Cara Therapeutics Reports Fourth Quarter and Full Year 2020 Financial Results

February 25, 2021

– U.S. FDA Accepts NDA Filing for KORSUVA™ Injection in CKD-aP –

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

STAMFORD, Conn., Feb. 25, 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 fourth quarter and full year ended December 31, 2020.

"During 2020, we made significant advances in our late-stage clinical pruritus programs, culminating in the acceptance by the U.S. Food and Drug Administration (FDA) of our first New Drug Application (NDA) filing for our lead product candidate, KORSUVA™ (CR845/difelikefalin) Injection for the treatment of moderate-to-severe pruritus in hemodialysis patients," said Derek Chalmers, Ph.D., D.Sc., President and Chief Executive Officer of Cara Therapeutics. "In addition, we executed a strategic commercial licensing agreement with Vifor (International) Ltd. (Vifor) that we believe will provide significant momentum for the launch and adoption of KORSUVA Injection in the United States, if approved. Looking forward, we also expect 2021 to be a very exciting year for our Oral KORSUVA pruritus programs as we report top-line data for the KARE Phase 2 dose-ranging trial in atopic dermatitis in the first half of 2021 and initiate our Phase 3 registration trials in stage III-V CKD patients in the second half of the year."

Fourth 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. If approved, KORSUVA Injection would be the first treatment for CKD-aP in dialysis patients. If granted priority review, potential approval and commercial launch of KORSUVA Injection could take place in the second half of 2021.

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.

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 expects to conduct an End of Phase 2 Meeting with the FDA regarding this indication in the second quarter of 2021. Following the meeting, the Company intends to initiate the Phase 3 program in patients with stage III-V CKD in the second half of 2021.

Oral KORSUVA: Atopic Dermatitis (AD)

In December 2020, the Company announced that it has completed full enrollment in the ongoing KARE Phase 2 dose-ranging trial of Oral KORSUVA for the treatment of moderate-to-severe pruritus in approximately 400 adult 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 four-week active extension phase.

KARE's primary efficacy endpoint is change from baseline in the weekly mean of the daily 24-hour Worst Itch – Numeric Rating Scale (WI-NRS) score at week 12 of the treatment period. The key secondary endpoint for KARE is the assessment of the proportion of patients achieving an improvement from baseline of ≥4 points with respect to the weekly mean of the daily 24-hour WI-NRS score at week 12. Itch-related quality of life scores at the end of week 12 are assessed by the total Skindex-10 and 5-D itch scales.

The Company aims to report top-line results from this trial 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 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 second half of 2021, due in part to delays related to the ongoing COVID-19 pandemic.

Oral KORSUVA: Notalgia Paresthetica (NP)

In January 2021, 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 to middle back.

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 four-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. 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 work remotely, and business travel has been restricted.

Expected 2021 Milestones

- Top-line data from the KARE Phase 2 dose-ranging trial of Oral KORSUVA in AD patients in the first half of 2021.
- End of Phase 2 Meeting with the FDA in the second quarter of 2021 to enable initiation of a Phase 3 program of Oral KORSUVA in non-hemodialysis CKD-aP patients in the second half of 2021.
- Potential FDA approval of NDA for KORSUVA Injection in the second half of 2021.
- Top-line data from the Phase 2 trial of Oral KORSUVA in CLD-aP in the second half of 2021.
- Initiate Phase 3 trial of Oral KORSUVA for CKD-aP patients in the second half of 2021.

Upcoming Meeting Activities

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

- National Kidney Foundation Spring Clinical Meeting, April 6-10, 2021
- Needham & Co. Annual Healthcare Conference, April 12-15, 2021
- American Nephrology Nurses Association National Symposium, May 2-5, 2021
- Bank of America Merrill Lynch Healthcare Conference, May 10-13, 2021

Fourth Quarter and Full Year 2020 Financial Results

Cash, cash equivalents and marketable securities at December 31, 2020 totaled $251.5 million compared to $218.2 million at December 31, 2019. The increase in the balance primarily resulted from $38.4 million from the sale of common stock in a license agreement with Vifor, partially offset by $5.5 million of cash used in operating activities, which includes $111.6 million of cash received from the Vifor Agreement which was included as license and milestone fees revenue.

For the fourth quarter of 2020, net income was $78.9 million, or $1.60 per basic share and $1.59 per diluted share, compared to a net loss of $28.6 million, or $0.61 per basic and diluted share, for the same period in 2019.

Revenues: Total revenue was $112.1 million for the fourth quarter of 2020, compared to $4.5 million during the same period of 2019. Total revenue primarily consisted of:

- $112.1 million of license and milestone fees revenue during the fourth quarter of 2020, of which $111.6 million related to the license agreement with Vifor and $0.5 million related to the license agreement with Vifor Fresenius Medical Care Renal Pharma Ltd. (VFMCRP). The Company recognized $4.5 million of license and milestone fees revenue during the fourth quarter of 2019, which related to the license agreement with VFMCRP.

Research and Development (R&D) Expenses: R&D expenses were $27.1 million in the fourth quarter of 2020 compared to $29.9 million in the same period of 2019. The lower R&D expenses in 2020 were principally due to a net decrease in costs associated with clinical trials and travel and related costs, partially offset by a $2.5 million milestone payment made in connection with the license agreement with Enteris Biopharma, Inc. (Enteris), increases in payroll and related costs, and increases in stock compensation expense.

General and Administrative (G&A) Expenses: G&A expenses were $6.7 million in the fourth quarter of 2020 compared to $4.6 million in the same period of 2019. The higher G&A expenses in 2020 were principally due to increases in payroll and related costs, commercial costs, and insurance costs.

Other Income, net: Other income, net was $0.4 million in the fourth quarter of 2020 compared to $1.2 million in the same period of 2019. The decrease in other income, net was primarily due to a decrease in net accretion income and a decrease in interest income resulting from a lower yield on our portfolio of investments in the 2020 period.

For the full year ended December 31, 2020, net income was $8.4 million, or $0.18 per basic and diluted share compared to a net loss of $106.4 million, or $2.49 per basic and diluted share, for the full year ended December 31, 2019.

Revenues: Total revenue was $135.1 million for the full year ended December 31, 2020 compared to $19.9 million for the full year ended December 31, 2019. Total revenue primarily consisted of:

- $134.4 million of license and milestone fees revenue for the year ended December 31, 2020, of which $111.6 million related to the license agreement with Vifor, $22.3 million related to the license agreement with VFMCRP, and $0.6 million related to the achievement of a milestone related to its license agreement with Chong Kun Dang Pharmaceutical Corp. The Company also recognized $19.7 million of license and milestone fees revenue for the year ended December 31, 2019, which related to the license agreement with VFMCRP.

- Approximately $643,000 and $140,000 of revenue from the sales of clinical compound during the years ended December 31, 2020 and 2019, respectively, in connection with the sale of clinical compound to VFMCRP and Maruishi Pharmaceutical Co. Ltd.

Research and Development (R&D) Expenses: R&D expenses were $107.9 million for the full year ended December 31, 2020 compared to $113.8 million for the full year ended December 31, 2019. The lower R&D expenses in 2020 were principally due to a net decrease in clinical trial costs and related consultant costs, lower payments made to Enteris during the year ended December 2020, and a decrease in travel and related costs, partially offset by increases in stock compensation expense, payroll and related costs, and cost of clinical compound sales.

General and Administrative (G&A) Expenses: G&A expenses were $21.8 million for the full year ended December 31, 2020 compared to $17.7 million for the full year ended December 31, 2019. The increase in 2020 was primarily due to increases in commercial costs, insurance costs, payroll and related costs, and accounting fees, partially offset by decreases in consultants' costs and stock compensation expense.

Other Income, net: Other income, net was $2.3 million for the full year ended December 31, 2020 compared to $4.5 million for the full year ended December 31, 2019. The decrease in 2020 was primarily due to a decrease in net accretion income and a decrease in interest income resulting from a lower yield on our lower average balance of our portfolio of investments in the 2020 period, partially offset by a realized gain of approximately $0.3 million from the sale of our available-for-sale marketable securities in the 2020 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 December 31, 2020 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 fourth quarter and full year 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 6676157. 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. 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, PBC and NP patients with moderate-to-severe pruritus.

The FDA has accepted the NDA filing for KORSUVA Injection for the treatment of moderate-to-severe pruritus in hemodialysis patients and 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 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 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,	
	2020	2019	2020	2019
Revenue:				
License and milestone fees	$ 112,062	$ 4,511	$ 134,439	$ 19,746
Clinical compound revenue	27	-	643	140
Total revenue	112,089	4,511	135,082	19,886
Operating expenses:				
Research and development	27,140	29,864	107,851	113,820
General and administrative	6,659	4,617	21,846	17,745
Total operating expenses	33,799	34,481	129,697	131,565
Operating income (loss)	78,290	(29,970)	5,385	(111,679)
Other income, net	364	1,193	2,334	4,490
Income (loss) before benefit from income taxes	78,654	(28,777)	7,719	(107,189)
Benefit from income taxes	255	166	691	816
Net income (loss)	$ 78,909	$ (28,611)	$ 8,410	$ (106,373)
Net income (loss) per share:				
Basic	$ 1.60	$ (0.61)	$ 0.18	$ (2.49)
Diluted	$ 1.59	$ (0.61)	$ 0.18	$ (2.49)
Weighted average shares:				
Basic	49,228,774	46,691,009	47,413,250	42,669,333
Diluted	49,701,864	46,691,009	47,915,030	42,669,333

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

	December 31,	
	2020	2019
Assets		
Current assets:		
Cash and cash equivalents	$ 31,683	$ 18,305
Marketable securities	149,242	136,701
Income tax receivable	1,507	816
Other receivables	557	971
Prepaid expenses	12,076	8,863
Total current assets	195,065	165,656
Operating lease right-of-use assets	4,279	3,036
Marketable securities, non-current	70,565	63,159
Property and equipment, net	840	700
Restricted cash	408	408
Total assets	$ 271,157	$ 232,959
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 16,881	$ 19,665

Operating lease liabilities, current	1,602	967
Current portion of deferred revenue	-	22,262
Total current liabilities	18,483	42,894
Operating lease liabilities, non-current	3,673	3,352
Commitments and contingencies	-	-
Stockholders' equity:		
Preferred stock	-	-
Common stock	50	47
Additional paid-in capital	641,195	587,223
Accumulated deficit	(392,317)	(400,727)
Accumulated other comprehensive income	73	170
Total stockholders' equity	249,001	186,713
Total liabilities and stockholders' equity	$ 271,157	$ 232,959

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