FDA Grants QIDP and Fast Track Designations to Cidara Therapeutics' Rezafungin Prophylaxis Development Program

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Rezafungin designated for the prevention of invasive fungal infections in adults undergoing bone marrow transplantation

SAN DIEGO--(BUSINESS WIRE)--Sep. 25, 2018-- Cidara Therapeutics, Inc. (Nasdaq: CDTX), a biotechnology company developing novel anti-infectives including immunotherapies, today announced that the U.S. Food and Drug Administration (FDA) has granted both Qualified Infectious Disease Product (QIDP) and Fast Track designations for the company's prophylaxis (prevention) development program for lead antifungal product candidate, rezafungin for injection. Specifically, the QIDP designation is for the development of rezafungin for the prevention of invasive fungal infections in adults undergoing allogeneic bone marrow transplantation. Cidara previously announced QIDP designation for rezafungin for the treatment of invasive fungal infections caused by *Candida*.

"This important FDA designation provides significant support for the development of rezafungin in the hematology setting," said Jeffrey Stein, Ph.D., president and chief executive officer of Cidara. "We now have the opportunity to expedite the development of rezafungin to address significant unmet needs both in the prevention of invasive fungal infections in immunocompromised patients undergoing bone marrow transplantation, as well as for the treatment of patients with existing severe invasive fungal infections."

Cidara is developing rezafungin, a novel antifungal echinocandin, as a once-weekly, high-exposure therapy for the treatment and prevention of serious invasive fungal infections. Rezafungin is being studied to address unmet needs in the treatment of candidemia and invasive candidiasis as well as for prophylaxis of invasive fungal infections due to common fungal pathogens: *Candida*, *Aspergillus* and *Pneumocystis*. No one agent is approved today to prevent infections caused by these pathogens and current prophylaxis regimens often require multiple antifungal drugs with safety and tolerability issues. Cidara plans to commence the Phase 3 ReSPECT prophylaxis clinical trial of rezafungin in patients undergoing allogeneic bone marrow transplantation in the first quarter of 2019.

The QIDP designation, provided under the Generating Antibiotic Incentives Now Act (GAIN Act), offers certain incentives for the development of new antifungal and antibacterial drugs, including Fast Track, priority review and, if rezafungin is ultimately approved by the FDA, eligibility for an additional five years of marketing exclusivity. Fast Track designation enables more frequent interactions with the FDA review team to expedite drug development.

To achieve QIDP designation, a drug candidate must be intended to treat serious or life-threatening infections, particularly those caused by bacteria and fungi that are resistant to treatment, or that treat qualifying resistant pathogens identified by the FDA. These listed qualified pathogens include *Candida* and *Aspergillus* species, which have the potential to pose a serious threat to public health.

About Invasive Fungal Infections

Approximately 97,000 Americans die from hospital-related invasive fungal infections each year and 90 percent of these infections are caused by two common fungi, *Candida* and *Aspergillus*. *Pneumocystis* Pneumonia (PCP) is another serious fungal infection that commonly afflicts people with weakened immune systems. Systemic fungal infections typically affect patients whose immune systems have been compromised, such as patients undergoing organ or bone marrow transplantation or chemotherapy, including patients with hematologic malignancies, or patients in intensive care units and those with prolonged hospital stays.

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, formerly known as CD101 IV, through clinical trials. Rezafungin has improved pharmacokinetics compared to existing echinocandins and the potential for expanded utility across patient settings. It is the only once-weekly product candidate in development for the treatment and prevention of life-threatening invasive fungal infections. The company's Phase 2 STRIVE clinical trial of rezafungin met its primary safety and efficacy objectives, and provides support for Cidara to initiate Phase 3 pivotal trials in the treatment of candidemia and invasive candidiasis and the prophylaxis of invasive fungal infections. Cidara is also leveraging its novel Cloudbreak™ platform to develop antibody-drug conjugates for the treatment of serious viral and Gram-negative bacterial infections. Cloudbreak is the first immunotherapy discovery platform designed specifically to create compounds that directly kill pathogens and also direct a patient's immune cells to attack and eliminate bacterial, fungal or viral 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 impact of the QIDP and Fast Track designations on our rezafungin development program, initiation of rezafungin Phase 3 pivotal trials, the potential for rezafungin to be a novel treatment and prophylactic agent against deadly invasive fungal infections, and rezafungin's potential for expanded utility across patient settings. 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.

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