral KORSUVA in non-hemodialysis CKD-aP patients 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 AD patients with moderate-to-severe pruritus. The 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. An interim statistical analysis will be conducted after approximately 50% of the targeted number of patients complete the designated 12-week treatment period, which is expected in the second quarter of 2020. The Company aims to report top-line data from this trial in 2020.

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 KOSRUVA (1.0 mg tablet, twice daily) versus placebo for 16 weeks. The Company aims to report top-line data from this trial in 2020.

Expected 2020 Milestones

- Top-line efficacy and safety data from the KALM-2 Phase 3 trial of KORSUVA Injection in hemodialysis patients with moderate-to-severe CKD-aP in the second quarter of 2020.
- Interim statistical analysis on the Phase 2 trial of Oral KORSUVA in AD in the second quarter of 2020.
- Submission of an NDA to the FDA for KORSUVA Injection in hemodialysis patients with moderate-to-severe CKD-aP in the second half of 2020.
- Top-line data from the Phase 2 trial of Oral KORSUVA in AD in 2020.

- Top-line data from the Phase 2 trial of Oral KORSUVA in CLD-aP in 2020.
- Completion of End of Phase 2 Meeting with the FDA to enable initiation of a Phase 3 program of Oral KORSUVA in non-hemodialysis CKD-aP patients in the second half of 2020.

Upcoming Meeting Activities

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

- American Academy of Dermatology Annual Meeting, March 20-24, 2020
- Needham & Co. Annual Healthcare Conference, April 14-15, 2020
- H.C. Wainwright Global Life Sciences Conference, April 19-21, 2020
- Bank of America Merrill Lynch Health Care Conference, May 12-14, 2020

Fourth Quarter and Full Year 2019 Financial Results

Cash, cash equivalents and marketable securities at December 31, 2019 totaled $218.2 million compared to $182.8 million at December 31, 2018. The increase in the balance resulted primarily from $136.5 million of cash raised in a follow-on offering of the Company's common stock in July 2019 and $6.1 million received from the exercise of stock options, partially offset by $109.2 million of cash used in operating activities.

For the fourth quarter of 2019, net loss was $28.6 million, or $0.61 per basic and diluted share, compared to a net loss of $20.7 million, or $0.52 per basic and diluted share, for the same period in 2018.

- *Revenues:* The Company recognized $4.5 million and $5.5 million of license and milestone fees revenue during the fourth quarter of 2019 and 2018, respectively, related to its collaboration agreement with Vifor Fresenius Medical Care Renal Pharma Ltd., or VFMCRP.

- *Research and Development (R&D) Expenses:* R&D expenses were $29.9 million in the fourth quarter of 2019 compared to $22.8 million in the same period of 2018. The higher R&D expenses in 2019 were principally due to a net increase in costs associated with clinical trials, as well as increases in payroll and related costs.

- *General and Administrative (G&A) Expenses:* G&A expenses were relatively consistent at $4.6 million during the fourth quarter of 2019 compared to $4.7 million in the same period of 2018.

- *Other Income:* Other income was $1.2 million in the fourth quarter of both 2019 and 2018.

For the full year ended December 31, 2019, net loss was $106.4 million, or $2.49 per basic and diluted share compared to a net loss of $74.0 million, or $2.06 per basic and diluted share, for the full year ended December 31, 2018.

- *Revenues:* Total revenue was $19.9 million for the full year ended December 31, 2019 as compared to $13.5 million for the full year ended December 31, 2018. Total revenue consisted of:

  (1) License and milestone fees revenue of $19.7 million and $13.4 million for the full year ended December 31, 2019 and 2018, respectively, was recognized by the Company related to its license agreement with VFMCRP.

  (2) There was no collaborative revenue recognized for the full year ended December 31, 2019 or 2018.

  (3) The Company recognized $140,000 and $33,000 of revenue from the sales of clinical compound during the full year ended December 31, 2019 and 2018, respectively, in connection with the sale of clinical compound to Maruishi Pharmaceuticals Co. Ltd.

- *Research and Development (R&D) Expenses:* R&D expenses were $113.8 million for the full year ended December 31, 2019 compared to $75.5 million for the full year ended December 31, 2018. The higher R&D expenses in 2019 were principally due to a net increase in clinical trial costs, increases in stock compensation expense, payroll and related costs as well as an expense in connection with the license agreement with Enteris Biopharma, Inc. in 2019.

- *General and Administrative (G&A) Expenses:* G&A expenses were $17.7 million for the full year ended December 31, 2019 compared to $15.3 million for the full year ended December 31, 2018. The increase in 2019 was primarily due to increases in stock compensation expense, payroll and related costs, consultants' costs, legal and accounting fees, insurance costs and franchise taxes. Those increases were partially offset by decreased rent, utilities and related costs.

- *Other Income:* Other income was $4.5 million for the full year ended December 31, 2019 compared to $3.0 million for the year ended 2018. The increase in 2019 was primarily due to a higher average balance of the Company's portfolio of investments in 2019.

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 December 31, 2019 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 fourth quarter and full year 2019 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 9907568. 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 Phase 3 trial and two Phase 2 trials, KORSUVA (CR845/difelikefalin) 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 and is currently being investigated in Phase 3 trials in hemodialysis patients with 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, and the Company's expected cash reach. 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.
STATEMENTS OF OPERATIONS
(amounts in thousands, except share and per share data)
(unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2019	2018	2019	2018
Revenue:				
License and milestone fees	$ 4,511	$ 5,533	$ 19,746	$ 13,436
Clinical compound revenue	-	-	140	33
Total revenue	4,511	5,533	19,886	13,469
Operating expenses:				
Research and development	29,864	22,799	113,820	75,531
General and administrative	4,617	4,711	17,745	15,320
Total operating expenses	34,481	27,510	131,565	90,851
Operating loss	(29,970)	(21,977)	(111,679)	(77,382)
Other income	1,193	1,200	4,490	2,980
Loss before benefit from income taxes	(28,777)	(20,777)	(107,189)	(74,402)
Benefit from income taxes	166	125	816	389

Net loss	$ (28,611)	$ (20,652)	$ (106,373)	$ (74,013)
Net loss per share:				
Basic and Diluted	$ (0.61)	$ (0.52)	$ (2.49)	$ (2.06)
Weighted average shares:				
Basic and Diluted	46,691,009	39,441,640	42,669,333	35,892,786

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

	December 31, 2019	2018
Assets		
Current assets:		
Cash and cash equivalents	$ 18,305	$ 15,081
Marketable securities	136,701	146,302
Income tax receivable	816	664
Other receivables	971	926
Prepaid expenses	8,863	4,805
Restricted cash, current	-	361
Total current assets	165,656	168,139
Operating lease right-of-use asset	3,036	-
Marketable securities, noncurrent	63,159	21,396
Property and equipment, net	700	880
Restricted cash	408	408
Total assets	$ 232,959	$ 190,823
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 19,665	$ 13,622
Operating lease liability, current	967	-
Current portion of deferred revenue	22,262	26,825
Total current liabilities	42,894	40,447
Operating lease liability, non-current	3,352	-
Deferred revenue, non-current	-	15,184
Deferred lease obligation	-	1,562
Commitments and contingencies	-	-
Stockholders' equity:		
Preferred stock	-	-
Common stock	47	39
Additional paid-in capital	587,223	428,059
Accumulated deficit	(400,727)	(294,354)
Accumulated other comprehensive income (loss)	170	(114)
Total stockholders' equity	186,713	133,630
Total liabilities and stockholders' equity	$ 232,959	$ 190,823

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Source: Cara Therapeutics, Inc.