

PRESS RELEASE

Basilea reports that ceftobiprole received QIDP designation from U.S. FDA for the treatment of *Staphylococcus aureus* bacteremia (SAB)

Basel, Switzerland, December 21, 2017 – Basilea Pharmaceutica Ltd. (SIX: BSLN) announced today that the U.S. Food and Drug Administration (FDA) designated its investigational drug ceftobiprole as a Qualified Infectious Disease Product (QIDP). The designation relates to the potential use of the drug in the treatment of bacterial bloodstream infections (bacteremia) caused by *Staphylococcus aureus*.

QIDP status, granted under the Generating Antibiotic Incentives Now (GAIN) Act in the United States, provides certain incentives for the development of antibiotics, such as priority review if the product is submitted for approval in the United States, and a five-year extension of certain periods of market exclusivity that may be applicable should it be approved.

Ronald Scott, Chief Executive Officer, commented, “*Staphylococcus aureus* is a leading cause of bloodstream infections, which are associated with significant morbidity and mortality specifically when caused by methicillin-resistant strains. Basilea is committed to address the issue of resistance in underserved areas of high medical need such as bacteremia. The FDA QIDP designation for ceftobiprole provides important support for us to achieve this goal.”

Basilea is preparing two cross-supportive clinical phase 3 studies with ceftobiprole to support a potential future registration in the United States. Both studies will be conducted under Special Protocol Assessment (SPA) agreements with the FDA. The first study, exploring ceftobiprole in the treatment of adult patients with acute bacterial skin and skin structure infections (ABSSSI), is going to start shortly. The second study is going to explore the utility of ceftobiprole in the treatment of adult patients with *Staphylococcus aureus* bacteremia and is anticipated to start in the first half of 2018.

The phase 3 program receives funding of up to approximately USD 108 million from the Biomedical Advanced Research and Development Authority (BARDA), the U.S. Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, under contract number HHSO100201600002C.

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.¹ Ceftobiprole is currently approved for sale in major European countries and several non-European countries for the treatment of adult patients with community-acquired pneumonia (CAP) and hospital-acquired pneumonia (HAP), excluding ventilator-associated pneumonia (VAP).¹ Basilea has entered into license and distribution agreements for the drug in Europe, Latin America, China, the Middle East and North Africa (MENA) region, Canada and Israel. Ceftobiprole is not approved for commercial sale in the United States.

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 Basilea

Basilea Pharmaceutica Ltd. is a commercial stage 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 is committed to discovering, developing and commercializing 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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