Press release

Basilea announces late breaking presentation on the successfully completed ERADICATE phase 3 study with ceftobiprole in *Staphylococcus aureus* bacteremia (SAB) at IDWeek 2022

- **First presentation of ERADICATE phase 3 study data**
- **Study met its primary and secondary endpoints comparing ceftobiprole versus daptomycin with or without aztreonam**

Basel/Allschwil, Switzerland, October 13, 2022

Basilea Pharmaceutica Ltd (SIX: BSLN), a commercial-stage biopharmaceutical company committed to meeting the needs of patients with severe bacterial and fungal infections, announced today that an abstract on the successfully completed phase 3 ERADICATE study[1], evaluating ceftobiprole in the treatment of adult patients with bacterial bloodstream infections caused by *Staphylococcus aureus*, (SAB), has been selected for a late breaking oral presentation at IDWeek 2022. The ERADICATE data will be presented by Thomas Holland, M.D., Associate Professor of Medicine at Duke University School of Medicine and Chair of the ERADICATE Data Review Committee.

IDWeek is the annual meeting of the Infectious Diseases Society of America (IDSA), jointly held with other infectious diseases societies in the U.S. and will take place in Washington, D.C. from 19 to 23 October 2022.

Positive topline results of the ERADICATE study, demonstrating non-inferiority to daptomycin, with or without aztreonam, for the primary objective, had been reported in June 2022.[2]

Dr. Marc Engelhardt, Chief Medical Officer, said: “This will be the first comprehensive presentation of the phase 3 ERADICATE study data. The study is the largest double-blind randomized study of a new antibiotic treatment conducted in SAB, which remains an area of high unmet medical need with limited treatment options available. The positive results underline the potent activity of ceftobiprole for treating serious bacterial infections and enable us to proceed with an NDA submission of ceftobiprole in the U.S.”

Basilea is planning to submit a New Drug Application (NDA) for ceftobiprole to the U.S. Food and Drug Administration (FDA) around year-end 2022.

Ceftobiprole at IDWeek 2022

22 October 2022, 1:45 p.m. ET (19:45 CEST)

Late Breaking Clinical Trials

- LB2302 - Ceftobiprole Compared to Daptomycin With or Without Optional Aztreonam for the Treatment of Complicated *Staphylococcus aureus* Bacteremia (SAB): Results of a Phase 3, Randomized, Double-Blind Trial (ERADICATE) – Thomas L. Holland, Sara E. Cosgrove, Sarah B. Doernberg, Oleksandr Pavlov, Ivan Titov, Boiko Atanasov, Maziar Assadi Gehr, Marc Engelhardt, Kamal Hamed, Daniel Ionescu, Mark Jones, Mikael Saulay, Jennifer Smart, Harald Seifert, Timothy C. Jenkins, Nicholas A. Turner, Vance G. Fowler Jr.

For further information please visit idweek.org.

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.[3] The brand is currently approved and marketed as Zevtera and Mabelio in a number of 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 in Europe, Eurasian countries, Latin America, China, Canada, Israel, and the Middle East and North Africa (MENA) regions.

About the ceftobiprole phase 3 program

The ERADICATE study[1] was a randomized, double-blind, multicenter phase 3 study, which enrolled 390 patients with SAB. The study compared the safety and efficacy of intravenous ceftobiprole medocaril with intravenous daptomycin, with or without intravenous aztreonam for coverage of Gram-negative pathogens, for up to 42 days of treatment. Patients were enrolled at more than 50 study centers in Eastern and Central Europe, Israel, Latin America, the Republic of South Africa, and the U.S.

The second study of the program, the TARGET study[4], was a randomized, double-blind, multicenter phase 3 study, which enrolled 679 patients with acute bacterial skin and skin structure infections (ABSSSI) and compared the safety and efficacy of intravenous ceftobiprole medocaril with intravenous vancomycin plus intravenous aztreonam. The study was conducted at more than 30 clinical centers in the U.S. and Europe.

The two phase 3 studies were conducted under Special Protocol Assessment (SPA) agreements with the U.S. FDA.

Basilea's ceftobiprole phase 3 program is funded in part (up to USD 136.4 million, which is approximately 70% of the total potential program costs) with federal funds from the U.S. Department of Health and Human Services; Administration for Strategic Preparedness and Response; Biomedical Advanced Research and Development Authority (BARDA), under contract number HHSO100201600002C.

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%.[5, 6] Several studies have demonstrated that MRSA bacteremia is associated with a significantly higher mortality rate compared with MSSA bacteremia.[7, 8] 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 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 several 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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For further information, please contact:

Peer Nils Schröder, PhD

Head of Corporate Communications & Investor Relations
Basilea Pharmaceutica International Ltd, Allschwil
Hegenheimermattweg 167b
4123 Allschwil
Switzerland

Phone +41 61 606 1102

E-mail media_relations@basilea.com
investor_relations@basilea.com

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

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3. Summary of Product Characteristics (SmPC) Zevtera: https://www.medicines.org.uk/emc/product/9164/smpc [Accessed: October 12, 2022]
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