Mundipharma and Cidara Therapeutics receive positive CHMP opinion for rezafungin for the treatment of Invasive Candidiasis in adults[1]

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- The opinion was based on positive results from the pivotal ReSTORE Phase III clinical trial and supported by the STRIVE Phase II clinical trials and extensive nonclinical development program.[2,3]
- If approved by the European Medicines Agency, rezafungin could be the first new treatment option in over 10 years for patients with invasive candidiasis.[4]

CAMBRIDGE, England and SAN DIEGO, October 13, 2023 – Mundipharma and Cidara Therapeutics (Nasdaq: CDTX) today announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion for rezafungin (rezafungin acetate) for the treatment of invasive candidiasis in adults.[1]

The CHMP based its positive opinion on results from the pivotal ReSTORE Phase III clinical trial, which demonstrated statistical non-inferiority* for rezafungin, dosed once weekly, when compared to the current standard of care, caspofungin, dosed once daily. This finding was supported by the STRIVE Phase II clinical trials and extensive nonclinical development program.[2,3] The ReSTORE trial provides evidence of the efficacy and safety of rezafungin as a potential new treatment option for invasive candidiasis with a once-weekly dosing schedule.[2]

Invasive candidiasis, is a severe, life-threatening infection of the bloodstream and/or deep/visceral tissues.[5,6] It affects seriously ill people, especially those with a weakened immune system where the mortality rate can be 40% or more.[7,8] There is a clear need for alternative options to treat this disease, particularly as there have been no new treatment options over the last decade.[4,9]

Professor Oliver Cornely, Head of the European Excellence Centre for Medical Mycology at the University Hospital Cologne, Germany, and Data Review Committee member in the Phase III ReSTORE trial, said, *"This positive opinion is welcome news for patients who suffer from invasive candidiasis in the European Union where the mortality rate for patients with invasive candidiasis remains high. A new treatment option for these serious infections is a much-needed addition."*

"We would like to thank the CHMP for their careful consideration of the use of rezafungin. This positive opinion represents an important step on the journey towards approval and brings us closer to providing clinicians with an alternative treatment option for invasive Candida infections, giving hope to patients battling this infection and their families," said Brian Sheehan, Ph.D., Chief Scientific Officer at Mundipharma.

**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.*[2]

SciA-RZF-2300034
Date of preparation: October 2023

"Following the FDA approval of rezafungin in the United States earlier this year, the positive CHMP opinion reinforces the benefit of rezafungin and marks an important milestone in our drive to help patients with deadly Candida infections in the European Union," said Taylor Sandison, M.D. M.P.H, Chief Medical Officer at Cidara.

The CHMP's positive opinion on rezafungin for the treatment of serious fungal infections, such as invasive candidiasis in adults, will be referred to the European Commission (EC), which will deliver a final decision in approximately two months.

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

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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 a number of available treatments, the mortality rate for patients with invasive candidiasis is as high as 40%.[7,8] IC is characterised as a severe, life-threatening systemic *Candida* infection of the bloodstream and/or deep/visceral tissues, known as candidemia and deep-seated tissue candidiasis.[10]

About rezafungin

Rezafungin is a novel once-weekly echinocandin being developed for both the treatment and prevention of serious fungal infections, such as invasive candidiasis and candidemia. Cidara has completed a Phase III clinical trial with rezafungin for the first-line treatment of candidemia and/or invasive candidiasis (ReSTORE trial).[11]

In this ReSTORE trial, rezafungin met the primary endpoint for the U.S. Food and Drug Administration (FDA) New Drug Application (NDA) submission of all-cause mortality at Day 30, and also met the primary endpoint for the European Medicines Agency (EMA) Marketing Authorisation Application (MAA) submission of global cure at Day 14. Both results demonstrated statistical non-inferiority of rezafungin dosed once-weekly versus caspofungin dosed once-daily, the current standard of care. Rezafungin was generally well tolerated and had a similar safety profile to caspofungin.[2]

Cidara is also currently conducting a second Phase III clinical trial of rezafungin for the prevention of invasive fungal disease in patients undergoing allogeneic blood and marrow transplantation (ReSPECT trial).

Rezafungin was first approved for the treatment of candidemia and invasive candidiasis in individuals with limited or no alternative treatment options by the FDA in March 2023.[12]

About Cidara Therapeutics

Cidara is using its proprietary Cloudbreak® platform to develop novel drug-Fc conjugates (DFCs). These targeted immunotherapies offer the unique opportunity to create “single molecule cocktails” comprised of targeted small molecules and peptides coupled to a human antibody fragment (Fc). DFCs are designed to save lives and improve the standard of care for patients facing cancers and other serious diseases by inhibiting specific disease targets while simultaneously engaging the immune system. In addition, Cidara received FDA approval for REZZAYO™ (rezafungin for injection), which it has licensed to multiple partners to commercialise in the U.S. and ex-U.S. 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. Their guiding principles, centred around Integrity and Patient-Centricity, are at the heart of everything they 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 harbour 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 it will be approved for marketing in the EU; and the likelihood that rezafungin, if approved in the EU, will be prescribed by physicians or approved for reimbursement. 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. 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.

SciA-RZF-2300034
Date of preparation: October 2023

MEDIA CONTACT:

Jan Milton-Edwards

Mundipharma

Media.relations@mundipharma.com

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