Rezafungin Awarded Promising Innovation Medicine (PIM) Designation by the UK's Medicines and Healthcare Products Regulatory Agency (MHRA) for the Treatment of Invasive Candidiasis

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For Trade and Medical Media Only

- 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.
- Despite currently available treatments, the mortality rate for patients with invasive candidiasis is up to 40%.[1]
- Promising Innovation Medicine designation is an early indication that rezafungin may be eligible for the Early Access to Medicines Scheme in the UK which permits the use of medicines not yet approved by the relevant regulatory authorities.

CAMBRIDGE, England & SAN DIEGO--(BUSINESS WIRE)--Mar. 3, 2022-- Mundipharma and Cidara Therapeutics, Inc. (NASDAQ: CDTX) today announced that 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. Invasive candidiasis is a severe, life-threatening systemic Candida infection of the bloodstream and/or deep/visceral tissues.

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For the MHRA to grant a PIM designation, medicinal products must meet the following criteria:[2]

- The condition should be life-threatening or seriously debilitating with a high unmet need for which there is no method of treatment, diagnosis or prevention available or where existing methods have serious limitations.
- The medicinal product is likely to offer major advantage over methods currently used in the UK.
- The potential adverse effects of the medicinal product are likely to be outweighed by the benefits, allowing for the reasonable expectation of a positive benefit risk balance.

A PIM designation is a pre-requisite for application to the UK's Early Access to Medicines Scheme (EAMS). This scheme aims to give patients with life threatening or seriously debilitating conditions such as invasive candidiasis, access to medicines that do not yet have a marketing authorisation. Mundipharma and Cidara plan to submit an EAMS application for rezafungin in Q3 2022.

Brian Sheehan, Ph.D., Chief Scientific Officer at Mundipharma, commented, "Despite currently available treatments, the mortality rate for patients with invasive candidiasis remains high, demonstrating that there is still a clear unmet need for new treatment options to address this serious disease. Rezafungin, as a next generation echinocandin, has the potential to help critically ill, vulnerable patients battling invasive Candida infections. We would like to thank the MHRA for this recognition and look forward to working closely with them to ensure that patients in the UK can benefit from rezafungin."

"This PIM designation for once-weekly rezafungin is indicative of the potential that this product may have in helping patients to fight deadly Candida infections," said Taylor Sandison, M.D., Chief Medical Officer at Cidara.

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

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%.[1] 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.[3]

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 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).[4]

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 Authorization 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.[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.[5,6]

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 UK and in other countries; the potential timing of marketing authorisation submissions; and the likelihood that rezafungin, if approved, 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, 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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