PRESS RELEASE

Basilea awarded USD 54.8 million of additional funding by BARDA to support phase 3 development of ceftobiprole

Basel, Switzerland, June 13, 2017 – Basilea Pharmaceutica Ltd. (SIX: BSLN) announced today that it has been awarded USD 54.8 million for two additional options on its existing contract with the Biomedical Advanced Research and Development Authority (BARDA), the Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response under Contract No. HHSO100201600002C, to support the phase 3 development of ceftobiprole. The total potential funding of up to approximately USD 108 million under the contract will enable Basilea to conduct two clinical phase 3 studies to evaluate Basilea's antibiotic ceftobiprole for the treatment of *Staphylococcus aureus* bacteremia (bloodstream infections) and acute bacterial skin and skin structure infections. The cross-supportive studies are part of the clinical phase 3 program aiming at regulatory approval of ceftobiprole in the United States.

Prof. Achim Kaufhold, Basilea's Chief Medical Officer, said: "Basilea has recently achieved important milestones, including the agreement with the FDA on Special Protocol Assessments for the two clinical phase 3 studies in *Staphylococcus aureus* bacteremia and skin infections. BARDA has therefore exercised options under our agreement releasing the funding to support the next stage of the program. We anticipate initiating these studies within the next three to six months. If successful, our phase 3 studies may allow for regulatory submission of ceftobiprole in the US as well as support label extensions in other parts of the world."

The newly committed USD 54.8 million add to the approximately USD 20 million initial funding that was allocated under the BARDA contract awarded in 2016 for the clinical phase 3 development of ceftobiprole to support a potential regulatory filing in the US. The total value of the contract could reach approximately USD 108 million over a period of 4.5 years if pre-defined milestones are met.

About ceftobiprole

Ceftobiprole is a cephalosporin antibiotic for intravenous administration with rapid bactericidal activity against a wide range of Gram-positive and Gram-negative bacteria, including methicillin-susceptible and resistant *Staphylococcus aureus* (MSSA, MRSA) and susceptible *Pseudomonas* spp. The drug is approved for sale in 13 European countries (European trade name Zevtera® or Mabelio®, depending on the country) and several non-European countries for the treatment of adult patients with community-acquired bacterial pneumonia (CABP) and hospital-acquired bacterial pneumonia (HABP), excluding ventilator-associated bacterial pneumonia (VABP).[1] Basilea is currently marketing the drug in Germany, Italy, the UK, France, Austria and Switzerland. Ceftobiprole received Qualified Infectious Disease Product (QIDP) designation from the US Food and Drug Administration (FDA) for the potential treatment of community-acquired bacterial pneumonia (CABP) and acute bacterial skin and skin structure infections (ABSSSI). Basilea has reached agreement with the FDA on Special Protocol Assessments (SPAs) for its two planned phase 3 clinical studies in *Staphylococcus aureus* bacteremia and ABSSSI. An SPA provides agreement between the study sponsor and the FDA that the design and planned analysis of a clinical study adequately address the objectives necessary to support a regulatory submission for the approval of a drug. Ceftobiprole is not approved for commercial sale in the United States.

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About *Staphylococcus aureus* bacteremia

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%.[2, 3] Several studies have demonstrated that MRSA bacteremia is associated with a significantly higher mortality rate compared with methicillin-susceptible *Staphylococcus aureus* (MSSA) bacteremia.[4, 5] Infections of the inner lining of the heart or heart valves (infective endocarditis) and bone infections (osteomyelitis) are common complications of *Staphylococcus aureus* bacteremia.

About acute bacterial skin and skin structure infections

Acute bacterial skin and skin structure infections (ABSSSIs) are among the most common infections encountered in both community and hospital settings, and include infections with resistance to previously effective antibacterial treatments.[6] Increasing in incidence, they have become a challenging medical problem associated with high direct and indirect costs to both the medical system and society.[7] Infections due to bacteria with resistance to previously effective antibacterial treatments, such as methicillin-resistant *Staphylococcus aureus* (MRSA), are increasing in incidence and have led to higher rates of complications and hospitalization. MRSA has emerged as the most common cause of pus-forming infections in the United States and many other areas.

About Basilea

Basilea Pharmaceutica Ltd. is a biopharmaceutical company developing products that address the medical challenge of increasing resistance and non-response to current treatment options in the therapeutic areas of bacterial infections, fungal infections and cancer. The company uses the integrated research, development and commercial operations of its subsidiary Basilea Pharmaceutica International Ltd. to discover, develop and commercialize innovative pharmaceutical products to meet the medical needs of patients with serious and life-threatening conditions. Basilea Pharmaceutica Ltd. is headquartered in Basel, Switzerland and listed on the SIX Swiss Exchange (SIX: BSLN). Additional information can be found at Basilea's website www.basilea.com.

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

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