Cara Therapeutics Reports Fourth Quarter and Full Year 2021 Financial Results

March 1, 2022

KORSUVA™ (difelikefalin) injectionU.S. commercial launch on track for April 2022 with extensive pre-launch activities completed

Initiation of Oral KORSUVA (difelikefalin) Phase 3 pruritus programs in non-dialysis dependent advanced chronic kidney disease and atopic dermatitis expected in 1Q 2022

Phase 3 programs to be highlighted in virtual R&D event on March 11, 2022 at 1:00 pm ET

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

STAMFORD, Conn., March 01, 2022 (GLOBE NEWSWIRE) -- Cara Therapeutics, Inc. (Nasdaq: CARA), an early commercial-stage biopharmaceutical company leading a new treatment paradigm to improve the lives of patients suffering from pruritus, today announced financial results and operational highlights for the fourth quarter and full year ended December 31, 2021.

“Cara Therapeutics made excellent progress in 2021 executing on our strategic priorities, underscored by our first FDA approval -- KORSUVA™ (difelikefalin) injection, the first and only therapy approved for the treatment of pruritus associated with chronic kidney disease in adults undergoing hemodialysis,” said Christopher Posner, President and Chief Executive Officer of Cara Therapeutics. “We have been collaborating with our partner Vifor Pharma to optimize the U.S. commercial launch, which is on track for April 2022. To that end, Vifor has been conducting an extensive array of pre-launch activities and we have a clear path to reimbursement.”

Mr. Posner continued, “Our Oral KORSUVA (difelikefalin) platform continues to advance in multiple pruritus indications. We are initiating Phase 3 programs in the first quarter of this year for Oral KORSUVA (difelikefalin) in pruritus associated with advanced chronic kidney disease and atopic dermatitis. We look forward to discussing these trials during our virtual R&D event on March 11. In addition, we continue to progress our two Phase 2 proof-of-concept studies for the treatment of pruritus associated with notalgia paresthetica and primary biliary cholangitis, for which we expect to have top-line data in the second quarter and second half of 2022, respectively. With the planned imminent U.S. launch of KORSUVA injection, an Oral KORSUVA (difelikefalin) pipeline with significant market opportunity and a firm financial foundation, we believe we are poised to make substantial progress in 2022 that will position us for long-term growth as we strive to become a category-defining leader in the treatment of chronic pruritus.”

Fourth Quarter and Recent Developments:

Leadership Appointment

In November 2021, the Company appointed board member Christopher Posner as President and Chief Executive Officer. Mr. Posner has more than 23 years of global pharmaceutical management, sales and product launch experience. He joined the Company from LEO Pharma, Inc., the U.S. affiliate of LEO Pharma A/S, a global leader in medical dermatology, where he served as President and Chief Executive Officer.

KORSUVA Injection: Chronic Kidney Disease-Associated Pruritus: Hemodialysis

Following the August 2021 FDA approval of KORSUVA™ (difelikefalin) injection for the treatment of moderate-to-severe pruritus associated with chronic kidney disease (CKD) in adults undergoing hemodialysis, the Company has been collaborating with its commercial partner, Vifor Pharma, to prepare for the U.S. commercial launch in April 2022. Vifor’s field force of roughly 100 representatives has been trained on the package insert, conducting disease state education for pruritus in CKD, and focused on patient identification with key prescribers and dialysis organizations. Sufficient launch quantities of KORSUVA injection are manufactured and ready to be shipped from the distribution center to wholesalers.

In December 2021, the U.S. Centers for Medicare & Medicaid Services (CMS) granted Transitional Drug Add-On Payment Adjustment (TDAPA) to KORSUVA injection in the anti-pruritic functional category. TDAPA will apply to KORSUVA injection beginning April 1, 2022, for two years. TDAPA enables payment for new injectable end-stage renal disease (ESRD)-related therapies to be reimbursed outside of the ESRD Prospective Payment System (PPS) bundle.

In February 2022, the European Medicines Agency’s (EMA) Committee for Medicinal Products for Human Use (CHMP) recommended approval of Kapruvia® (difelikefalin) for the treatment of moderate-to-severe pruritus associated with CKD in hemodialysis patients. The CHMP opinion is the basis for the European Commission’s final decision regarding marketing authorization for Kapruvia ®. The European Commission decision for EU Marketing Authorization is expected in the second quarter of 2022.

In January 2022, the Company’s licensing partner Maruishi Pharmaceutical Co., Ltd., and its sublicensee Kissei Pharmaceutical Co., Ltd., announced the primary and secondary endpoints were achieved in a Japanese Phase 3 clinical trial (double-blind, placebo-controlled period) of difelikefalin injection for the treatment of pruritus in hemodialysis patients. Difelikefalin was generally well-tolerated in the trial.

Oral KORSUVA (difelikefalin): Pruritus Associated with Non-Dialysis Dependent Advanced Chronic Kidney Disease

In April 2021, the Company held an End-of-Phase 2 Meeting with the FDA to discuss the results of the Phase 2 clinical trial of Oral KORSUVA (difelikefalin) in non-dialysis dependent chronic kidney disease-associated pruritus and the potential Phase 3 program. Based on meeting guidance, the FDA indicated the acceptability of Stage 5 pre-dialysis CKD patients as a viable patient population for a Phase 3 trial.

In November 2021, the FDA provided the Company with written guidance indicating the patient population can be expanded to include the group of Stage 4 pre-dialysis patients with advanced CKD in a Phase 3 program consisting of two Phase 3 clinical trials. The Company expects to initiate this Phase 3 program in the first quarter of 2022. The Phase 3 program will be discussed during the virtual R&D event on March 11, 2022.

Oral KORSUVA (difelikefalin): Atopic Dermatitis

In October 2021, the Company announced the results from the KARE Phase 2 clinical trial of Oral KORSUVA (difelikefalin) for the treatment of moderate-to-severe pruritus in mild-to-severe atopic dermatitis (AD) patients. The results were presented as a late-breaking presentation at the 2021 European Academy of Dermatology and Venereology (EADV) Virtual Congress by Brian Kim, MD, Associate Professor of Dermatology and Co-Director of the Center for the Study of Itch and Sensory Disorders at Washington University School of Medicine.

The Company expects to initiate a Phase 3 clinical program of Oral KORSUVA (difelikefalin) in AD patients in the first quarter of 2022. The Phase 3 program will be discussed during the virtual R&D event on March 11, 2022.

Oral KORSUVA (difelikefalin): Chronic Liver Disease-Associated Pruritus: Primary Biliary Cholangitis

The Company is currently conducting a Phase 2 clinical trial of Oral KORSUVA (difelikefalin) for the treatment of pruritus in patients with hepatic impairment due to primary biliary cholangitis (PBC). The trial is evaluating the safety and efficacy of Oral KORSUVA (difelikefalin) (1.0 mg tablet, twice daily) versus placebo for 16 weeks. The Company continues to screen patients in this ongoing Phase 2 trial and, primarily due to the ongoing effects of the COVID-19 pandemic on patient enrollment, now expects to report top-line data in the second half of 2022.

Oral KORSUVA (difelikefalin): Notalgia Paresthetica

The Company is evaluating the efficacy and safety of Oral KORSUVA (difelikefalin) for moderate-to-severe pruritus in approximately 120 subjects with notalgia paresthetica (NP) in a Phase 2 multicenter, randomized, double-blind, placebo-controlled 8-week trial. Subjects are randomized to receive Oral KORSUVA (difelikefalin) 2.0 mg twice daily versus placebo for 8 weeks, followed by a 4-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.

The Company expects to report top-line data from this trial in the second quarter of 2022.

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 trials. The Company is working closely with its clinical and commercial manufacturing partners to continue to ensure sufficient supply of KORSUVA is available for the commercial launch of KORSUVA injection and its ongoing and planned clinical trials.

Expected 2022 Milestones:

- Initiate Oral KORSUVA (difelikefalin) Phase 3 clinical program in pruritus associated with advanced CKD in the first quarter of 2022
- Initiate Oral KORSUVA (difelikefalin) Phase 3 clinical program in AD in the first quarter of 2022
- Launch KORSUVA injection in the U.S. in April 2022
- EMA decision on Kapruvia® (difelikefalin) in the second quarter of 2022
- Report Oral KORSUVA (difelikefalin) Phase 2 top-line data in NP in the second quarter of 2022
- Report Oral KORSUVA (difelikefalin) Phase 2 top-line data in PBC in the second half of 2022

Upcoming Meeting Activities:

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

- American Academy of Dermatology Annual Meeting, March 25-29, 2022
- National Kidney Foundation Spring Clinical Meeting, April 6-10, 2022
- Needham 21st Annual Healthcare Conference, April 11-14, 2022

Virtual R&D Event

As previously announced, the Company will be hosting a virtual R&D event at 1:00 pm ET on March 11, 2022, which will focus on the initiation of Oral KORSUVA (difelikefalin) Phase 3 programs for the treatment of pruritus in patients with non-dialysis dependent advanced CKD and AD. An interactive Q&A session will follow the presentation. Presenters will include:

- Christopher Posner, President & Chief Executive Officer and Director of Cara Therapeutics
- Joana Goncalves, MD, Chief Medical Officer of Cara Therapeutics
- Brian Kim, MD, MTR, Icahn School of Medicine at Mount Sinai, NY
- Jonathan Silverberg, MD, PhD, MPH, George Washington University School of Medicine and Health Sciences

A live audio webcast of the presentation and accompanying slides will be accessible under "Events & Presentations" in the News & Investors section of the Company's website at www.CaraTherapeutics.com. A replay of the webcast will be archived on the Company's website following the presentation.

Fourth Quarter and Full Year 2021 Financial Results

Cash, cash equivalents and marketable securities at December 31, 2021 totaled $236.8 million compared to $251.5 million at December 31, 2020. The decrease in the balance primarily resulted from $60.1 million of cash used in operating activities partially offset by $65 million of milestone payments received from Vifor and Vifor Fresenius Medical Care Renal Pharma Ltd (VFMCRP) upon the FDA approval of KORSUVA injection, of which $20 million was recorded as revenue.

For the fourth quarter of 2021, net loss was $33.4 million, or $(0.63) per basic and diluted share, compared to net income of $78.9 million, or $1.60 per basic and $1.59 per diluted share, for the same period in 2020.

Revenues: Total revenue was $0.8 million for the three months ended December 31, 2021, compared to $112.1 million during the same period of 2020. Total revenue primarily consisted of:

- $112.1 million of license and milestone fees revenue for the three months ended December 31, 2020, of which $111.6 million related to the license agreement with Vifor and $0.5 million related to the license agreement with VFMCRP. There was no license and milestone fees revenue for the three months ended December 31, 2021.

- $0.7 million of commercial supply revenue related to our sales of KORSUVA injection to Vifor Pharma for the three months ended December 31, 2021. There was no commercial supply revenue for the same period in 2020.

Research and Development (R&D) Expenses: R&D expenses were $22.8 million for the three months ended December 31, 2021 compared to $27.1 million in the same period of 2020. The lower R&D expenses in 2021 were principally due to a decrease in costs associated with clinical trials, and decreases in payroll and related costs, partially offset by $5.0 million in milestones earned by Enteris during the three months ended December 31, 2021 as compared to $2.5 million during the same period of 2020.

General and Administrative (G&A) Expenses: G&A expenses were $11.5 million for the three months ended December 31, 2021 compared to $6.7 million in the same period of 2020. The higher G&A expenses in 2021 were principally due to increases in stock-based compensation expense, which includes $5.1 million of incremental expense relating to the modification of our former CEO's equity awards in November 2021, payroll costs, legal fees, and insurance costs, partially offset by decreases in consultants' costs and commercial costs.

Other Income, net: Other income, net was $0.1 million for the three months ended December 31, 2021 compared to $0.4 million in the same period of 2020. The decrease in other income, net was primarily due to an increase in net amortization expense of available-for-sale marketable securities for the three months ended December 31, 2021 and realized gains on our sales of available-for-sale marketable securities during the three months ended December 31, 2020.

For the full year ended December 31, 2021, net loss was $88.4 million, or $(1.74) per basic and diluted share, compared to net income of $8.4 million, or $0.18 per basic and diluted share for the full year ended December 31, 2020.

Revenues: Total revenue was $23.0 million for the full year ended December 31, 2021, compared to $135.1 million for the full year ended December 31, 2020. Total revenue primarily consisted of:

- $20.0 million of license and milestone fees revenue for the year ended December 31, 2021 was related to milestone payments we earned upon the regulatory approval of KORSUVA injection in August 2021 from (1) $15 million from VFMCRP and (2) $5 million from Vifor (the $5 million related to premium paid by Vifor for their $50 million stock purchase). We recognized $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 our license agreement with Chong Kun Dang Pharmaceutical Corp.

- $1.9 million of revenue for the year ended December 31, 2021 that we earned in January 2021 from Maruishi's first initiation of a Phase 3 trial for uremic pruritus in Japan under the Maruishi Agreement.

- $0.7 million of commercial supply revenue related to our sales of KORSUVA injection to Vifor for the year ended December 31, 2021. There was no commercial supply revenue for the year ended December 31, 2020.

Research and Development (R&D) Expenses: R&D expenses were $82.7 million for the full year ended December 31, 2021 compared to $107.9 million for the full year ended December 31, 2020. The lower R&D expenses in 2021 were principally due to a decrease in clinical trial costs and related consultant costs, partially offset by $15.0 million in milestones earned by Enteris during the year ended December 31, 2021 as compared to $5.0 million during the same period in 2020, increases in stock-based compensation expense, and payroll and related costs.

General and Administrative (G&A) Expenses: G&A expenses were $29.4 million for the full year ended December 31, 2021 compared to $21.8 million for the full year ended December 31, 2020. The increase in 2021 was primarily due to increases in stock-based compensation expense, which includes $5.1 million of incremental stock-based compensation expense relating to the modification of our former CEO's equity awards in November 2021, payroll and related costs, legal fees, and insurance costs, partially offset by decreases in consultants' costs and commercial costs.

Other Income, net: Other income, net was approximately $0.6 million for the full year ended December 31, 2021 compared to $2.3 million for the full year ended December 31, 2020. The decrease was primarily due to a decrease in interest income and an increase in net amortization expense of available-for-sale marketable securities.

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, 2021 will be sufficient to fund its currently anticipated operating expenses and capital requirements through 2023, without giving effect to any potential milestone payments under existing collaborations or product revenue from the commercialization of KORSUVA injection.

Conference Call

Cara management will host a conference call today at 4:30 p.m. ET to discuss fourth quarter and full year 2021 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 1891805. 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 an early commercial-stage biopharmaceutical company leading a new treatment paradigm to improve the lives of patients suffering from pruritus. The Company's novel KORSUVA ™ (difelikefalin) injection is the first and only FDA-approved treatment for moderate-to-severe pruritus associated with chronic kidney disease in adults undergoing hemodialysis. The Company is developing an oral formulation of difelikefalin and plans to initiate Phase 3 programs in the first quarter of 2022 for the treatment of pruritus in patients with non-dialysis dependent advanced chronic kidney disease and atopic dermatitis. Phase 2 trials of Oral KORSUVA (difelikefalin) are ongoing in primary biliary cholangitis and notalgia paresthetica patients with moderate-to-severe pruritus. For more information, visit www.CaraTherapeutics.com and follow the company on Twitter, LinkedIn and Instagram.

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 Company's ability to successfully commercialize KORSUVA injection, including the timing of the product launch, planned future regulatory submissions and potential future regulatory approvals, the Company's ability to obtain and maintain coverage and adequate reimbursement for KORSUVA injection, the performance of our commercial partners, including Vifor Pharma, expected timing of the initiation, enrollment and data readouts from the Company's planned and ongoing clinical trials, the potential results of ongoing clinical trials, timing of future regulatory and development milestones for 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 commercial launch, 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.
BALANCE SHEETS
(in thousands)
(unaudited)

	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 13,453	$ 31,683
Marketable securities	153,582	149,242
Income tax receivable	697	1,507
Other receivables	455	557
Inventory, net	2,584	-
Prepaid expenses	2,519	12,076
Total current assets	173,290	195,065
Operating lease right-of-use assets	2,973	4,279
Marketable securities, non-current	69,754	70,565
Property and equipment, net	631	840
Restricted cash	408	408
Total assets	$ 247,056	$ 271,157
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 15,861	$ 16,881
Operating lease liabilities, current	1,755	1,602
Total current liabilities	17,616	18,483
Operating lease liabilities, non-current	1,918	3,673
Commitments and contingencies	-	-
Stockholders' equity:		
Preferred stock	-	-
Common stock	53	50
Additional paid-in capital	708,585	641,195
Accumulated deficit	(480,758)	(392,317)
Accumulated other comprehensive (loss) income	(358)	73
Total stockholders' equity	227,522	249,001
Total liabilities and stockholders' equity	$ 247,056	$ 271,157

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,	
	2021	2020	2021	2020
Revenue:				
License and milestone fees	-	$ 112,062	$ 21,223	$ 134,439
Collaborative revenue	-	-	706	-
Commercial supply revenue	701	-	701	-
Clinical compound revenue	120	27	398	643
Total revenue	821	112,089	23,028	135,082
Operating expenses:				
Research and development	22,831	27,140	82,701	107,851
General and administrative	11,512	6,659	29,410	21,846
Total operating expenses	34,343	33,799	112,111	129,697
Operating (loss) income	(33,522)	78,290	(89,083)	5,385

Other income, net	140	364	642	2,334
(Loss) income before income tax benefit	(33,382)	78,654	(88,441)	7,719
Income tax benefit	-	255	-	691
Net (loss) income	$ (33,382)	$ 78,909	$ (88,441)	$ 8,410
Net (loss) income per share:				
Basic	$ (0.63)	$ 1.60	$ (1.74)	$ 0.18
Diluted	$ (0.63)	$ 1.59	$ (1.74)	$ 0.18
Weighted average shares:				
Basic	52,757,808	49,228,774	50,718,765	47,413,250
Diluted	52,757,808	49,701,864	50,718,765	47,915,030

MEDIA CONTACT:
Annie Spinetta
6 Degrees
973-768-2170
aspinetta@6degreespr.com

INVESTOR CONTACT:
Iris Francesconi, Ph.D.
Cara Therapeutics
203-406-3700
investor@caratherapeutics.com

Source: Cara Therapeutics, Inc.