



## Cidara Therapeutics Announces New Clinical and Preclinical Data for Rezafungin and Influenza AVCs at IDWeek 2020

October 21, 2020

*Presentations highlight clinical and preclinical progress of long-acting drug candidates for serious fungal and viral infections*

*Posters presenting new analyses from completed Phase 2 STRIVE trial support the efficacy and pharmacokinetics of once-weekly rezafungin in the treatment of candidemia and invasive candidiasis*

*Oral and poster presentations highlight potential of antiviral conjugates (AVCs) for universal prevention and treatment of influenza*

SAN DIEGO, Oct. 21, 2020 (GLOBE NEWSWIRE) -- Cidara Therapeutics, Inc. (Nasdaq: CDTX), a biotechnology company developing long-acting therapeutics designed to transform the standard of care for patients facing serious fungal or viral infections, today announced data from two oral abstracts and seven posters at IDWeek 2020, the joint annual meeting of the Infectious Diseases Society of America (IDSA), Society for Healthcare Epidemiology of America (SHEA), the HIV Medical Association (HIVMA), the Pediatric Infectious Diseases Society (PIDS) and the Society of Infectious Diseases Pharmacists (SIDP), taking place virtually Oct. 21-25, 2020.

"We are pleased to share new clinical and preclinical data from our antifungal and antiviral programs at IDWeek 2020," said Jeffrey Stein, Ph.D., president and chief executive officer of Cidara. "Analyses of the completed Phase 2 STRIVE trial of our novel echinocandin, rezafungin, for the treatment of candidemia and/or invasive candidiasis, adds to the body of evidence of rezafungin's efficacy, specifically against multiple *Candida* species and across a wide array of patient populations. From our Cloudbreak antiviral program, we are excited to present non-clinical data on our AVC candidate, CD377, supporting its development for universal influenza protection for all people, regardless of immune status."

Five of the poster presentations report new findings on rezafungin, Cidara's novel, Phase 3, once-weekly echinocandin being developed for the treatment and prevention of serious fungal infections, and on patterns of echinocandin use. Highlights from these published abstracts are as follows:

- Analyses from the completed Phase 2 STRIVE trial of rezafungin for treatment of candidemia and/or invasive candidiasis demonstrate rezafungin pharmacokinetics (PK) were consistent across diverse patient populations, with no meaningful differences observed across a wide range of patient factors, including sex, race, age and body weight.
- Analysis of patient outcomes stratified by *Candida* species from the STRIVE trial demonstrated the efficacy of rezafungin across multiple *Candida* species, with similar or better outcomes observed with rezafungin compared to standard of care, caspofungin.
- Results from an excretion balance, metabolism and PK study in healthy adults showed that fecal excretion of unmetabolized drug is the major route of elimination of rezafungin in humans, consistent with preclinical results from rats and monkeys.
- Pharmacoepidemiologic analysis of echinocandin use during hospitalization and upon discharge, at a large, quaternary care medical center showed that a significant portion of echinocandin courses continued after hospital discharge, where a long-acting echinocandin could be of benefit.

Two oral and two poster presentations report new findings from Cidara's Cloudbreak antiviral platform, specifically the AVC development candidate, CD377, for prevention and treatment of influenza. Data highlights from the published abstracts on CD377 are as follows:

- A single dose of CD377 was protective against lethal challenge with a panel of seasonal and pandemic influenza subtypes in mice, demonstrating its potent broad-spectrum activity.
- CD377 demonstrated superior dose-dependent viral load reduction in the lung compared to approved influenza treatment oseltamivir in lethal influenza mouse and ferret models.
- Additional data in mice demonstrated the efficacy of a single dose of CD377 in both prevention and treatment of influenza infection. CD377 administered 28 days prior to infection completely protected against several strains of influenza, and treatment efficacy was observed with a single dose of CD377 72- hours-post infection. High bioavailability of CD377 (77%) was observed after subcutaneous or intramuscular administration. PK studies performed in mice, rats, ferrets and monkeys demonstrated that CD377 is stable and has a long half-life, with no adverse effects observed in a monkey toxicology study.
- Further studies demonstrated the efficacy of CD377 in both immune-competent and immune-deficient mice lethally challenged with influenza, with similar PK and potent *in vitro* activity observed at equivalent doses irrespective of immune status.

Presentation details will be accessible on the [Publications](#) section of the Cidara website at the conclusion of the conference.

### **About Rezafungin**

Rezafungin is a novel once-weekly echinocandin being developed for both the treatment and prevention of serious fungal infections, such as candidemia and invasive candidiasis. The structure and properties of rezafungin are specifically designed to improve upon a clinically validated mechanism intended to enhance 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) and a second Phase 3 clinical trial of once-weekly rezafungin for the

prevention of invasive fungal disease 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 proliferation while simultaneously engaging the immune system. AVCs are initially being studied for the prevention and treatment of 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 other life-threatening viruses, such as RSV, HIV and CoV, including COVID-19.

#### **About Cidara Therapeutics**

Cidara is developing long-acting therapeutics designed to transform the standard of care for patients facing serious fungal or viral infections. The Company's portfolio is comprised of its lead antifungal candidate, rezafungin, in addition to antiviral conjugates (AVCs) for the prevention and treatment of 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](http://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," "may," "plan" or "will". Forward-looking statements in this release include, but are not limited to, statements related to rezafungin's efficacy and potential as a once-weekly treatment and its ability to prevent severe fungal infections and disease, our Cloudbreak AVCs' potential to directly inhibit viral proliferation while simultaneously engaging the immune system, and the ability of our influenza AVC to treat and deliver universal protection for an entire flu season with a single dose. 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 clinical trials or pre-clinical studies or other obstacles to the development of rezafungin or Cidara's Cloudbreak AVCs. These and other risks are identified under the caption "Risk Factors" in Cidara's most recent Quarterly Report on Form 10-Q 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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