Cidara Therapeutics Provides Corporate Update and Reports Fourth Quarter and Full Year 2021 Financial Results

March 7, 2022

SAN DIEGO, March 07, 2022 (GLOBE NEWSWIRE) -- Cidara Therapeutics, Inc. (NASDAQ: CDTX), a biotechnology company developing long-acting therapeutics designed to improve the standard of care for patients facing serious diseases, today reported financial results for the three months and full year ended December 31, 2021 and provided an update on its corporate activities and product pipeline.

"We made significant progress on several key initiatives during the fourth quarter," said Jeffrey Stein, Ph.D., president and chief executive officer of Cidara. "Of particular note is our December 2021 announcement of positive topline results from our pivotal ReSTORE Phase 3 clinical trial of rezafungin as a potential first-line treatment for candidemia and invasive candidiasis, which, combined with the data from the previously completed STRIVE trial, we expect will form the basis of a New Drug Application (NDA) filing with the U.S. Food and Drug Administration (FDA) and other regulators outside of the U.S. in mid-2022."

Dr. Stein continued, "In addition, we announced in February 2022 that the FDA had accepted Cidara's Investigational New Drug Application (IND) for our lead influenza drug-FC conjugate (DFC), CD388. This represents a significant milestone for our Cloudbreak program, which we anticipate will allow us to advance CD388 into the clinic this quarter."

Recent Corporate Highlights

- **Announced FDA acceptance of IND for CD388:** In February 2022, Cidara announced that the FDA has accepted Cidara's IND for its lead flu DFC, CD388, which is being developed in collaboration with Janssen. Cidara intends to initiate a Phase 1 study in healthy volunteers before the end of the current quarter. Janssen will fund the Phase 1 trial-related development costs and all future research, development, manufacturing and commercialization for CD388. Later this year, Cidara expects the availability of new preclinical data for other antiviral DFCs, including RSV and SARS, as well as preclinical data for its oncology DFCs directed against solid tumors.

- **Announced positive topline results for rezafungin:** In December 2021, Cidara and Mundipharma announced positive topline data from the pivotal ReSTORE Phase 3 clinical trial evaluating the efficacy and safety of its once-weekly antifungal candidate rezafungin as a potential first-line treatment for candidemia and invasive candidiasis. Rezafungin met the primary endpoint for the FDA NDA submission of all-cause mortality at Day 30, and also met the primary endpoint for the European Medicines Agency (EMA) Marketing Authorization Application (MAA) of submission of global cure at Day 14. Both results demonstrated statistical non-inferiority of rezafungin dosed once-weekly, versus caspofungin dosed once-daily, the current standard of care. Rezafungin was generally well tolerated and had a similar safety profile to caspofungin.

  Based on the positive topline results of the ReSTORE trial, Cidara intends to file an NDA for rezafungin for the treatment of candidemia and/or invasive candidiasis with the FDA, and similar applications with other regulators outside the U.S., in mid-2022.

  In addition, integrated results from both the Phase 3 ReSTORE trial and the Phase 2 STRIVE trial across all patients who received the 400mg / 200mg dosing regimen showed improved outcomes as compared to caspofungin across several key measures:

  – All-cause mortality at Day 30, the primary endpoint for the FDA, was 18.7% for rezafungin and 19.4% for caspofungin.

  – Mycological eradication at Day 5 and Day 14 was 73.4% and 71.9%, respectively, for rezafungin and 64.5% and 68.4%, respectively, for caspofungin.

  – Mycological eradication at Day 5 for patients with candidemia only was 80.0% for rezafungin and 67.8% for caspofungin.

  – Patients receiving rezafungin had faster median time to negative blood culture (22.3 days) compared to caspofungin (26.3 days).

- **Held pre-NDA discussions with the FDA:** Following recent positive pre-NDA discussions with the FDA about Cidara's clinical and nonclinical data package, Cidara remains on track to file its NDA for rezafungin for the treatment of candidemia and/or candidiasis in mid-2022.

- **Announced granting of Promising Innovation Medicine designation for rezafungin:** In March 2022, Cidara and

Mundipharma announced that the Medicines and Healthcare Products Regulatory Agency (MHRA) in the UK has granted rezafungin the Promising Innovative Medicine (PIM) designation for the treatment of invasive candidiasis, which permits the use of medicines not yet approved by the relevant regulatory authorities.

- **Named San Diego Metro Area Top Workplace:** In November 2021, Cidara was named a Top Workplace by The San Diego Union-Tribune for the fifth consecutive year, ranking among the top 100 companies.

- **Raised $38.5 million in equity sales:** In October 2021, Cidara sold and issued 17,064,511 shares of its common stock and 744,194 shares of its Series X Convertible Preferred stock in two concurrent but separate underwritten public offerings. The gross proceeds to Cidara from these offerings, before deducting underwriting discounts and commissions and estimated offering expenses, were approximately $38.5 million.

Fourth Quarter and Full Year 2021 Financial Results

- Revenue totaled $7.2 million and $49.6 million for the three months and full year ended December 31, 2021, respectively, compared with $3.7 million and $12.1 million for the same periods in 2020.

- Cash, cash equivalents and restricted cash totaled $62.3 million as of December 31, 2021, compared with $42.9 million as of December 31, 2020.

- As of December 31, 2021, Cidara had 67,863,674 shares of common stock outstanding, and 1,818,472 shares of Series X Convertible Preferred Stock outstanding, which are convertible into 18,184,720 shares of common stock.

- Research and development expenses were $19.0 million and $73.1 million for the three months and full year ended December 31, 2021, respectively, compared to $21.1 million and $68.0 million for the same periods in 2020. The increase in research and development expenses for the full year ended December 31, 2021 compared to the full year ended December 31, 2020 is primarily due to increased expense associated with Cidara's Cloudbreak platform and higher personnel costs.

- General and administrative expenses were $5.0 million and $18.7 million for the three months and full year ended December 31, 2021, respectively, compared to $4.1 million and $15.9 million for the same periods in 2020. The increase in general and administrative expenses is primarily due to higher consulting, legal, and personnel costs.

- Net loss for the three months ended December 31, 2021 was $16.8 million, compared to a net loss of $21.6 million for the fourth quarter of 2020. Net loss for the full year ended December 31, 2021 was $42.5 million, compared to a net loss of $72.1 million for the year ended December 31, 2020.

About Cidara Therapeutics

Cidara is developing long-acting therapeutics designed to improve the standard of care for patients facing serious diseases. The Company's portfolio is comprised of new approaches aimed at transforming existing treatment and prevention paradigms, first with its lead Phase 3 antifungal candidate, rezafungin, in addition to DFCs targeting viral and oncology diseases from Cidara's proprietary Cloudbreak ® platform. Cidara is headquartered in San Diego, California. For more information, please visit www.cidara.com.

Forward-Looking Statements

This release contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and such forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. "Forward-looking statements" describe future expectations, plans, results, or strategies and are generally preceded by words such as "anticipates," "expect," "intend," "may," "plan" or "will". Forward-looking statements in this release include, but are not limited to, statements related to our therapeutics potential to improve the standard of care for patients facing serious diseases; our expectations that the ReSTORE trial and STRIVE trial data will support an NDA submission in the U.S. and similar marketing authorization submissions in other countries; the potential timing of such submissions; the likelihood that rezafungin, if approved, will be prescribed by physicians or included in formularies or treatment guidelines; whether we will be able to advance CD388 into clinical studies and complete a Phase 1 clinical study of CD388; the potential timing of and funding for such studies; and the availability and timing of new preclinical data for other antiviral and oncology DFCs. Such statements are subject to a multitude of risks and uncertainties that could cause future circumstances, events, or results to differ materially from those projected in the forward-looking statements, such as unanticipated delays in or negative results from Cidara's pre-clinical or clinical trials, delays in action by regulatory authorities due to limitations on inspections and other COVID-19-related effects, and impacts of the COVID-19 pandemic or other obstacles on the enrollment of patients or other aspects of rezafungin development. These and other risks are identified under the caption "Risk Factors" in Cidara's Annual Report on Form 10-K for the fiscal year ended December 31, 2021 and other filings subsequently made with 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 and are based on management's assumptions and estimates as of such date. Cidara does not undertake any obligation to publicly update any forward-looking statements, whether as a result of the receipt of new information, the occurrence of future events or otherwise.

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CIDARA THERAPEUTICS, INC.
Condensed Consolidated Statements of Operations

	Three months ended December 31,		Year ended December 31,	
(In thousands, except share and per share data)	**2021**	**2020**	**2021**	**2020**
Revenues:	**(unaudited)**			
Collaboration revenue	$ 7,225	$ 3,729	$ 49,572	$ 12,067
Total revenues	7,225	3,729	49,572	12,067
Operating expenses:				
Research and development	19,013	21,129	73,087	68,017
General and administrative	4,982	4,148	18,740	15,899
Total operating expenses	23,995	25,277	91,827	83,916
Loss from operations	(16,770)	(21,548)	(42,255)	(71,849)
Other expense:				
Interest expense, net	(33)	(86)	(212)	(262)
Total other expense	(33)	(86)	(212)	(262)
Net loss and comprehensive loss	(16,803)	(21,634)	(42,467)	(72,111)
Recognition of beneficial conversion feature	—	—	—	(2,762)
Net loss attributable to common shareholders	$ (16,803)	$ (21,634)	$ (42,467)	$ (74,873)
Basic and diluted net loss per common share	$ (0.26)	$ (0.49)	$ (0.81)	$ (1.80)
Shares used to compute basic and diluted net loss per common share	64,475,463	44,153,016	52,453,452	41,557,350

Condensed Consolidated Balance Sheet Data

	December 31,	
	2021	**2020**
(In thousands)		
Cash, cash equivalents, and restricted cash	$ 62,273	$ 42,949
Total assets	75,325	60,424
Term loan	2,591	7,023
Total liabilities	53,752	49,709
Total stockholders' equity	21,573	10,715