Ad hoc announcement pursuant to Art. 53 LR

Basilea announces positive results of phase 3 ERADICATE study with ceftobiprole in *Staphylococcus aureus* bacteremia (SAB)

- **Ceftobiprole met primary and secondary efficacy endpoints**
- **Basilea plans to submit a New Drug Application (NDA) in the U.S. around year end 2022**

Basel, Switzerland, June 28, 2022

Basilea Pharmaceutica Ltd (SIX: BSLN), a commercial-stage biopharmaceutical company, announced today positive topline results for the phase 3 ERADICATE study, evaluating ceftobiprole in the treatment of adult patients with bacterial bloodstream infections caused by *Staphylococcus aureus* (SAB).[1] 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. In accordance with the agreed Special Protocol Assessment (SPA), Basilea will seek approval for SAB and acute bacterial skin and skin structure infection (ABSSSI) indications based on the successfully completed ERADICATE study and the TARGET phase 3 study[2], which was successfully completed in patients with ABSSSI in 2019. In addition, the company will explore the possibility for gaining approval for a third indication based on a previously performed phase 3 study in community-acquired bacterial pneumonia (CABP).[3]

Dr. Marc Engelhardt, Chief Medical Officer, stated: “The successful completion of the ERADICATE study is an exceptional achievement. ERADICATE is the largest double-blinded randomized study conducted of a new antibiotic treatment in SAB. The positive results underline the potent activity of ceftobiprole for treating serious bacterial infections. Achieving this important milestone enables us to proceed with a regulatory filing. Ceftobiprole would be the first beta-lactam antibiotic approved in the U.S. for the treatment of SAB caused by methicillin-susceptible or methicillin-resistant strains of *Staphylococcus aureus,* addressing important medical needs.”

Thomas Holland, M.D., Associate Professor of Medicine at Duke University School of Medicine and chair of the ERADICATE Data Review Committee said: “This is a landmark study in an area with a high need to provide new treatments to patients. Complicated *Staphylococcus aureus* bloodstream infections are common and associated with high morbidity and significant mortality and available antibiotic treatment options are limited, especially when methicillin-resistant *Staphylococcus aureus* is involved. The ERADICATE study provides strong support for the efficacy and safety of ceftobiprole in complicated SAB. This large phase 3 study included patients with a wide spectrum of underlying complications, underscoring its broad applicability to routine clinical practice.”

The ERADICATE study enrolled 390 patients with complicated SAB, including right-sided endocarditis. Ceftobiprole met the pre-specified efficacy objective of overall success in the modified intent-to-treat (mITT) population at 70 days after randomization, assessed by an independent Data Review Committee, within the pre-specified non-inferiority margin of 15% compared to daptomycin, with or without aztreonam.

The overall success rate was 69.8% with ceftobiprole compared to 68.7% with daptomycin, with or without aztreonam. The statistically adjusted difference between ceftobiprole and the comparator group was 2.0% (95% confidence interval: -7.1% to 11.1%). Initial subgroup analyses showed no significant differences between the two treatment groups.

Ceftobiprole was well tolerated and the observed safety profile was consistent with previous phase 3 studies and the post-marketing experience with ceftobiprole. In the ERADICATE study the overall rate of adverse events was similar between the two treatment groups. As expected, gastrointestinal side effects were more frequent with ceftobiprole.

Basilea plans to submit the full data from this study for presentation at an upcoming scientific conference.

Ceftobiprole was designated a Qualified Infectious Disease Product (QIDP) by the FDA for SAB, ABSSSI and CABP. Therefore, if approved, ceftobiprole would be eligible to receive ten years of market exclusivity in the U.S. from the date of approval. The U.S. represents the most important commercial market for ceftobiprole, with Basilea's estimate ranging from 80 to 90 percent of the global potential.

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.

Conference call and webcast

Basilea Pharmaceutica Ltd. will host a conference call and webcast today, Tuesday, June 28, 2022, at 4 p.m. (CEST), to discuss the ERADICATE topline results.

Via audio webcast with presentation

The live audio webcast of the presentation of the results can be followed here: https://event.choruscall.com/mediaframe/webcast.html?webcastid=28DAz4AN. Please note that there is no function to ask questions via webcast. For questions, please additionally dial in via phone (see below).

Via phone

To listen by phone and ask questions, please use the dial-in details below. To ensure prompt access, please call approximately five minutes prior to the scheduled start of the call.

+41 (0) 58 310 5000 (Europe and RoW)
+1 (1) 866 291 4166 (USA)
+44 (0) 207 107 0613 (U.K.)

Replay

The webcast, along with the presentation will be available online shortly after the event and accessible for three months.

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.[4] 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 the ceftobiprole phase 3 program

The ERADICATE study[1] was a randomized, double-blind, multicenter phase 3 study, which enrolled 390 patients with SAB and compared the safety and efficacy of intravenous ceftobiprole medocaril with intravenous daptomycin plus optional intravenous aztreonam for coverage of Gram-negative pathogens. 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 TARGET study[2] was a randomized, double-blind, multicenter phase 3 study, which enrolled 679 patients with 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.

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 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 severe 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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This communication expressly or implicitly contains certain forward-looking statements, such as "believe", "assume", "expect", "forecast", "project", "may", "could", "might", "will" or similar expressions concerning Basilea Pharmaceutica Ltd. and its business, including with respect to the progress, timing and completion of research, development and clinical studies for product candidates. Such statements involve certain known and unknown risks, uncertainties and other factors, which could cause the actual results, financial condition, performance or achievements of Basilea Pharmaceutica Ltd. to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Basilea Pharmaceutica Ltd. is providing this communication as of this date and does not undertake to update any forward-looking statements contained herein as a result of new information, future events or otherwise.

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

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