European Medicines Agency Accepts Rezafungin Marketing Authorisation Application for the Treatment of Invasive Candidiasis

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
- The European Medicines Agency (EMA) filing is supported by the pivotal ReSTORE Phase III clinical trial results, where rezafungin demonstrated non-inferiority to the current standard of care, caspofungin in the treatment of candidemia and/or invasive candidiasis [1]
- If approved by the EMA, rezafungin could be the first new treatment option in Europe (EU) for patients with candidemia or invasive candidiasis for over 10 years

CAMBRIDGE, England, August 22, 2022 (BUSINESS WIRE) – Mundipharma today announced that the European Medicines Agency (EMA) has accepted the marketing authorisation application (MAA) for rezafungin for the treatment of invasive candidiasis in adult patients. The MAA is based on results from the pivotal ReSTORE Phase III clinical trial, which demonstrated statistical non-inferiority of rezafungin dosed once weekly when compared to the current standard of care, caspofungin, dosed once daily. This trial provides evidence of efficacy and safety of rezafungin as potential first-line treatment for candidemia and invasive candidiasis.[1]

Invasive candidiasis is a severe, life-threatening systemic Candida infection of the bloodstream and/or deep/visceral tissues.[2] Despite currently available treatments, the mortality rate for patients with invasive candidiasis remains high at up to 40%.[3] There is a real need for new treatment options to address this serious disease, especially as there has been no significant progress in treatment over the last decade.

“Rezafungin, as a next generation echinocandin, represents the first advancement in the treatment of invasive Candida infections in a very long time. If approved, the treatment could bring new hope for critically ill, vulnerable patients battling with this deadly disease in the EU,“ said Brian Sheehan, Ph.D., Chief Scientific Officer at Mundipharma. “We are pleased that the EMA has accepted our marketing authorisation application for rezafungin, and we look forward to working with the EMA to bring this medicine to patients.”

Rezafungin has already been granted Orphan Drug Designation for its use in the treatment of invasive candidiasis in both the EU and US.[4,5] A New Drug Application was recently submitted to the US Food and Drug Administration (FDA) for the treatment of candidemia and invasive candidiasis the USA. The FDA has previously identified rezafungin as a Qualified Infectious Disease Product (QIDP), which grants both Fast Track and Priority Review status.

Cidara has partnered with Mundipharma, which 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%.[3] 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.[2]

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 III clinical trial with rezafungin for the first-line treatment of candidemia and/or invasive candidiasis (ReSTORE trial).[6]

In this ReSTORE trial, rezafungin met the primary endpoint for the European Medicines Agency (EMA) Marketing Authorization Application (MAA) submission of global cure at Day 14, and also 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. Both of these results demonstrated statistical non-inferiority of rezafungin dosed once-weekly, versus caspofungin dosed once-daily, which is the current standard of care. Rezafungin was generally well tolerated and had a similar safety profile to caspofungin.[6]

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).

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.

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