Cidara Therapeutics Submits NDA for Rezafungin and Announces License Agreement with Melinta Therapeutics for Commercialization of Rezafungin in the U.S.

July 27, 2022

- *Submitted NDA for rezafungin for candidemia and invasive candidiasis to the U.S. FDA on July 22, 2022, with an anticipated PDUFA target action date in the first quarter of 2023, if accepted for review following application validation*
- *Melinta acquires exclusive rights to commercialize rezafungin in the U.S.*
- *Cidara to receive up to $460 million, with an upfront cash payment of $30 million, $60 million in regulatory milestones, and up to $370 million in commercial milestones, plus tiered low double digits to mid-teens royalties on net sales*
- *Cidara to focus on advancing Cloudbreak DFC platform in oncology and viral infections*

SAN DIEGO, July 27, 2022 (GLOBE NEWSWIRE) -- Cidara Therapeutics, Inc. (Nasdaq: CDTX) announced today that it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for rezafungin for the treatment of candidemia and invasive candidiasis. The company also announced that it has entered into a license agreement with Melinta Therapeutics under which Cidara has granted Melinta an exclusive license to commercialize rezafungin in the U.S. Rezafungin is a novel, once-weekly echinocandin antifungal being developed for the treatment of candidemia and invasive candidiasis, as well as for the prophylaxis of invasive fungal infections in patients undergoing allogeneic blood and marrow transplantation.

Cidara submitted the NDA for rezafungin for candidemia and invasive candidiasis, for which no new therapies have been approved in over a decade, to the FDA on July 22, 2022. The FDA has previously granted Qualified Infectious Disease Product (QIDP) designation to rezafungin for injection which confers priority review of the NDA. Additionally, the treatment indication has orphan designation. Cidara expects to be assigned a Prescription Drug User Fee Act (PDUFA) target action date in the first quarter of 2023, if the NDA is accepted for review following application validation. The NDA submission for rezafungin was based on positive results from Cidara's global ReSTORE Phase 3 and STRIVE Phase 2 trials. ReSTORE met the primary endpoints for both the FDA and the European Medicines Agency (EMA). Rezafungin dosed once-weekly demonstrated statistical non-inferiority versus caspofungin, the current standard of care, dosed once-daily.

"The NDA submission for rezafungin for the treatment of candidemia and invasive candidiasis is an important milestone for Cidara," said Jeffrey Stein, Ph.D., President and Chief Executive Officer of Cidara. "If approved, rezafungin would represent an important new treatment option for patients at risk of these potentially deadly diseases. We thank our clinical investigators, the patients who participated in the global study, as well as our partner, Mundipharma, whose collaboration and insights in their licensed territory outside the U.S. and Japan was instrumental in the execution of the pivotal study for rezafungin. We believe our new partner, Melinta, with its existing U.S. commercial infrastructure and significant experience in commercializing infectious disease products, including once-weekly antibiotics, is ideally positioned to bring rezafungin to the U.S. market and patients in need."

Under the terms of the agreement with Melinta, in exchange for granting Melinta exclusive commercialization rights to rezafungin in the U.S., Cidara will receive a $30 million upfront payment, and is eligible to receive $60 million in regulatory milestone payments and up to $370 million in commercial milestone payments, representing a total potential transaction value of $460 million, plus royalties on tiers of annual net sales of rezafungin in the U.S., subject to offset for certain expenses incurred by Melinta. Cidara will be responsible for completing the ongoing global Phase 3 ReSPECT prophylaxis study, CMC and other activities required by the FDA to obtain NDA approval of rezafungin in the treatment and prophylaxis indications in the U.S. Cidara retains the rights to rezafungin in Japan, while Mundipharma retains the commercial rights to rezafungin outside the U.S. and Japan.

"Our ability to rapidly commercialize rezafungin in the U.S. makes this partnership a win for Cidara, a win for Melinta and, most importantly, a win for patients in need," said Christine Miller, President and CEO of Melinta. "Our deep experience commercializing infectious disease products, especially within the hospital and acute care settings, means we have not only the commercial infrastructure but a commercial team with the expertise, passion and drive needed to put rezafungin in the hands of physicians and their patients. We are excited about adding this highly differentiated once-weekly antifungal to complement our antibiotic lineup, a move that will continue to strengthen our ambition to become the recognized leader in acute care."

Dr. Stein added, "This transaction eliminates the need for Cidara to build commercial infrastructure to launch rezafungin in the U.S. The upfront proceeds and additional expected near-term payments from this partnership and our current collaborations with Mundipharma and Janssen provide multiple sources of non-dilutive capital that could support the completion of the rezafungin development program and enable us to further advance our Cloudbreak DFC platform programs. In addition, as we approach the potential approval of rezafungin in the U.S., we will prioritize streamlining our operating costs accordingly, which may further extend our cash runway. We also remain focused on identifying an appropriate partner for rezafungin in Japan. In the interim, we continue to execute on generating compelling preclinical and clinical data from our oncology and antiviral Cloudbreak programs."

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 has completed a Phase 3 clinical trial with rezafungin for the first-line treatment of candidemia and/or invasive candidiasis (ReSTORE trial) and is currently conducting a second Phase 3 clinical trial of rezafungin for the prevention of invasive fungal disease in patients undergoing allogeneic blood and marrow transplantation (ReSPECT trial). Rezafungin has been designated a QIDP with Fast Track status by the FDA, and has been granted Orphan Drug Designation for its use in the treatment of invasive candidiasis in both the U.S. and EU.

About Cidara Therapeutics
Cidara is developing long-acting therapeutics designed to improve the standard of care for patients facing serious diseases. The Company's portfolio is comprised of new approaches aimed at transforming existing treatment and prevention paradigms, first with its lead Phase 3 antifungal candidate, rezafungin, in addition to drug-Fc conjugates (DFCs) targeting viral and oncology diseases from Cidara's proprietary Cloudbreak® platform. Cidara is headquartered in San Diego, California. For more information, please visit www.cidara.com.

About Melinta Therapeutics
Melinta Therapeutics, LLC provides innovative therapies to people impacted by acute and life-threatening illnesses. Our portfolio currently includes five commercial-stage antibiotics: BAXDELA® (delafloxacin), KIMYRSA™ (oritavancin), MINOCIN® (minocycline) for Injection, ORBACTIV® (oritavancin), and VABOMERE® (meropenem and vaborbactam) and a commercial-stage cardiovascular product: TOPROL-XL® (metoprolol succinate). With an unsurpassed commitment to providers and the patients they serve, we work to ensure that all people who need our therapies can receive them. We focus our expanding portfolio on serving patients with an unmet need because that's how we make the most meaningful impact. At Melinta, we're visionaries dedicated to innovation while staying grounded in what matters most: patients. Visit www.melinta.com for more information.

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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 our expectations that the ReSTORE trial data will support an NDA submission in the U.S.; that the ReSPECT trial will be completed on a timely basis or at all; that the ReSPECT trial data will support a supplemental NDA submission in the U.S.; as to the anticipated rezafungin PDUFA target action date; that the FDA will accept or approve any NDA or supplemental NDA filed for rezafungin; as to potential milestone payments and royalties under the Melinta agreement, including, but not limited to, as to whether Cidara will receive royalties from Melinta after the royalty offsets to which Melinta is entitled; as to Cidara's ability to complete the rezafungin development program, perform its rezafungin supply obligations, and further advance the Cloudbreak DFC platform programs; as to Cidara's ability to further extend its cash runway; as to Melinta's ability to commercialize rezafungin in the U.S.; and as to Cidara's ability to identify an appropriate partner for rezafungin in Japan. 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 pre-clinical or clinical trials, delays in action by regulatory authorities due to limitations on inspections and other COVID-19-related effects, and impacts of the COVID-19 pandemic or other obstacles on the enrollment of patients or other aspects of rezafungin development. 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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