FDA Grants QIDP and Fast Track Designations to CD101 IV, Cidara Therapeutics' Lead Antifungal Product Candidate

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-CD101 IV designated for treatment of serious or life-threatening Candida infections-

SAN DIEGO--(BUSINESS WIRE)--May 11, 2015-- Cidara Therapeutics, Inc. (Nasdaq:CDTX), a biotechnology company developing novel anti-infectives and immunotherapies to treat fungal and other infections, today announced that the U.S. Food and Drug Administration (FDA) has designated the company's lead antifungal product candidate, CD101 IV, as a Qualified Infectious Disease Product (QIDP) with Fast Track status. The QIDP and Fast Track designations are for the use of CD101 IV in the treatment of candidemia and invasive candidiasis.

The QIDP designation, provided under the Generating Antibiotic Incentives Now Act (GAIN Act), offers certain incentives for the development of new antibacterial or antifungal drugs, including eligibility for Fast Track, priority review and, if CD101 IV 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 to expedite drug development and review.

"The mortality rate in patients with candidemia can exceed 35 percent. This high mortality rate, coupled with rising drug resistance and the fact that no new antifungal agents have been approved for candidemia since 2007, leaves doctors with few therapeutic options for their patients," said Jeffrey Stein, Ph.D., president and chief executive officer of Cidara. "The QIDP and Fast Track designations for CD101 IV will enable Cidara to expedite development of this promising compound, which could ultimately provide physicians with a new treatment option for their patients fighting these serious, potentially life-threatening fungal infections."

Cidara is developing CD101 IV, a novel long-acting agent in the echinocandin class of antifungals, for the treatment of systemic *Candida* infections, including candidemia and related cases of invasive candidiasis. Systemic fungal infections are associated with high mortality rates and typically affect patients whose immune systems have been compromised, such as patients undergoing organ or bone marrow transplantation, chemotherapy, and many patients in ICUs. Cidara plans to file an investigational new drug application (IND) and initiate a Phase 1 clinical trial for CD101 IV in the second half of 2015.

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 pathogens include *Candida* species, which have the potential to pose a serious threat to public health. According to the Centers for Disease Control and Prevention (CDC), certain species of *Candida* are becoming increasingly resistant to existing antifungal medications. This emerging resistance intensifies the need for new antifungal agents to treat these serious infections.

About Cidara Therapeutics

Cidara is a biotechnology company focused on the discovery, development and commercialization of novel anti-infectives for the treatment of diseases that are inadequately addressed by current standard-of-care therapies. Cidara's initial product portfolio comprises two formulations of the company's novel echinocandin, CD101, for the treatment of serious fungal infections. CD101 IV is a long-acting therapy for the treatment and prevention of systemic fungal infections, and CD101 topical is for the treatment of vulvovaginal candidiasis (VVC) and recurrent VVC (RVVC), a prevalent mucosal infection. In addition, Cidara has developed a proprietary immunotherapy platform, Cloudbreak™, designed to create compounds that direct a patient's immune cells to attack and eliminate pathogens that cause infectious disease. Cidara is headquartered in San Diego, California.

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 Cidara's ability to expedite development of its product candidates, the timing of filing of an IND for CD101 IV, and the timing of initiation of a Phase 1 clinical trial for CD101 IV. 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 documents most recently filed with the United States Securities and Exchange Commission (SEC), including its Registration Statement on Form S-1 declared effective by the SEC on April 14, 2015, under the heading "Risk Factors." 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.

Source: Cidara Therapeutics, Inc.

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