PRESS RELEASE

Basilea awarded contract by BARDA of up to USD 100 million funding for ceftobiprole phase 3 program

Basel, Switzerland, April 20, 2016 – Basilea Pharmaceutica Ltd. (SIX: BSLN) announced today that the Biomedical Advanced Research and Development Authority (BARDA), a division within the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response, has entered into a contract with Basilea Pharmaceutica International Ltd. ("Basilea") for the clinical phase 3 development aiming at regulatory approval of Basilea's broad-spectrum antibiotic ceftobiprole in the United States.

Under the terms of the contract, BARDA will provide funding of approximately USD 20 million over an initial period of 18 months. During this initial period, Basilea will work towards gaining agreement on the development program from the U.S. Food and Drug Administration (FDA) and obtaining first health authority approvals for the initiation of clinical phase 3 studies, which are targeted to be started towards the end of this year or the beginning of next year. During the term of the agreement BARDA may exercise further options, which would bring the total value of the contract up to USD 100 million over a period of 4.5 years, upon successful completion of pre-defined milestones including pre-clinical, clinical, manufacturing and associated regulatory activities.

Ronald Scott, Basilea's Chief Executive Officer, commented: "Resistance against currently available antibiotics is a global healthcare risk. Our agreement with BARDA demonstrates the potential value of ceftobiprole to treat life-threatening infections and will enable us to start a phase 3 program, initially in bacteremia and acute bacterial skin and skin structure infections, with the goal of achieving U.S. regulatory approval and to expand ceftobiprole's label in other territories."

Basilea is preparing protocols for three phase 3 studies with ceftobiprole to support the potential submission of New Drug Applications (NDAs) for the treatment of patients with *Staphylococcus aureus* bacteremia (SAB), acute bacterial skin and skin structure infections (ABSSSI) and community-acquired bacterial pneumonia (CABP). Basilea intends to submit these protocols to the FDA, seeking the agency's agreement on Special Protocol Assessments (SPAs). An SPA provides written guidance by the FDA and documents agreement between the study sponsor and the agency that a clinical study is adequately designed so that it would support a regulatory submission for drug approval, should the study meet its objectives.

Prof. Achim Kaufhold, Basilea's Chief Medical Officer, commented: "Based on recent FDA feedback we understand that any two adequate and well-controlled studies in either SAB, ABSSSI or CABP, demonstrating safety and efficacy in each of those studies, would be sufficient to support regulatory approval of ceftobiprole in the United States. We believe that within the three indications under consideration the highest medical need is in *Staphylococcus aureus* bacteremia where new antibiotics with bactericidal activity against both methicillin-susceptible and resistant strains are urgently needed. Ceftobiprole offers a potential treatment option for this area of high medical need."

The project will be funded in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical

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Advanced Research and Development Authority (BARDA) under Contract No. HHSO100201600002C.

About ceftobiprole

Ceftobiprole (ceftobiprole medocaril) is a broad-spectrum antibiotic for intravenous administration with bactericidal activity against certain Gram-positive and Gram-negative bacteria, including methicillin-resistant *Staphylococcus aureus* (MRSA) and susceptible *Pseudomonas* spp.[1]

Ceftobiprole is approved for sale in 13 European countries and Canada for the treatment of adult patients with community-acquired pneumonia and hospital-acquired pneumonia (excluding ventilator-associated pneumonia) and has been launched in Germany, France, Italy, the United Kingdom and Austria.[1] Ceftobiprole received Qualified Infectious Disease Product (QIDP) designation from the U.S. Food and Drug Administration for the potential treatment of community-acquired bacterial pneumonia and acute bacterial skin and skin structure infections. Ceftobiprole is not approved in the United States.

About Basilea

Basilea Pharmaceutica Ltd. is a biopharmaceutical company developing products that address 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 potentially 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.

References

1 UK Summary of Product Characteristics (SPC): http://www.mhra.gov.uk/ [Accessed: April 19, 2016]