Basilea Pharmaceutica Ltd.
Grenzacherstrasse 487 | PO Box | 4005 Basel | Switzerland
basilea.com

Ad hoc announcement pursuant to Art. 53 LR

Basilea awarded additional USD 4.3 million by BARDA to support phase 3 development of ceftobiprole

- **BARDA further supports phase 3 program aiming at regulatory approval in the U.S.**
- **ERADICATE study on track for topline results in first half of 2022**

Basel, Switzerland, August 16, 2021

Basilea Pharmaceutica Ltd. (SIX: BSLN) announced today that it has been awarded an additional USD 4.3 million of non-dilutive funding by the Biomedical Advanced Research and Development Agency (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services, in the context of the existing contract to support the phase 3 program of Basilea's antibiotic ceftobiprole. The total contract value thus increases up to USD 134.2 million.

Dr. Marc Engelhardt, Chief Medical Officer, said: "We are very pleased that BARDA continues to fund the development of new antibiotics, which are urgently needed, as recently highlighted by the United Nations when announcing their Call to Action on Antimicrobial Resistance 2021. BARDA funding has supported the successful completion of our skin infections phase 3 TARGET study. With the continued support, we are looking forward to the upcoming completion of patient enrolment in the bloodstream infections ERADICATE study and to filing a New Drug Application (NDA) in the U.S., if the study is successful."

The first pivotal study, the TARGET study, in patients with acute bacterial skin and skin structure infections, was completed successfully in 2019.[1] The second study, the ERADICATE study, is evaluating the use of ceftobiprole for the treatment of patients with *Staphylococcus aureus* bacteremia, a form of complicated bacterial bloodstream infection, for which there are only limited treatment options available.[2] Basilea expects that patient enrolment into the ERADICATE study will be completed around year-end 2021 and that topline results of the study will become available as planned in the first half of 2022.

If approved by the U.S. Food and Drug Administration (FDA), the brand would have ten years of market exclusivity in the U.S., based on its status as a Qualified Infectious Disease Product, which was granted by the FDA to ceftobiprole under the U.S. GAIN Act.

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. Basilea has entered into license and distribution agreements for the brand in Europe, Eurasian countries, Latin America, China, Canada, Israel, and the Middle East and North Africa (MENA) regions.

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 *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%.[4, 5] Several studies have demonstrated that MRSA bacteremia is associated with a significantly higher mortality rate compared with MSSA bacteremia.[6, 7] 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 medical 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 a number of 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.

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For further information, please contact:

Peer Nils Schröder, PhD

Head of Corporate Communications & Investor Relations

Phone +41 61 606 1102

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

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

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