Cidara Therapeutics Announces New Clinical and Preclinical Data for Rezafungin and Influenza AVCs from the European Congress of Clinical Microbiology and Infectious Diseases (ECCMID)

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Abstract Book highlights new data from Cidara accepted for presentation at ECCMID 2020

Phase 2 trial shows superiority of rezafungin in time to clear deadly infection

Seven abstracts highlight new data on influenza antiviral conjugates (AVCs) from Cloudbreak® antiviral platform

SAN DIEGO, May 05, 2020 (GLOBE NEWSWIRE) -- Cidara Therapeutics, Inc. (Nasdaq: CDTX), a biotechnology company developing long-acting therapeutics to transform the standard of care for patients facing serious fungal or viral infections, today announced the publication of 10 abstracts reporting new clinical and preclinical data on the Company's antifungal rezafungin program and preclinical data on its Cloudbreak® antiviral program. The abstracts are being published by the European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) in an online book of abstracts that had been accepted for presentations at ECCMID 2020, which was canceled due to the coronavirus global pandemic.

"We appreciate the decision of the ECCMID 2020 organizers to publish the abstract book to communicate important scientific results at a time when our collective efforts are focused on dealing with COVID-19," said Jeffrey Stein, Ph.D., president and chief executive officer of Cidara. "Our data accepted for ECCMID 2020 highlight critical clinical and preclinical efficacy differentiation for our programs. We also appreciate now more than ever that we need novel approaches to prevent and treat viral infections, which is the focus of our Cloudbreak antiviral platform. The seven abstracts accepted for our lead AVC, CD377, support its advancement in IND enabling studies toward our goal of providing a non-vaccine approach to universal influenza protection for all people with a single dose per flu season."

Three of the published abstracts detail new findings related to rezafungin, Cidara's novel, Phase 3, once-weekly echinocandin being developed for the treatment and prophylaxis of invasive fungal disease. Copies of the abstracts can be accessed on the Publications section of the Cidara website. Data highlights from the published abstracts on rezafungin are as follows:

- Analysis of the complete STRIVE Phase 2 trial (Parts A and B) results demonstrate that a single dose of rezafungin had a Day 5 success rate (resolution of clinical signs of infection + mycological eradication) of 62.3% versus 55.7% for the approved echinocandin comparator, caspofungin, dosed once-daily. Moreover, the time to negative blood culture in the rezafungin-treated patients was statistically faster than that in caspofungin treated patients. These findings show early efficacy of rezafungin and support front-loaded plasma exposure as a pharmacometric determinant of efficacy.
- A second analysis from Parts A and B of the STRIVE Phase 2 trial demonstrate that outcomes following treatment with rezafungin were comparable between the North American and European patients.
- Preclinical data in a rabbit model of *Candida* endophthalmitis show treatment with rezafungin significantly lowered fungal burden as compared to micafungin, an echinocandin approved for the treatment of *Candida* infection, voriconazole, an azole for the treatment of *Candida* infection, and vehicle control in multiple tissues of the eye. The rezafungin treated group was the only one to demonstrate no eye lesions following treatment.

Seven of the published abstracts detail new findings around Cidara's Cloudbreak antiviral platform candidate, CD377, for the prevention and treatment of influenza. Copies of the abstracts can be accessed on the Publications section of the Cidara website. Data highlights from the published abstracts on Cidara's lead antiviral conjugate (AVC) CD377 are as follows:

- Preclinical *in vitro* and *in vivo* data highlight CD377's tolerability and stability. CD377 was stable and intact after incubations in mouse and human plasma and human hepatocytes. In the mouse, rat, and monkey, the half-life of CD377 was five to 10 days with high bioavailability (77%) observed after subcutaneous or intramuscular administration. A two-week toxicology study in monkeys showed no adverse effect on body weight, clinical chemistry, hematology, coagulation, cytokines or urinalysis.
- Single doses of CD377 in a lethal mouse model of influenza A showed a greater decrease in lung viral burden and cytokine levels compared to oseltamivir dosed for 5 days, twice daily at 10X the human equivalent dose. Treatment with one dose of CD377 two hours post-infection resulted in a dose-dependent reduction in viral burden in the lungs four days post-infection, which correlated with a dose-dependent reduction in inflammatory cytokines.
- Additional preclinical data show that mice treated with single, low doses of CD377 are protected in lethal challenge models with several seasonal influenza subtypes. A single CD377 dose resulted in complete recovery from lethal challenge with several influenza strains.
- CD377 fully protected immune-competent and severely immunodeficient mice with similar doses in lethal influenza challenge models. Immune-competent mice treated with CD377 fully recovered by the end of the study (day 14), while vehicle mice succumbed to infection by day 6. Varying doses of CD377 protected immune-compromised mice challenged with the same virus for the duration of the 28-day study. Immune-compromised mice treated with baloxavir reached 40% mortality after 28 days.
- Preclinical *in vitro* data show lower resistance potential of CD377 compared to approved influenza treatments, baloxavir

and oseltamivir, against a pandemic strain of influenza. Over the course of 10 serial passages, there was no increase in viral titer in the presence of CD377, in contrast to a 2.5 log increase in viral titer at six and eight passages with baloxavir and oseltamivir, respectively.

- Additional preclinical *in vitro* data indicate that CD377 has potent, broad-spectrum antiviral activity encompassing seasonal, pandemic and drug resistant influenza A strains, as well as both lineages of influenza B. Its ability at a low dose to inhibit an essential enzyme on the surface of the influenza virus, neuraminidase, was superior to approved influenza treatments, oseltamivir and zanamivir, and comparable or superior to baloxavir.
- CD377 also induces, as designed, a robust immune response against cells infected with multiple strains of seasonal and pandemic influenza. CD377 induced potent induction of mechanisms of cell-mediated immune defense, antibody-dependent cellular cytotoxicity and antibody-dependent cellular phagocytosis through its Fc-mediated interaction with Fcg receptors.

The abstract book is published online and freely accessible on ECCMID's website .

About Rezafungin
Rezafungin is a novel once-weekly echinocandin being developed for both the treatment and prophylaxis of severe fungal infections, such as candidemia and invasive candidiasis. The structure and properties of rezafungin were specifically designed to improve upon a clinically validated mechanism, enhancing its efficacy and safety potential for patients. Cidara is currently conducting a Phase 3 clinical trial with rezafungin for the first-line treatment of candidemia and/or invasive candidiasis (ReSTORE trial). The Company is also advancing a second Phase 3 clinical trial of once-weekly rezafungin for prophylaxis against invasive fungal infections in patients undergoing allogeneic blood and marrow transplantation (ReSPECT trial).

About Cloudbreak AVCs
Cidara is developing a new generation of immunotherapeutic antivirals from its Cloudbreak antiviral platform that couple potent antivirals to a human antibody fragment. These long-acting, antiviral conjugates (AVCs) directly inhibit viral replication while simultaneously engaging the immune system. AVCs are initially being studied for the prevention and treatment of the seasonal and pandemic influenza, with the potential to deliver universal protection for an entire flu season with a single dose. Cidara is also advancing preclinical and discovery AVC programs to target additional life-threatening viruses, including HIV, parainfluenza, RSV and coronaviruses, including COVID-19.

About Cidara Therapeutics
Cidara is developing therapeutics to improve the standard of care for patients facing serious fungal or viral infections. The Company's portfolio is comprised of breakthrough approaches aimed at transforming existing treatment and prevention paradigms, first with its lead Phase 3 antifungal candidate, rezafungin, in addition to antiviral conjugates (AVCs) targeting influenza and other viral diseases from Cidara's proprietary Cloudbreak antiviral platform. 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, whether we can successfully develop rezafungin and differentiate it from existing therapies, whether we will be successful in identifying novel approaches to prevent and treat viral infections using our Cloudbreak antiviral platform, whether we will be able to continue the development of our AVCs, including CD377, and whether we will be successful in developing a product for universal single-dose influenza protection, or at all. Risks that contribute to the uncertain nature of the forward-looking statements include: the success and timing of Cidara's 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; the success and timing of Cidara's discovery and pre-clinical programs; 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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