

Ad hoc announcement pursuant to Art. 53 LR

Basilea announces US FDA approval of antibiotic ZEVTERA® (ceftobiprole medocartil) for three indications

Allschwil, Switzerland, April 04, 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 the US Food and Drug Administration (FDA) approved ZEVTERA® (ceftobiprole medocartil sodium for injection), for the treatment of adult patients with *Staphylococcus aureus* bloodstream infections (bacteremia) (SAB), including those with 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).

David Veitch, Chief Executive Officer of Basilea, said: "We are excited with the US approval of ZEVTERA. The positive decision by the FDA is a key milestone towards bringing ZEVTERA to patients in the US. ZEVTERA has 10 years of market exclusivity from the date of approval and we believe the US provides the most important global commercial opportunity for the brand."

Dr. Marc Engelhardt, Chief Medical Officer of Basilea, stated: "We are very pleased that the FDA approved ZEVTERA for all three indications that were submitted with the NDA, including a pediatric labelling. This approval is a landmark for ceftobiprole and reflects its broad clinical utility. The indication in adult patients with *Staphylococcus aureus* bacteremia, including those with right-sided infective endocarditis, caused by methicillin-susceptible and methicillin-resistant isolates, MSSA and MRSA, addresses a real medical need, as current treatment options are limited."

The New Drug Application (NDA) was supported by clinical efficacy and safety data from the phase 3 studies ERADICATE (SAB)¹ and TARGET (ABSSSI),² and a phase 3 study in CABP.³ The ERADICATE study was the largest double-blind randomized registrational study conducted for a new antibiotic treatment in SAB.

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

Thomas Holland, M.D., Associate Professor in the Department of Medicine at the Duke University School of Medicine and chair of the data review committee of the ERADICATE study, added: “There is a high medical need in *Staphylococcus aureus* bacteremia, therefore, the first approval of a therapy for this indication in over 15 years is highly welcome.”

Adesh Kaul, Chief Financial Officer of Basilea, added: “As we were moving towards completion of the regulatory review, especially with increasing visibility on the expected label, the external interest for commercial partnering increased. Whilst our initial goal was to have announced a commercial partnership by the time of approval of ZEVTERA in the US, in order to explore fully all potential partnering opportunities, we now expect to complete the process around mid-year. In parallel, we are also taking preparatory steps to shorten the launch timelines, once we have entered into a commercialization partnership.”

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.

About ZEVTERA® (ceftobiprole medocartil sodium for injection)

Ceftobiprole, the active moiety of the prodrug ceftobiprole medocartil, 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 medocartil 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 $\geq 4\%$ 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 $\geq 2\%$ 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 $\geq 2\%$ 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 $\geq 2\%$ 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](https://www.basilea.com).

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This ad hoc announcement can be downloaded from www.basilea.com.

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