Mundipharma and Cidara Therapeutics Announce First Presentation of Results from Global Phase 3 ReSTORE Trial of Rezafungin for Treatment of Candidemia and/or Invasive Candidiasis Demonstrating its Positive Efficacy and Safety Profile

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For Trade and Medical Media Only

- ReSTORE trial met both primary endpoints and demonstrated non-inferiority of rezafungin versus current standard of care, caspofungin[1]
- Rezafungin demonstrated high mycological efficacy rates in initial days of treatment[1]
- There were no concerning trends in treatment emergent adverse events (TEAEs) or serious adverse events (SAEs)[1]

SAN DIEGO & CAMBRIDGE, England--(BUSINESS WIRE)--Apr. 25, 2022-- Mundipharma and Cidara Therapeutics, Inc. (NASDAQ: CDTX) today presented data from the Phase 3 ReSTORE clinical trial of rezafungin in the treatment of candidemia and/or invasive candidiasis at the 32nd European Congress of Clinical Microbiology and Infectious Diseases (ECCMID). The data, presented in a late-breaking poster, showed non-inferiority for rezafungin dosed once-weekly compared to caspofungin, the current standard of care, dosed once-daily, for both primary endpoints.[1]

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Results from ReSTORE showed the primary endpoints were met with:[1]

- 23.7% all-cause mortality on day 30 for rezafungin compared to 21.3% for caspofungin (difference, 2.4; 95% CI for risk difference -9.7 to 14.4*)
- global cure on day 14 of 59.1% for rezafungin and 60.6% for caspofungin (difference, -1.1; 95% CI for risk difference -14.9* to 12.7)
    - *To meet the pre-specified limit of non-inferiority, the upper (for all-cause mortality) and lower (for global cure) 95% confidence limits for the difference between arms must be within 20%. Both endpoints met the pre-specified 20% limit, establishing non-inferiority.

Further data from the ReSTORE trial demonstrated high rates of early mycological efficacy with rezafungin:[1]

- negative blood culture at 24 hours was 53.7% for rezafungin versus 46.2% for caspofungin and 74.2% versus 64.1% at 48 hours
- median time to negative blood culture was 23.9 hours for rezafungin versus 27.0 hours for caspofungin (p=0.175)

Additional data from an oral late-breaking presentation at ECCMID from an integrated analysis of the Phase 2 STRIVE and Phase 3 ReSTORE data of rezafungin in the treatment of candidemia and/or invasive candidiasis, supports the analysis of ReSTORE[2]:

- 18.7% all-cause mortality on day 30 for rezafungin compared to 19.4% for caspofungin (weighted mortality difference, -1.5%; 95% CI: -10.7 to 7.7, stratified analysis by study)
- percentage of subjects with negative blood culture at 24 hours was 60.0% for rezafungin versus 49.1% for caspofungin and 77.7% versus 63.5% at 48 hours
- median time to negative blood culture was 22.3 hours for rezafungin versus 26.3 hours for caspofungin (p=0.0051)

Both the STRIVE and ReSTORE trials demonstrated similar tolerability outcomes for rezafungin and caspofungin and did not reveal any concerning trends in TEAEs or SAEs.[1,2]

Further data presented at ECCMID assessing the pharmacokinetics of drug interactions between rezafungin and anticancer agents venetoclax or ibrutinib demonstrated that in subjects receiving multiple drug interventions, rezafungin can be given with no dose adjustments due to pharmacokinetics. [3]

“The results of both the STRIVE and ReSTORE trials, as well as the pharmacokinetics data, provide clear evidence of the potential impact that rezafungin could have for patients fighting serious and hard to treat invasive *Candida* infections,” said Jeffrey Stein, Ph.D., president and chief executive officer of Cidara. “We look forward to submitting our NDA to the FDA in mid-2022 and subsequent ex-US submissions, and to making a difference in the lives of patients.”

Oliver Cornely investigator in the ReSTORE trial and Professor of Internal Medicine at the University of Cologne, Germany, added, “As the mortality rate for patients with invasive candidiasis remains high there is a real unmet need for new treatment options to address this serious disease. Rezafungin could be the first new treatment option for patients with candidemia or invasive candidiasis for over 10 years.”

Brian Sheehan, Ph.D., Chief Scientific Officer at Mundipharma, commented, “We are extremely pleased that these data presented today may help pave the way for once-weekly rezafungin to help critically ill patients with invasive *Candida* infections. The results from these important trials provide

initial evidence that the unique pharmacokinetic/pharmacodynamic profile of rezafungin may lead to quicker fungal clearance for patients with *Candida* infections."

Cidara has partnered with Mundipharma who has commercial rights to rezafungin outside the U.S. and Japan.

About ReSTORE

ReSTORE (NCT03667690) is a global, multicentre, randomized, double-blind, controlled Phase 3 efficacy and safety study of once weekly rezafungin injections versus an active comparator regimen of caspofungin followed by optional oral fluconazole step-down therapy in subjects with candidemia and/or invasive candidiasis. ReSTORE evaluated one 400 milligram (mg) dose of rezafungin in week 1 followed by 200 mg of rezafungin dosed once-weekly for up to four weeks. The treatment arm was compared to approved daily dosing of caspofungin in a 1:1 randomization (n=98 in each arm).[1] It completed enrollment with 199 patients diagnosed with candidemia and/or invasive candidiasis in 66 clinical sites across 18 countries. Study sites in China are still recruiting patients for submission of rezafungin to the Center for Drug Evaluation in China.

About STRIVE

STRIVE (NCT02734862) was a global, multicenter, randomized, double-blind Phase 2 study of the safety, tolerability, and efficacy of intravenous rezafungin (n=138)[2] versus intravenous caspofungin (n=69)[2] followed by optional oral fluconazole step-down in the treatment of subjects with candidemia and/or invasive candidiasis. It was completed with 207 participants enrolled in 63 clinical sites across 10 countries.

About Pharmacokinetics Study

An open-label study of 16 male and 16 female healthy volunteers assessed drug-drug interactions between rezafungin and anticancer agents 280mg ibrutinib or 50mg venetoclax (females only). The two anticancer agents were each given along and with IV rezafungin (400mg followed by once-weekly 200mg).[3]

About Invasive Candidiasis

Invasive candidiasis (IC) continues to be an area of significant unmet need, especially for critically ill patients in hospitals and patients with compromised immune systems. Despite available treatments, the mortality rate for patients with invasive candidiasis remains as high as 40%.[4] IC is characterized as a severe, life-threatening systemic *Candida* infection of the bloodstream and/or deep/visceral tissues, known as candidemia and deep-seated tissue candidiasis.[5]

About Rezafungin

Rezafungin is a next-generation once-weekly echinocandin being developed for both the treatment and prevention of serious fungal infections, such as invasive candidiasis and candidemia. The structure and properties of rezafungin are specifically designed 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).[4]

Cidara is also 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 Qualified Infectious Disease Product (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.[6,7] In addition, the Medicines and Healthcare Products Regulatory Agency (MHRA) in the UK has granted rezafungin Promising Innovative Medicine (PIM) designation for the treatment of invasive candidiasis.[8]

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 Mundipharma

Mundipharma is a global healthcare company with a presence across Africa, Asia Pacific, Canada, Europe, Latin America, and the Middle East.

Mundipharma is dedicated to bringing innovative treatments to patients in the areas of Pain Management, Infectious Disease and Consumer Healthcare as well as other severe and debilitating disease areas. Our guiding principles, centered around Integrity and Patient-Centricity, are at the heart of everything we do. For more information visit www.mundipharma.com.

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 whether an unmet medical need exists for rezafungin; whether rezafungin will be approved for marketing in the US, the UK and other countries; the potential timing of marketing authorisation submissions; the likelihood that rezafungin, if approved for treatment of fungal infections, will be prescribed by physicians or approved for reimbursement, and whether rezafungin can be proven safe or effective in prevention of fungal infections in patients receiving oral anticancer agents. 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.

References:

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