Press release

Basilea announces New England Journal of Medicine publication of phase 3 data on ceftobiprole for the treatment of *Staphylococcus aureus* bacteremia

Allschwil, Switzerland, September 28, 2023

Basilea Pharmaceutica Ltd, Allschwil (SIX: BSLN), a commercial-stage biopharmaceutical company committed to meeting the needs of patients with severe bacterial and fungal infections, announced today that data from the successful phase 3 study ERADICATE were published in the New England Journal of Medicine (NEJM), one of the world's leading peer-reviewed medical journals.[1] In the study, Basilea's ceftobiprole, a beta-lactam antibiotic, was evaluated for the treatment of bacterial bloodstream infections caused by *Staphylococcus aureus* in adult patients, also known as *Staphylococcus aureus* bacteremia (SAB). ERADICATE is the largest registrational study for SAB conducted to date and ceftobiprole showed similar clinical benefit compared to daptomycin, which is a standard of care antibiotic in the treatment of SAB.

ERADICATE was a double-blind, non-inferiority study, which included 390 adult patients with complicated SAB, including right-sided infective endocarditis, at 60 sites in 17 countries.[2] Patients were randomized to receive infusions of ceftobiprole or daptomycin (plus optional aztreonam) for up to 42 days.

The primary outcome of the study was overall treatment success at 70 days after randomization defined by survival, bacteremia clearance, symptom improvement, no new SAB-related complications, and no receipt of other potentially effective antibiotics.

Using a pre-defined non-inferiority margin of 15%, treatment with ceftobiprole was non-inferior to daptomycin with overall treatment success achieved in 69.8% of patients in the ceftobiprole group compared to 68.7% in the daptomycin group.

The results for the primary study outcome were consistent in key subgroups, including patients with either methicillin-resistant *Staphylococcus aureus* (MRSA) or methicillin-susceptible *Staphylococcus aureus* (MSSA). Clearance of MRSA bacteria from the bloodstream was achieved in 93.3% of patients in the ceftobiprole group compared with 87.8% in the daptomycin group after a median of 5 days of treatment, and clearance of MSSA bacteria from the bloodstream was achieved in 94.3% of patients in the ceftobiprole group after a median of 3 days of treatment compared with 95.2% in the daptomycin group after a median of 4 days of treatment.

Ceftobiprole was generally well tolerated and showed a safety profile consistent with previous phase 3 studies and the post-marketing experience. The overall percentage of patients reporting adverse events was similar between the two treatment groups with more patients reporting gastrointestinal adverse events in the ceftobiprole group, typical for the beta-lactam class of antibiotics. There were no reports of *Clostridioides difficile* infections in either group.

Thomas Holland, M.D., Associate Professor in the department of Medicine at Duke University School of Medicine and chair of the data review committee of the study, said: “This is an area with a high need to provide new treatments to patients and there has not been a new antibiotic approved for the treatment of *Staphylococcus aureus* bacteremia for over 15 years.”

Vance G. Fowler, Jr., M.D., Professor in the departments of Medicine and Molecular Genetics & Microbiology at Duke University School of Medicine and academic lead investigator, added: “Complicated *Staphylococcus aureus* infections have a high mortality rate and are associated with substantial morbidity and we need more options for treating these infections, especially if MRSA is involved.”

Dr. Marc Engelhardt, Chief Medical Officer of Basilea, stated: “The data from the ERADICATE study published in the NEJM support the potent activity of ceftobiprole for treating serious bacterial infections. Based on ERADICATE and additional randomized controlled phase 3 studies, we have recently submitted a New Drug Application to the US Food and Drug Administration, seeking approval of ceftobiprole for treating patients in three indications: *Staphylococcus aureus* bacteremia, including right-sided infective endocarditis, acute bacterial skin and skin structure infections and community-acquired bacterial pneumonia.”

Basilea’s ceftobiprole phase 3 program is funded in part with federal funds from the US Department of Health and Human Services (HHS); Administration for Strategic Preparedness and Response (ASPR); Biomedical Advanced Research and Development Authority (BARDA), under contract number HHSO100201600002C. Basilea has been awarded approximately USD 112 million, or approximately 75 percent of the costs related to the phase 3 studies in SAB and acute bacterial skin and skin structure infections (ABSSSI), regulatory activities and non-clinical work.

About ceftobiprole

Ceftobiprole, the active moiety of the prodrug ceftobiprole medocaril, is an advanced generation cephalosporin antibiotic for intravenous administration, with rapid bactericidal activity against a wide range of Gram-positive bacteria such as *Staphylococcus aureus*, including methicillin-resistant strains (MRSA), and Gram-negative bacteria.[3] The brand is currently approved and marketed as Zevtera® and Mabelio® in several countries in Europe and beyond for the treatment of adult patients with hospital-acquired bacterial pneumonia (HABP), excluding ventilator-associated bacterial pneumonia (VABP), and for the treatment of community-acquired bacterial pneumonia (CABP). Basilea has entered into license and distribution agreements covering more than 80 countries. Ceftobiprole is currently not approved or partnered in the US. Ceftobiprole was designated a Qualified Infectious Disease Product (QIDP) by the US Food and Drug Administration (FDA) for SAB, ABSSSI and CABP. Therefore, if approved, ceftobiprole would be eligible to receive ten years of market exclusivity in the US from the date of approval.

About Basilea

Basilea is a commercial-stage biopharmaceutical company founded in 2000 and headquartered in Switzerland. We are committed to discovering, developing and commercializing innovative drugs to meet the needs of patients with severe bacterial or fungal infections. We have successfully launched two hospital brands, Cresemba for the treatment of invasive fungal infections and Zevtera for the treatment of bacterial infections. In addition, we have preclinical anti-infective assets in our portfolio. Basilea is listed on the SIX Swiss Exchange (SIX: BSLN). Please visit basilea.com.

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This press release can be downloaded from www.basilea.com.

References

1. T. L. Holland, S. E. Cosgrove, S. B. Doernberg et al. Ceftobiprole for treatment of complicated *Staphylococcus aureus* bacteremia. New England Journal of Medicine 2023 Sep 27; DOI: 10.1056/NEJMoa2300220. Epub ahead of print.
2. ERADICATE: ClinicalTrials.gov identifier NCT03138733
3. Summary of Product Characteristics (SmPC) Zevtera: https://www.medicines.org.uk/emc/product/9164/smpc [Accessed September 27, 2023]