Cidara Therapeutics Selects First Clinical Development Candidate from its Cloudbreak Influenza (Antiviral) Program

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CB-012 demonstrates potent antiviral activity against influenza A and B viruses

Cidara presenting preclinical results today at ECCMID 2019

SAN DIEGO--(BUSINESS WIRE)--Apr. 15, 2019-- Cidara Therapeutics, Inc. (Nasdaq: CDTX), a biotechnology company developing novel anti-infectives including immunotherapies, today announced that the company has selected the antiviral conjugate (AVC) CB-012 as its first clinical development candidate from the company's Cloudbreak ® influenza (antiviral) program. Data supporting the selection will be presented today in an oral session at the 29th European Congress of Clinical Microbiology and Infectious Diseases (ECCMID). CB-012 is a novel conjugate of a highly potent antiviral agent linked to a human antibody fragment.

"The data clearly demonstrate the potential for CB-012 as either a long-acting preventative or fast-acting therapy with potent activity against seasonal and pandemic strains of influenza. A single molecule which links a potent antiviral drug with a long-acting immune system engager has the potential for important advantages over traditional vaccines and therapies," said Jeffrey Stein, Ph.D., president and chief executive officer of Cidara. "We are committed to advancing our portfolio of promising development candidates, including CB-012, and are progressing IND-enabling studies this year."

Applying the principles of oncology immunotherapy, Cidara's Cloudbreak AVCs attack influenza through a dual mechanism: The antiviral agent neutralizes the influenza virus directly, while the human antibody fragment engages a patient's immune system to accelerate elimination of the pathogen. The approach is designed to improve on, and combine, the preventive effects of vaccination with an antiviral drug's capability to treat flu illness. Cidara's vision is that a single dose of an AVC could prevent influenza for an entire flu season, with or without concurrent vaccine administration, cover strains that are missed by vaccines in any given year, and be effective even in people with decreased immune function.

Today's ECCMID presentation describes results from nonclinical studies, which evaluated the potential of CB-012 for the treatment and prevention of seasonal and pandemic influenza A as well as influenza B infections. Key findings suggest CB-012 offers:

- Superior *in vitro* activity compared to standard-of-care antivirals and coverage of both influenza A and B viruses
- Full protection from, or treatment of, H1N1, H3N2, and Tamiflu- (oseltamivir) resistant H1N1-related infections with a single dose of CB-012 in preclinical efficacy models
- Long half-life in multiple preclinical species
- Efficacy in multiple dosing formulations including intravenous, subcutaneous and intramuscular
- Expanded treatment window in preclinical models to 72 hours post-infection versus Tamiflu (oseltamivir), which loses its ability to protect when administered beyond 24 hours post-infection

"The data being presented today at ECCMID suggest CB-012 could provide longer, effective protection for patients from the influenza virus as compared to current standards of care," said Les Tari, Ph.D., senior vice president of research for Cidara, and presenter of the CB-012 data at ECCMID. "We believe Cloudbreak AVCs offer an exciting new approach in the global fight against seasonal and pandemic influenza."

About Influenza Virus

Influenza, or flu, is a respiratory infection caused by influenza viruses. The flu virus can cause mild to severe illness and, at times, can lead to death. Young children, the elderly (people aged 65 years and older), pregnant women and immunocompromised patients are more prone to infection, but even healthy people are at risk of infection with seasonal flu. While influenza vaccines are critical to global health, they have limited efficacy and must be redesigned every year as scientists attempt to predict the next season's dominant circulating strains.

On average, vaccines are only 40 percent effective, with lower rates in young children and the elderly. The U.S. Centers for Disease Control and Prevention (CDC) estimates that as many as 646,000 people may die from influenza each year worldwide. According to CDC estimates for the United States, approximately 50 million people became ill from the flu and almost 80,000 people died in the 2017-18 season alone.

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, statements regarding the potential for CB-012 as a long-acting preventative or fast-acting therapy and to provide potent activity against seasonal and pandemic strains of influenza, and the potential for CB-012 to treat and prevent influenza and represent an improvement over current vaccines and therapies. In addition, such statements also include the potential for *in vitro* results or results in animal studies with CB-012 to provide similar clinical results in humans, including the ability to provide the following in humans: full protection from, or treatment of, H1N1, H3N2, and Tamiflu- (oseltamivir) resistant H1N1-related infections, a long half-life, efficacy in different dosing formulations, and an expanded influenza treatment window to 72 hours post-infection. Such statements also 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 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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