



## Cidara Provides Corporate Update and Reports Third Quarter 2017 Financial Results

November 8, 2017

**Conference call and webcast today at 1:05 p.m. PST/4:05 p.m. EST**

SAN DIEGO, Nov. 08, 2017 (GLOBE NEWSWIRE) -- Cidara Therapeutics, Inc. (Nasdaq:CDTX), a biotechnology company developing novel anti-infectives including immunotherapies, today reported financial results for the three months ended September 30, 2017 and provided an update on its corporate activities and product pipeline.

"We are pleased to report Cidara's continued progress during the third quarter of 2017 and subsequently, including receiving clarity on the regulatory path for our planned Phase 3 programs in treatment and prophylaxis for rezafungin acetate, which is our new non-proprietary name for CD101," said Jeffrey Stein, Ph.D., president and chief executive officer of Cidara. "With topline results from our STRIVE Phase 2 trial for rezafungin in candidemia and invasive candidiasis expected in the first quarter of 2018, coupled with a strengthened cash position after our October PIPE financing, we are a step closer to realizing the potential for rezafungin to improve patients' lives and to generate value for our stockholders."

### Rezafungin Program Update

#### ***Rezafungin (formerly known as CD101) treatment program***

- The company is completing enrollment of the 90-patient Phase 2 clinical trial of rezafungin called the STRIVE trial. Topline data are expected in the first quarter of 2018.
- Cidara recently received feedback from the U.S. Food and Drug Administration, or FDA, that the results of the STRIVE trial, along with those of a single Phase 3 trial with a non-inferiority margin of 20%, will provide efficacy data supportive of registration of rezafungin for the treatment of candidemia and invasive candidiasis in the U.S., assuming positive results. As a result, pending final results from the STRIVE trial, and subject to feedback from European regulators, the company plans to conduct a single, randomized, double-blind, controlled Phase 3 pivotal clinical trial in approximately 150 patients. The global Phase 3 trial is expected to begin in mid-2018, with topline data expected in mid-2020.
- With this Phase 3 trial size, Cidara estimates that the total number of patients exposed to the selected dose and duration of rezafungin treatment from the combined treatment program will be less than the target safety database of 300 patients for a New Drug Application filing. For this reason, as well as to maintain enrollment momentum before the start of the Phase 3 trial, the company intends to continue enrollment at STRIVE trial sites after database lock. This continuation of the STRIVE trial, which is called STRIVE Part B, will evaluate the dose selected from the STRIVE trial in comparison to caspofungin in a 2:1 randomization regime.

#### ***Rezafungin prophylaxis program***

- Cidara believes there is significant unmet medical need for a safe and well tolerated agent with the spectrum of rezafungin in the prevention of fungal infections in vulnerable patients, including those undergoing bone marrow or solid organ transplant or patients with hematologic malignancies undergoing chemotherapy. The company has conducted preclinical studies demonstrating the efficacy of rezafungin in preventing *Candida*, *Aspergillus* and *Pneumocystis* infections in neutropenic animals. Based on these studies and in conjunction with clinical safety, tolerability and pharmacokinetic data, the company believes that once-weekly rezafungin could be an effective and well-tolerated prophylactic agent for invasive fungal infections in at-risk patients.
- Based on FDA and MHRA feedback the company has received to date, and subject to further European regulatory feedback and financial resources, Cidara plans to conduct a single, global, randomized, double-blind, controlled Phase 3 pivotal clinical trial of a 90-day prophylaxis regimen of rezafungin in patients undergoing allogeneic bone marrow transplant. Subject to further regulatory discussions, the company believes that this trial could start in mid-2018 and produce topline results in mid-2020.
- Based on interactions with the FDA and the MHRA, Cidara believes that its planned Phase 3 trial in prophylaxis, supported by the data from its planned Phase 3 clinical trial in the treatment of candidemia and invasive candidiasis and the remainder of its rezafungin treatment program, could suffice for approval of rezafungin for both prophylaxis and treatment of invasive fungal infections.

#### ***Non-proprietary name***

- CD101 has been granted the international non-proprietary name, or INN, "rezafungin acetate" by the World Health

Organization. The USAN Council has also approved this name as the United States Adopted Name, or USAN, for CD101.

#### Other Third Quarter 2017 and Subsequent Highlights

- **Successfully completed private placement of common stock:** In October 2017, Cidara announced the pricing of a private placement of 3,360,000 shares of its common stock at a price of \$6.00 per share. The syndicate of investors in the private placement was comprised of new and existing investors. The gross proceeds to Cidara from the private placement were approximately \$20 million.
- **Presented data at ID Week and Mycology infectious disease meetings highlighting the unique attributes of rezafungin:** In October 2017, Cidara presented preclinical data in six presentations at ID Week 2017 in San Diego and at the 8<sup>th</sup> Trends in Medical Mycology meeting in Belgrade. The data showcased potential advantages of rezafungin, including: *in vivo* activity against emerging resistant organisms; high target attainment and exposure to treat less susceptible pathogens; superior tissue penetration compared to micafungin; and biofilm activity.
- **Partnered with T2 Biosystems to support rezafungin drug trials:** In September 2017, Cidara announced an exclusive pricing program for the commercial placement of T2Dx Instruments. The preferred pricing structure will be exclusive to Cidara's clinical trial sites. The program is designed to accelerate enrollment in clinical trials evaluating rezafungin.
- **Published data from a study investigating the deep tissue distribution of rezafungin:** In August 2017, Cidara announced publication of data from an *in vivo* study demonstrating that rezafungin had superior tissue penetration within the site of infection compared to the current standard of care echinocandin in the U.S., micafungin, in intra-abdominal candidiasis (IAC) infections, one of the most lethal forms of invasive candidiasis. See [www.cidara.com/publications](http://www.cidara.com/publications).

#### Third Quarter 2017 Financial Results

- Cash, cash equivalents and short-term investments totaled \$64.2 million as of September 30, 2017, compared with \$78.0 million as of June 30, 2017 and \$104.6 million as of December 31, 2016. This does not include the gross proceeds of approximately \$20 million from the private placement completed in October 2017.
- Research and development expenses were \$9.2 million and \$32.6 million for the three and nine months ended September 30, 2017, respectively, compared to \$8.7 million and \$24.4 million for the same periods in 2016. The increases were primarily attributable to the escalation of clinical development activities for rezafungin.
- General and administrative expenses were \$3.1 million and \$9.7 million for the three and nine months ended September 30, 2017, compared to \$3.6 million and \$9.7 million for the same periods in 2016.
- Net loss for the three months ended September 30, 2017 was \$12.3 million, compared to a net loss of \$12.2 million for the third quarter of 2016. For the nine months ended September 30, 2017 and 2016, the company's net loss was \$42.3 million and \$33.8 million, respectively.
- As of October 31, 2017, Cidara had 20,238,143 common shares outstanding.

#### Webcast and Conference Call

Cidara management will host a webcast and conference call regarding this announcement at 4:05 p.m. EST/1:05 p.m. PST today. The live call may be accessed by dialing 844-358-8763 for domestic callers, or 703-736-7375 for international callers, using conference ID # 2899958. A live webcast of the call will be available online in the investor relations section of Cidara's website at [www.cidara.com](http://www.cidara.com) and will be archived there for 30 days.

#### About Cidara Therapeutics

Cidara is a clinical-stage biotechnology company focused on developing new anti-infectives that have the potential to transform the standard of care and save or improve patients' lives. The company is currently advancing its novel echinocandin antifungal, rezafungin acetate, through Phase 2 and developing CD201, its bispecific antibiotic immunotherapy, for the treatment of multi-drug resistant Gram-negative bacterial infections. Rezafungin has improved pharmacokinetics compared to existing echinocandins and has the potential for expanded utility across patient settings. Rezafungin is the only once-weekly product candidate in development for the treatment and prevention of life-threatening invasive fungal infections. CD201 is the first drug candidate selected from Cidara's novel Cloudbreak™ platform, the first immunotherapy discovery platform designed specifically to create compounds that directly kill bacterial, fungal or viral pathogens and also direct a patient's immune cells to attack and eliminate such pathogens. Cidara has received a grant for up to \$6.9 million from CARB-X (Combating Antibiotic Resistant Bacteria Accelerator) to advance the development of CD201 and back-up candidates. Cidara is headquartered in San Diego, California. For more information, please visit [www.cidara.com](http://www.cidara.com).

#### 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. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to, statements regarding the

effectiveness, safety, and other attributes of rezafungin and CD201 and other potential product candidates, including the potential for these compounds to successfully treat or prevent infections, including those caused by resistant pathogens, and potentially transform the way infectious diseases are treated, the design and timing of rezafungin Phase 3 clinical trials, and the potential for the Cloudbreak platform to result in future drug candidates. Risks that contribute to the uncertain nature of the forward-looking statements include: the success and timing of Cidara's preclinical studies and clinical trials; regulatory developments in the United States and foreign countries; changes in Cidara's plans to develop and commercialize its product candidates; Cidara's ability to obtain additional financing; Cidara's ability to obtain and maintain intellectual property protection for its product candidates; and the loss of key scientific or management personnel. These and other risks and uncertainties are described more fully in Cidara's Form 10-Q most recently filed with the United States Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. Cidara undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

**Cidara Therapeutics, Inc.**  
**Condensed Consolidated Balance Sheets**

<b>(In thousands)</b>	<b>September 30, 2017</b>	<b>December 31, 2016</b>
	<b>(unaudited)</b>	
<b>ASSETS</b>		
Cash, cash equivalents, and short-term investments	\$ 64,152	\$ 104,619
Other current assets	2,051	779
Non-current assets	1,233	1,564
Total assets	<u>\$ 67,436</u>	<u>\$ 106,962</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Total liabilities	\$ 16,863	\$ 18,783
Stockholders' equity	50,573	88,179
Total liabilities and stockholders' equity	<u>\$ 67,436</u>	<u>\$ 106,962</u>

**Cidara Therapeutics, Inc.**  
**Condensed Consolidated Statements of Operations**  
**(unaudited)**

<b>(In thousands, except share and per share data)</b>	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2017</b>	<b>2016</b>	<b>2017</b>	<b>2016</b>
Operating expenses:				
Research and development	\$ 9,159	\$ 8,729	\$ 32,593	\$ 24,389
General and administrative	3,090	3,607	9,669	9,694
Total operating expenses	<u>12,249</u>	<u>12,336</u>	<u>42,262</u>	<u>34,083</u>
Loss from operations	(12,249)	(12,336)	(42,262)	(34,083)
Other income (expense):				
Interest income (expense), net	(8)	109	(38)	312
Total other income (expense)	<u>(8)</u>	<u>109</u>	<u>(38)</u>	<u>312</u>
Net loss	<u>\$ (12,257)</u>	<u>\$ (12,227)</u>	<u>\$ (42,300)</u>	<u>\$ (33,771)</u>
Basic and diluted net loss per share	<u>\$ (0.73)</u>	<u>\$ (0.88)</u>	<u>\$ (2.51)</u>	<u>\$ (2.44)</u>
Shares used to compute basic and diluted net loss per share	<u>16,864,211</u>	<u>13,910,145</u>	<u>16,830,749</u>	<u>13,863,453</u>

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