Ad hoc announcement pursuant to Art. 53 LR

Basilea announces submission of a New Drug Application to the US Food and Drug Administration for its antibiotic ceftobiprole

- **Seeking approval for *Staphylococcus aureus* bacteremia (SAB), acute bacterial skin and skin structure infections (ABSSSI), and community-acquired bacterial pneumonia (CABP)**
- **NDA eligible for Priority Review**

Allschwil, Switzerland, August 04, 2023

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 it has submitted a New Drug Application (NDA) to the US Food and Drug Administration (FDA). With this NDA, Basilea is seeking approval of its antibiotic ceftobiprole for treating patients in three indications: *Staphylococcus aureus* bacteremia (SAB), including right-sided infective endocarditis, acute bacterial skin and skin structure infections (ABSSSI) and community-acquired bacterial pneumonia (CABP).

Dr. Marc Engelhardt, Chief Medical Officer, said: "*Staphylococcus aureus* bacteremia is a common bloodstream infection with an estimated 120,000 cases in the US per year and is associated with substantial morbidity and mortality. Our completed phase 3 program demonstrates the efficacy of ceftobiprole in this complicated infection. The additional successfully completed phase 3 studies in ABSSSI and CABP support the broad clinical utility of ceftobiprole. Based on its potent antibacterial activity ceftobiprole could become a valuable new treatment option for severe bacterial infections in the US, especially when methicillin-resistant *Staphylococcus aureus* bacteria, MRSA, are of concern."[1]

The NDA submission includes clinical efficacy and safety data from the phase 3 studies ERADICATE (SAB),[2] TARGET (ABSSSI),[3] and a phase 3 study in CABP.[4] The ERADICATE study was the largest double-blind randomized registrational study conducted for a new antibiotic treatment in SAB.

Ceftobiprole has been designated a Qualified Infectious Disease Product (QIDP) under the US Generate Antibiotics Incentives Now (GAIN) Act, which provides for a Priority Review within eight months from submission. Provided that the NDA submission is accepted, Basilea expects a decision by the FDA on the NDA in the second quarter of 2024. Basilea plans to commercialize ceftobiprole in the US through a partner and intends to enter into such a partnership prior to the FDA's decision on the NDA.

Basilea's ceftobiprole phase 3 program 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. 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 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 bacteria such as *Staphylococcus aureus*, including methicillin-resistant strains (MRSA), and Gram-negative bacteria.[5] The brand is currently approved and marketed as Zevtera® and Mabelio® in several 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 covering more than 80 countries. Ceftobiprole is currently not approved and partnered in the US.

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 or 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 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, Allschwil 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, Allschwil to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Basilea Pharmaceutica Ltd, Allschwil 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.

References

1. Source for number of SAB cases in the quote: A. P. Kourtis, K. Hatfield, J. Baggs et al. Vital signs: Epidemiology and recent trends in methicillin-resistant and in methicillin-susceptible *Staphylococcus aureus* bloodstream infections – United States. MMWR Morbidity and mortality weekly report 2019 (68), 214-219
2. ERADICATE: ClinicalTrials.gov identifier NCT03138733
   T. L. Holland, S. E. Cosgrove, S. B. Doernberg et al. Ceftobiprole compared to daptomycin with or without optional aztreonam for the treatment of complicated *Staphylococcus aureus* (SAB): Results of a phase 3, randomized, double-blind trial (ERADICATE). Open Forum Infectious Diseases 2022 Dec (9), Suppl. 2 (LB2302)
3. TARGET: ClinicalTrials.gov identifier NCT03137173
   J. S. Overcash, C. Kim, R. Keech R et al. Ceftobiprole compared with vancomycin plus aztreonam in the treatment of acute bacterial skin and skin structure infections: Results of a phase 3, randomized, double-blind trial (TARGET). Clinical Infectious Diseases 2021 (73), e1507-e1517
4. CABP study: ClinicalTrials.gov identifier NCT00326287
   S. C. Nicholson, T. Welte, T. M. File Jr. et al. A randomised, double-blind trial comparing ceftobiprole medocaril with ceftriaxone with or without linezolid for the treatment of patients with community-acquired pneumonia requiring hospitalization. International Journal of Antimicrobial Agents 2012 (39), 240-246
5. Summary of Product Characteristics (SmPC) Zevtera: https://www.medicines.org.uk/emc/product/9164/smpc [Accessed August 03, 2023]