

## PRESS RELEASE

# Basilea awarded contract by BARDA of up to USD 89 million for the development of its novel antibiotic BAL30072

- **BAL30072 current multiple ascending dose study reached maximum tolerated dose**
- **Further development, including combination studies with carbapenems, planned under BARDA agreement**

*Basel, Switzerland, June 25, 2013* – 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, has entered a contract with Basilea for the development of BAL30072, Basilea's novel monosulfactam antibiotic, due to the drug's broad coverage against multidrug-resistant Gram-negative pathogens including those that pose a biothreat.

Under the terms of the contract, BARDA will provide funding of approximately USD 17 million over the initial agreement period of twenty-two months. Subsequent options which may be exercised over a total six-year-period would bring the total value of the contract up to USD 89 million. Exercise of these options is conditioned upon successful completion of pre-defined milestones, including microbiological, pre-clinical, clinical, manufacturing and associated regulatory activities.

BAL30072 is being developed for the treatment of severe infections, such as nosocomial pneumonia due to multidrug-resistant Gram-negative bacteria. To date, Basilea has conducted a single ascending dose, double-blind, randomized, placebo-controlled trial and double-blind, randomized, placebo-controlled dose-ranging studies with multiple ascending doses in healthy volunteers assessing the pharmacokinetics, safety and tolerability of BAL30072. For the current multiple ascending dose study, the maximum tolerated dose has been reached. Consistent with previous findings the dose-limiting factor was reversible elevated liver enzyme levels.

In pre-clinical *in-vitro* and in animal studies, an additive or synergistic activity of BAL30072 when combined with antibiotics from the carbapenem class has been demonstrated. Under the contract with BARDA, Basilea will now continue to test in phase 1 safety and tolerability of BAL30072 also in combination with carbapenems. Basilea is continuing the profiling of BAL30072 to establish the optimal dosing regimens for clinical testing of combinations. The phase 1 development program, including studies in combination and in special patient populations, will continue in 2014.

Ronald Scott, Basilea's Chief Executive Officer, commented: "BAL30072 is a potent, bactericidal antibiotic covering a broad range of clinically relevant multidrug-resistant Gram-negative bacteria. The drug originated from our portfolio of exciting research compounds addressing multiple mechanisms of drug resistance. Our integrated research, development and manufacturing organization is focused on making drugs that fight resistance available to patients. Through the BARDA contract, we will move forward with the development of our innovative antibiotic BAL30072, advancing a medical countermeasure for a potential biological threat to national security and public health."

Prof. Achim Kaufhold, Basilea's Chief Medical Officer added: "Given the evidence of synergistic or additive activity of BAL30072 in combination with carbapenems and its broad coverage of multidrug-resistant Gram-negative pathogens, the drug has the potential of becoming an important treatment option for serious infections, including hospital-acquired infections due to resistant pathogens which are increasing in frequency. BAL30072 addresses the global concerns of antibiotic resistance and also has a potential role in biodefense, treating infections caused by potential biowarfare agents."

BARDA is a division within the Office of the Assistant Secretary for Preparedness and Response in the U.S. Department of Health and Human Services.

### About BAL30072

BAL30072 is a novel monosulfactam antibiotic with bactericidal activity against multidrug-resistant Gram-negative bacteria. It has demonstrated broad *in-vitro* and *in-vivo* coverage of Gram-negative pathogens including multidrug-resistant *Pseudomonas aeruginosa* and *Acinetobacter baumannii*. It has robust activity against common and resistant pathogens including those that produce antibiotic-inactivating enzymes such as metallo-beta-lactamases including the New Delhi metallo-beta-lactamase 1 (NDM-1). In addition, BAL30072 has been shown to enhance the activity of antibiotics from the carbapenem class. Due to its potent antimicrobial activity against a broad range of clinically relevant and resistant Gram-negative bacteria, BAL30072 has the potential to play an important role in the therapy of serious and life-threatening infections such as hospital-acquired pneumonia, complicated intra-abdominal infections or complicated urinary tract infections.

### About Basilea

Basilea Pharmaceutica Ltd. is headquartered in Basel, Switzerland, and listed on the SIX Swiss Exchange (SIX: BSLN). Through the fully integrated research and development operations of its Swiss subsidiary Basilea Pharmaceutica International Ltd., the Company focuses on innovative pharmaceutical products in the therapeutic areas of bacterial infections, fungal infections and oncology, targeting the medical challenge of rising resistance and non-response to current treatment options.

### Disclaimer

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