

## Press release

# Basilea announces completion of patient enrolment in phase 3 ERADICATE study investigating ceftobiprole in bloodstream infections

**Basel, January 11, 2022**

Basilea Pharmaceutica Ltd. (SIX: BSLN), a commercial-stage biopharmaceutical company committed to meeting the needs of patients with infectious diseases and cancer, announced today the completion of patient enrolment into the phase 3 ERADICATE study<sup>1</sup>. This study is investigating ceftobiprole in the treatment of patients with complicated bloodstream infections caused by *Staphylococcus aureus*, also referred to as *Staphylococcus aureus* bacteremia (SAB). ERADICATE reached its target enrolment of 390 patients.

ERADICATE is the second of two phase 3 studies necessary for a regulatory filing of ceftobiprole in the U.S. The first study, TARGET<sup>2</sup>, in patients with acute bacterial skin and skin structure infections (ABSSSI) reported positive results in 2019. If the results of the ERADICATE study are also positive, a New Drug Application will be submitted to the U.S. Food and Drug Administration (FDA). The U.S. is the largest potential market for ceftobiprole, considering the high incidence of MRSA (methicillin-resistant *Staphylococcus aureus*) infections in the U.S.

Dr. Marc Engelhardt, Chief Medical Officer, said: “ERADICATE is the largest randomized study conducted for registrational purposes of a new antibiotic treatment in *Staphylococcus aureus* bacteremia, or SAB. With patient enrolment now completed, we expect topline data from ERADICATE to become available in around six months, and these data will define our regulatory strategy for the U.S. SAB is an area of high unmet medical need with limited treatment options. With the ERADICATE study, our goal is to leverage the unique properties of ceftobiprole, for the benefit of patients with these severe bacterial infections, including those with complications such as right-sided infective endocarditis or osteomyelitis.”

Basilea's ceftobiprole phase 3 program is funded in part (up to USD 134.2 million, which is approximately 70% of the total potential program costs) with federal funds from the U.S. Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority (BARDA), under contract number HHSO100201600002C.

## About ceftobiprole

Ceftobiprole medocaril, the prodrug of the active moiety ceftobiprole, is a cephalosporin antibiotic for intravenous administration, with rapid bactericidal activity against a wide range of Gram-positive and Gram-negative bacteria. This includes methicillin-susceptible and resistant

*Staphylococcus aureus* (MSSA, MRSA) and susceptible *Pseudomonas* spp.<sup>3</sup> The brand is currently approved and marketed as Zevtera and Mabelio in a number of countries in Europe and beyond. Basilea has entered into license and distribution agreements in Europe, Eurasian countries, Latin America, China, Canada, Israel, and the Middle East and North Africa (MENA) regions.

### **About *Staphylococcus aureus* bacteremia (SAB)**

*Staphylococcus aureus* bacteremia is a leading cause of bloodstream infections, responsible for a broad variety of complications and has been associated with significant morbidity and a mortality of 20 to 40%.<sup>4,5</sup> Several studies have demonstrated that MRSA bacteremia is associated with a significantly higher mortality rate compared with MSSA bacteremia.<sup>6,7</sup> Infections of the inner lining of the heart or heart valves (infective endocarditis) and bone infections (osteomyelitis) are common complications of SAB.

### **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 cancer and infectious diseases. We have successfully launched two hospital brands, Cresemba for the treatment of invasive fungal infections and Zevtera for the treatment of severe bacterial infections. We are conducting clinical studies with two targeted drug candidates for the treatment of a range of cancers and have several preclinical assets in both cancer and infectious diseases in our portfolio. Basilea is listed on the SIX Swiss Exchange (SIX: BSLN). Please visit [basilea.com](http://basilea.com).

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