Cidara Therapeutics Highlights New Data from Multiple Rezafungin Studies Presented at ECCMID 2019

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Data featured in three oral and five poster presentations reinforce potential of novel antifungal for the treatment and prevention of serious invasive infections

SAN DIEGO--(BUSINESS WIRE)--Apr. 16, 2019-- Cidara Therapeutics, Inc. (Nasdaq: CDTX), a biotechnology company developing novel anti-infectives including immunotherapies, highlighted new data from multiple studies of rezafungin, the company's lead investigational compound, this week during the 29th European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) in Amsterdam, Netherlands. Rezafungin is the only once-weekly product candidate in development for the treatment and prevention of life-threatening invasive fungal infections.

Three oral presentations at ECCMID showcased results from nonclinical and *in vivo* studies that demonstrate the potential of rezafungin to fight and protect against difficult-to-treat fungal infections. Additionally, researchers presented five rezafungin posters at the meeting, including new analyses from Cidara's Phase 2 STRIVE trial investigating rezafungin for the treatment of candidemia and invasive candidiasis.

"Collectively, the data presented at ECCMID this year underscore our commitment to developing rezafungin to its full potential in multiple, serious infections where there is urgent need for innovation. We are particularly excited by new data from *in vivo* studies that demonstrated rezafungin efficacy in prevention of *Pneumocystis* infection as well as in treatment of intra-abdominal *Candida* infections," said Jeffrey Stein, Ph.D., president and chief executive officer of Cidara. "We look forward to continuing our clinical development of rezafungin as we progress our global Phase 3 ReSTORE treatment trial and plan for initiation of the Phase 3 ReSPECT prophylaxis trial."

Overall, the rezafungin presentations at ECCMID demonstrate the novel agent's potent antifungal activity and distinct pharmacokinetic and pharmacodynamic profile that together provide for prolonged drug exposure and stable, long-acting efficacy. In addition, analyses of STRIVE study data reinforce rezafungin's broad efficacy, safety and reliability across a variety of patient populations, including those with impaired renal function.

"The data presented at ECCMID provide further evidence of the potential safety and efficacy of rezafungin as a novel once-weekly antifungal for the treatment and prevention of invasive fungal infections, which are particularly pervasive in immunocompromised patients," said Juan P. Horcajada, M.D., Ph.D., chief of the Department of Infectious Diseases, coordinator of the Infection Control Program and president of the Infection Control Committee at Hospital del Mar, in Barcelona, Spain. "Current strategies for treating and preventing these infections have significant limitations, including toxicity and tolerability issues, drug-to-drug interactions, and increasing resistance, all of which complicate therapy in patients who are often already very ill and on multiple medications. Rezafungin could provide a much needed, new and effective option. Moreover, once-weekly administration makes a difference for the practical management of most patients."

Key findings from the three rezafungin ECCMID oral presentations are summarized below.

Title: Rezafungin is more effective than micafungin in treating FKS-mutant *Candida glabrata* intra-abdominal candidiasis: This study compared the *in vivo* activity of rezafungin to micafungin in an intra-abdominal candidiasis (IAC) infection model. Researchers concluded that rezafungin achieved greater and more prolonged penetration at the sites of IAC than the standard-of-care therapy micafungin, which correlated with significantly greater rezafungin activity against *FKS* mutant *Candida glabrata*, a species known to harbor multidrug resistance. Rezafungin also demonstrated greater effectiveness with once-weekly dosing than with micafungin dosed once daily, supporting the potential for extended dosing intervals in patients, and the potential of rezafungin as a treatment and a prophylactic agent against IAC.

Title: Rezafungin PK/PD in a mouse model of *Pneumocystis* pneumonia: This presentation highlighted results from two *in vivo* studies of rezafungin as prophylaxis in a mouse model of *Pneumocystis* pneumonia (PCP). Based on the study findings, researchers concluded that exposures of rezafungin needed for PCP prophylaxis will be achieved in most patients (≥ 90%) with doses as low as 50 mg per week. This finding supports the dose-selection rationale of rezafungin for PCP prophylaxis and also highlights the benefits of the front-loaded drug exposure curve of rezafungin versus a conventional daily exposure curve.

Title: EUCAST susceptibility testing of rezafungin: MIC data for contemporary Danish clinical yeast isolates: Using the EUCAST susceptibility testing model, this study evaluated the *in vitro* activity of rezafungin and comparators (anidulafungin, micafungin, amphotericin B, voriconazole and fluconazole) against 404 Danish clinical yeast isolates, including common *Candida* spp. isolates and isolates with non-wild-type minimum inhibitory concentration (MIC) values. The study showed that resistant isolates to rezafungin were rare and less frequent as compared to the other drugs. These results contribute to the EUCAST-based international *in vitro* surveillance MIC dataset for rezafungin and support its ongoing clinical development for the treatment of candidemia and invasive candidiasis.

Cidara also presented new analyses of the Phase 2 STRIVE data at ECCMID. STRIVE was an international, multicenter, double-blind, trial evaluating the safety, tolerability and efficacy of once-weekly intravenous (IV) dosing of rezafungin compared to once-daily dosing of caspofungin in patients with candidemia and/or invasive candidiasis (IC). Findings from these poster presentations are summarized below.

Title: Phase II STRIVE clinical trial of rezafungin for the treatment of candidemia and/or invasive candidiasis: results stratified by baseline renal function: This presentation highlights results from an analysis of the completed Part A of the STRIVE trial, in which researchers stratified patients treated with rezafungin by baseline renal function and classified them into the following categories: those with creatinine clearance (CrCl, normalized for body surface area) ≥60 mL/min/1.73 m^2 and those with CrCl <60 mL/min/1.73 m^2. Researchers evaluated data for differences in safety, efficacy, or pharmacokinetics between renal categories. The analysis found no meaningful trends in outcomes based on renal function, suggesting renal elimination is not an important route of rezafungin clearance.

Title: Outcomes in Europe from the STRIVE clinical trial of rezafungin treatment of candidemia and/or invasive candidiasis: In this analysis,

researchers stratified data from the completed Part A of STRIVE by enrollment region (Europe, N=62; North America [NA], N=45) and analyzed respective patient demographics and baseline characteristics, treatment patterns, and outcomes. The STRIVE population in Europe was generally older and more homogeneous (mean age, 63.7 years; 96.8% white) than in North America (mean age, 50.7 years; 64.4% white, 26.7% Black or African-American, 4.4% Asian). Patients in Europe - on average - also had lower BMI and higher rates of infections caused by non-albicans *Candida*. Based on the analyses, researchers concluded that there were no differentiating trends by geographic region in terms of severity of illness or efficacy outcomes.

All rezafungin abstracts can be accessed through the ECCMID website: www.eccmid.org. Following the meeting, the presentation slides and posters will be available on the Cidara website: www.cidara.com.

About Rezafungin

Rezafungin, currently in Phase 3 testing, is a novel antifungal echinocandin being developed as a once-weekly, high-exposure therapy for the treatment and prevention of serious invasive fungal infections. Rezafungin has a unique pharmacokinetic profile with a prolonged half-life and front-loaded plasma exposure which, in contrast to all other echinocandins, allows for once-weekly IV therapy. Rezafungin is being developed to address unmet needs in the treatment of candidemia and invasive candidiasis as well as for prophylaxis (prevention) of invasive fungal infections in patients undergoing allogeneic blood and marrow transplantation.

About Invasive Fungal Infections

Invasive fungal infections (IFIs) represent a serious global health threat, resulting in more than 1.5 million deaths annually and mortality rates ranging from 15 to 65 percent. These infections are especially relevant for patients whose immune systems have been compromised, such as patients undergoing organ or blood and marrow transplantation or chemotherapy, including patients with hematologic malignancies. Of the most significant IFIs, approximately 90 percent of related deaths are primarily caused by *Candida, Aspergillus*, and *Pneumocystis*. *Candida* species are most common in hospital-acquired infections, while *Aspergillus* species are predominant in patients with weakened immune systems or lung diseases. *Pneumocystis* infections also commonly afflict immunocompromised patients.

About Cidara Therapeutics

Cidara is a clinical-stage biotechnology company focused on the discovery, development and commercialization of novel anti-infectives that have the potential to transform the standard of care and save or improve patients' lives. Cidara is currently advancing its novel echinocandin antifungal, rezafungin acetate, in a Phase 3 clinical trial for the treatment of candidemia and invasive candidiasis, and continues to discuss with regulatory authorities its plans for the design and the initiation of a second Phase 3 trial in the prophylaxis of invasive fungal infections in patients undergoing allogeneic blood and marrow transplantation. Rezafungin is the only once-weekly product candidate in development for the treatment and prevention of life-threatening invasive fungal infections. Cidara also is leveraging its proprietary Cloudbreak® platform to develop antiviral conjugates (AVCs) for serious infections, including further investigation of the high potency and long half-life observed in its AVCs for influenza. The Cloudbreak platform is designed to discover compounds that both directly kill pathogens and direct a patient's immune system to attack and eliminate pathogens. Cidara is headquartered in San Diego, California. For more information, please visit 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, the potential for rezafungin to successfully treat or prevent invasive fungal infections and represent an improvement over current approaches, the potential for rezafungin in high-risk patient populations and Cidara's ability to successfully develop rezafungin. 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-K 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.

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