



Cidara Therapeutics Doses First Patient in Pivotal Phase 3 ReSPECT Trial of Rezafungin for Prevention of Invasive Fungal Disease in Patients Undergoing Allogeneic Blood and Marrow Transplantation

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SAN DIEGO and CAMBRIDGE, England, May 20, 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, and Mundipharma today announced that the first patient has been dosed in its ReSPECT pivotal Phase 3 clinical trial evaluating the efficacy and safety of the company's lead antifungal candidate, rezafungin, for the prevention of invasive fungal disease in patients undergoing allogeneic blood and marrow transplantation (BMT). Rezafungin is a novel, once-weekly echinocandin being developed for both the treatment and prevention of severe fungal infections.

Johan A. Maertens, M.D., Ph.D., FECCM, Professor of Internal Medicine and Hematology, University Hospitals Leuven, Leuven, Belgium and investigator in the ReSPECT study, said, "Rezafungin has the potential to become the new standard of care to prevent invasive fungal disease in patients undergoing allogeneic blood and marrow transplants. The cocktail of preventative options used today has significant limitations, such as toxicities, hazardous drug-drug interactions and patient compliance. With one drug, rezafungin, given once-weekly, we may be able to overcome these substantial limitations to improve patient outcomes in this highly immunosuppressed population."

Jeffrey Stein, Ph.D., president and chief executive officer of Cidara, added, "The ReSPECT pivotal Phase 3 trial studying rezafungin for the prevention of severe fungal infections, along with our ongoing ReSTORE Phase 3 trial evaluating rezafungin for the treatment of invasive *Candida* infections, positions rezafungin to potentially become the first new antifungal approved for both the treatment and prevention of serious fungal infections in nearly 15 years. Patients with compromised immune systems face complex drug regimens when undergoing BMT and experience a high mortality rate if infected. Shifting the antifungal standard of care to a single once-weekly drug, rezafungin, which has the potential to protect against three deadly pathogens, could significantly transform the approach and outcomes for patients and health care providers alike."

Cidara is supported in the ongoing development of rezafungin by Mundipharma, who will be responsible for bringing the therapy to patients outside the U.S. and Japan.

Brian Sheehan, senior vice president Innovation at Mundipharma commented: "We are pleased to be working in partnership with Cidara Therapeutics on this promising therapy in an area that has seen little innovation in over a decade. The launch of this pivotal Phase 3 trial is an important milestone in our joint efforts to support vulnerable patients around the world."

The ReSPECT trial is a global, randomized, double-blind, controlled, pivotal Phase 3 trial of rezafungin versus the standard antimicrobial regimen to prevent invasive fungal disease due to *Candida*, *Aspergillus* and *Pneumocystis* in subjects undergoing allogeneic BMT. Rezafungin, dosed once-weekly, will be compared to a daily regimen containing multiple drugs including fluconazole or posaconazole, and trimethoprim-sulfamethoxazole, also known as Bactrim, for 90 days, at which time fungal-free survival will be measured as the primary efficacy outcome. The trial will enroll approximately 462 adults with underlying conditions, such as acute myeloid leukemia, acute lymphoblastic leukemia, chronic myelogenous leukemia, myelodysplastic syndrome(s), lymphoma and aplastic anemia, across approximately 30 BMT centers.

Further information on the ReSPECT trial can be found at: <https://clinicaltrials.gov/ct2/show/NCT04368559>

About Invasive Fungal Disease

Each year, an estimated 1.5 million people with compromised or suppressed immune systems die of invasive fungal infections worldwide.¹ The current standard of care for the prevention of invasive fungal disease requires complex patient-specific plans and drug cocktails that are subject to change due to the underlying disease, toxicities and the local epidemiology of fungal infections.^{2,3} Patients who have received a blood and marrow transplant, cancer chemotherapy or solid organ transplant may receive prophylaxis to prevent deadly *Candida*, *Aspergillus* and/or *Pneumocystis* infections for several weeks to over a year, depending on the period of immunosuppression or development of Graft Versus Host Disease.³

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 were specifically designed to improve upon a clinically validated mechanism, enhancing its efficacy and safety potential for patients. Cidara and its strategic partner Mundipharma are currently conducting a Phase 3 clinical trial with rezafungin for the first-line treatment of candidemia and/or invasive candidiasis (ReSTORE trial)⁴, as well as a second Phase 3 clinical trial of once-weekly rezafungin for prevention against invasive fungal infections in patients undergoing allogeneic blood and marrow transplantation (ReSPECT trial).⁵ Mundipharma has exclusive rights to develop and commercialize rezafungin in all markets outside of the United States and Japan, which are retained by Cidara.

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.

About the Mundipharma network

Mundipharma is a global network of privately-owned independent associated companies whose purpose is to move medicine forward. With a high performing and learning organisation that strives for innovation and commercial excellence through partnerships, we successfully transformed and diversified our European portfolio of medicines to create value for patients, payers and wider healthcare systems across important therapeutic areas

such as Diabetes, Respiratory, Oncology, Pain and Biosimilars.

Safe Harbor Statement

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, establish it as a new standard of care or whether rezafungin can overcome limitations of existing therapies, whether the Phase 3 development program for rezafungin will be successful and be approved both for treatment and prevention of serious fungal infections, or whether as a therapy it will protect against deadly pathogens and transform the approach and outcomes for patients and healthcare providers. Risks that contribute to the uncertain nature of the forward-looking statements include, but are not limited to: 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; the loss of key scientific or management personnel; and the impacts of global health crises, including the recent COVID-19 pandemic. 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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3. Fleming S, Yannakou CK, Haeusler GM et al. Consensus guidelines for antifungal prophylaxis in haematological malignancy and haemopoietic stem cell transplantation, 2014. *Internal Medicine Journal* 2014; 44 (12b):1283-97.
4. <https://clinicaltrials.gov/ct2/show/NCT03667690>
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Source: Cidara Therapeutics, Inc.