Press release

Basilea reports presentation of new data for ceftobiprole (Zevtera®) at ESCMID Global 2024

Allschwil, Switzerland, May 03, 2024

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 scientific presentations with new data on its antibiotic ceftobiprole (Zevtera®) have been presented at ESCMID Global 2024, the annual meeting of the European Society of Clinical Microbiology and Infectious Diseases, which took place from April 27 to 30, 2024 in Barcelona, Spain.

Dr. Marc Engelhardt, Chief Medical Officer of Basilea, stated: “The data presented at ESCMID Global 2024 provide further evidence for the differentiated profile of ceftobiprole in the treatment of severe bacterial bloodstream infections, including those involving methicillin-resistant *Staphylococcus aureus*, MRSA, and pulmonary infections.”

Ceftobiprole was recently approved by the US Food and Drug Administration (FDA), supported by data from three phase 3 studies: ERADICATE, conducted in patients with *Staphylococcus aureus* bacteremia (SAB), TARGET, in acute bacterial skin and skin structure infections (ABSSSI), and a study in community-acquired bacterial pneumonia (CABP).[1, 2, 3]

Additional data from the ERADICATE phase 3 study were presented in three posters, comparing ceftobiprole to daptomycin in the treatment of complicated *Staphylococcus aureus* bacteremia. One poster focused on subgroup analyses in patients with renal impairment, demonstrating consistent efficacy and safety of ceftobiprole in this specific patient group, which included patients with chronic dialysis, representing 13% of patients in the ERADICATE study. Furthermore, baseline characteristics of patients in the ERADICATE study were presented, underlining the complexity of the infections in the studied patient population, with about 30% of patients presenting with more than one underlying infectious condition, foci, or complications at baseline, including soft tissue infections, dialysis, abdominal and thoracic abscesses, osteoarticular infections and right-sided endocarditis. Data presented on a third poster demonstrated that bloodstream clearance was achieved at a median of four days after the start of treatment in both the ceftobiprole and comparator groups. In the group treated with ceftobiprole, fewer patients had *Staphylococcus aureus*-positive blood cultures after ten days compared to the comparator treatment group.

An oral presentation focused on a re-analysis of the previously conducted ceftobiprole phase 3 study in patients with community-acquired bacterial pneumonia (CABP). The study compared ceftobiprole with ceftriaxone ± linezolid and was performed prior to the availability of the current FDA guidance for the development of drugs for the treatment of CABP (FDA-CABP-2020).

Using the FDA-CABP-2020 primary endpoint of early clinical success at day 3 after study start, this re-analysis supported the non-inferiority of ceftobiprole to ceftriaxone ± linezolid.

Basilea's phase 3 program for ceftobiprole 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. Through this partnership, Basilea has been awarded approximately USD 112 million, or approximately 75 percent of the costs related to the SAB and ABSSSI phase 3 studies, regulatory activities and non-clinical work.

Ceftobiprole data presented at ESCMID Global 2024

- Poster P0769 / Abstract 1493 – Ceftobiprole is safe and efficacious in treating renally impaired patients with complicated *Staphylococcus aureus* Bacteremia (SAB), including those on dialysis – results from the ERADICATE Phase 3 study – M. Engelhardt, S. E. Cosgrove, S. B. Doernberg, T. C. Jenkins, N. A. Turner, H. W. Boucher, M. Jones, D. Ionescu, J. Smart, M. Saulay, V. G. Fowler, Jr

- Poster P0771 / Abstract 1559 – An analysis of baseline conditions or complications of *S. aureus* bacteremia from a double-blind randomized Phase 3 study (ERADICATE) comparing ceftobiprole versus daptomycin – T. L. Holland, S. E. Cosgrove, S. B. Doernberg, T. C. Jenkins, N. A. Turner, H. W. Boucher, M. Jones, D. Ionescu, J. Smart, M. Saulay, M. Engelhardt, V. G. Fowler, Jr

- Poster P0774 / Abstract 1577 – Comparison of ceftobiprole versus daptomycin for time to *S. aureus* bloodstream clearance in the recent double-blind randomized Phase 3 study (ERADICATE) – T. L. Holland, S. E. Cosgrove, S. B. Doernberg, T. C. Jenkins, N. A. Turner, H. W. Boucher, M. Jones, D. Ionescu, J. Smart, M. Saulay, M. Engelhardt, V. G. Fowler, Jr

- Abstract O1068 – Ceftobiprole versus ceftriaxone ± linezolid in community-acquired bacterial pneumonia (CABP): Re-analysis of a Phase 3 study according to the FDA-CABP-2020 guidance – T. Welte, M. Engelhardt, M. Jones, S. Friedmann, D. Ionescu, M. Saulay, J. Smart, A. Shorr

About Zevtera® (ceftobiprole medocaril sodium for injection)

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.[4] In several countries in Europe and beyond, the brand is currently approved and marketed as Zevtera® and Mabelio® 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. In the United States, ZEVTERA® is indicated for the treatment of adult patients with *Staphylococcus aureus* bloodstream infections (bacteremia) (SAB), including right-sided infective endocarditis, and adult patients with acute bacterial skin and skin structure infections (ABSSSI) and for adult and pediatric patients (3 months to less than 18 years old) with community-acquired bacterial pneumonia (CABP).

Important US safety information for ZEVTERA (ceftobiprole medocaril sodium for injection)

Contraindications

ZEVTERA is contraindicated in patients with a known history of severe hypersensitivity to ZEVTERA, or to other members of the cephalosporin class.

Warnings and precautions

– Increased Mortality with Unapproved use in Ventilator-Associated Bacterial Pneumonia (VABP) Patients: The safety and effectiveness of ZEVTERA for the treatment of VABP has not been established and the use of ZEVTERA for VABP is not approved.

– Hypersensitivity Reactions: Discontinue ZEVTERA if a hypersensitivity reaction occurs, and institute appropriate treatment.

– Seizures and other adverse central nervous system (CNS) reactions have been associated with the use of ZEVTERA. If seizures or other CNS adverse reactions occur, evaluate patients to determine whether ZEVTERA should be discontinued.

– *Clostridioides difficile*-associated diarrhea (CDAD) has been reported with nearly all systemic antibacterial agents, including ZEVTERA. Evaluate if diarrhea occurs.

Adverse reactions

– SAB (adult patients): The most common adverse reactions occurring in ≥ 4% of adult patients were anemia, nausea, hypokalemia, vomiting, hepatic enzyme and bilirubin increased, diarrhea, blood creatinine increased, hypertension, leukopenia and pyrexia.

– ABSSSI (adult patients): The most common adverse reactions occurring in ≥ 2% of adult patients were nausea, diarrhea, headache, injection site reaction, hepatic enzyme increased, rash, vomiting, and dysgeusia.

- CABP (adult and pediatric patients 3 months to less than 18 years of age):
  - Adult Patients: The most common adverse reactions occurring in ≥ 2% of adult patients were nausea, hepatic enzyme increased, vomiting, diarrhea, headache, rash, insomnia, abdominal pain, phlebitis, hypertension and dizziness.
  - Pediatric Patients: The most common adverse reactions occurring in ≥ 2% of pediatric patients were vomiting, headache, hepatic enzyme increased, diarrhea, infusion site reaction, phlebitis and pyrexia.

For full US prescribing information, please visit here:
https://www.basilea.com/ZEVTERA_US_prescribing_information_46b9y4wk

About *Staphylococcus aureus* bacteremia (SAB)

Staphylococcus aureus bacteremia (SAB) is a serious bloodstream infection associated with significant morbidity and mortality.[5] Complications include concomitant infections such as bone, joint or heart valve infections, persistent bacteremia or bacteremia in patients on dialysis. With a 30-day all-cause mortality of around 20%, there is a high medical need for improved therapies for SAB.[6]

About acute bacterial skin and skin structure infections (ABSSSI)

Acute bacterial skin and skin structure infections (ABSSSI) are common infections in the healthcare setting. *Staphylococcus aureus* is the most common pathogen associated with these infections, which can be difficult to treat if methicillin-resistant *Staphylococcus aureus* (MRSA) is involved.[7]

About community-acquired bacterial pneumonia (CABP)

Community-acquired bacterial pneumonia (CABP) is a leading cause of morbidity and mortality worldwide. It is the leading cause of infectious disease-related death in the US.[8]

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 and 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 and clinical 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.

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