# PRESS RELEASE

# Basilea reports clinical phase 3 study start with antibiotic ceftobiprole in skin infections under BARDA contract

***Basel, Switzerland, February 23, 2018*** – Basilea Pharmaceutica Ltd. (SIX: BSLN) announced today that it has commenced enrollment in the first of its two planned clinical phase 3 registration studies of the antibiotic ceftobiprole. The first study evaluates the safety and efficacy of the antibiotic in the treatment of adult patients with acute bacterial skin and skin structure infections (ABSSSI). Basilea expects to begin enrollment in the second phase 3 clinical trial of ceftobiprole in the treatment of adult patients with bacteremia (bloodstream infection) caused by *Staphylococcus aureus* mid-2018. The two trials are designed to be cross-supportive for a potential U.S. registration and are conducted under a Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration (FDA).

Ronald Scott, Chief Executive Officer, said: "We are pleased to have commenced enrollment of the phase 3 ABSSSI program for ceftobiprole with the goal to bring our broad-spectrum anti-MRSA antibiotic to patients in the U.S. Acute bacterial skin and skin structure infections are among the most common bacterial infections encountered in both community and hospital settings. Skin infections caused by resistant bacteria such as MRSA have become a challenging medical problem associated with extended hospitalization, high costs and increased mortality. Ceftobiprole offers a potential treatment option in an area of high medical need."

The randomized, double-blind, multicenter study aims to establish the safety and efficacy of intravenously (i.v.) administered ceftobiprole versus i.v. vancomycin (plus aztreonam for Gram-negative infections) in the treatment of ABSSSI. The FDA-agreed primary objective of the study is to demonstrate non-inferiority of ceftobiprole to the comparator regimen with respect to early clinical response based on reduction of lesion size. The study is anticipated to enroll approximately 675 male and female adult patients.

Basilea's phase 3 ceftobiprole program is being conducted under a contract with the U.S. Biomedical Advanced Research and Development Authority (BARDA) which provides funding of up to USD 108 million.

## 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] It is marketed in major European countries. Basilea has entered into license and distribution agreements for the drug in Europe, Latin America, China, Canada, Israel, and the Middle East and North Africa (MENA) region. Ceftobiprole has Qualified Infectious Disease Product (QIDP) status in the U.S. for the potential treatment of ABSSSI, *Staphylococcus aureus* bacteremia (SAB) and CAP, providing priority review and an extension of market exclusivity in the U.S. to ten years after approval. Basilea's clinical phase 3 program aims at the regulatory approval of ceftobiprole in the United States. It includes two cross-supportive phase 3 studies and receives funding from the Biomedical Advanced Research and Development Authority



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

(BARDA), the U.S. Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, under contract number HHSO100201600002C. Subject to the successful outcomes of these studies, there may an option to apply for label extensions in Europe and other regions. Ceftobiprole is not currently approved for commercial sale in the U.S.

## 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.

## Disclaimer

This communication expressly or implicitly contains certain forward-looking statements concerning Basilea Pharmaceutica Ltd. and its business. 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.

For further information, please contact:

Peer Nils Schröder, PhD
Head of Corporate Communications & Investor Relations
+41 61 606 1102
media_relations@basilea.com
investor_relations@basilea.com

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

## References

1 UK Summary of Product Characteristics (SPC) Zevtera: http://www.mhra.gov.uk/ [Accessed: February 22, 2017]