PRESS RELEASE

Basilea initiates phase 1 combination study with its Gram-negative antibiotic BAL30072 and meropenem

- **Development program conducted under BARDA agreement**

Basel, Switzerland, June 12, 2014 – Basilea Pharmaceutica Ltd. (SIX: BSLN) has initiated a phase 1 clinical study with its Gram-negative antibiotic BAL30072 evaluating the safety, tolerability and pharmacokinetics of multiple-ascending doses of intravenously administered BAL30072 in combination with meropenem, an antibiotic of the carbapenem class.

Basilea is developing BAL30072 for the potential treatment of infections with multidrug-resistant Gram-negative bacteria. Gram-negative pathogens account for approximately a third of all hospital-acquired infections and are recognized as a global health threat.[1, 2] In preclinical studies, BAL30072 demonstrated synergistic or additive effects when combined with carbapenem antibiotics.[3]

Prof. Achim Kaufhold, Basilea's Chief Medical Officer, stated: "Based on the recent encouraging preclinical data on the synergistic or additive effects of BAL30072 and carbapenems we are exploring such combinations in the clinical setting. We are assessing the safety and tolerability of BAL30072 alone and in combination with meropenem in preparation for phase 2 development. Combinations with meropenem may add synergistic or additive coverage to the potent activity of BAL30072 against a broad range of clinically relevant multidrug-resistant Gram-negative pathogens, such as *Acinetobacter baumannii and Pseudomonas aeruginosa* and other less common pathogens causing serious infections for which there are currently few or no treatments available."

The phase 1 study is designed as a double blind, placebo-controlled, parallel-group study enrolling healthy female and male adults and randomized to receive multiple-ascending doses of BAL30072 or placebo alone or in combination with meropenem.

About BAL30072

BAL30072 is an intravenous monosulfactam antibiotic in phase 1 clinical development with bactericidal activity against infections by multidrug-resistant Gram-negative bacteria. The investigational drug demonstrated *in-vitro* and *in-vivo* coverage of Gram-negative pathogens including multidrug-resistant *Acinetobacter baumannii and Pseudomonas aeruginosa* and has robust activity against strains that produce antibiotic-inactivating enzymes such as metallo-beta-lactamases. BAL30072 has shown synergistic or additive activity with antibiotics from the carbapenem class. In previous phase 1 studies, the maximum tolerated dose for BAL30072 was determined, with reversible elevated liver enzyme levels as the dose-limiting factor. In June 2013, Basilea entered a contract for the development of BAL30072 with the Biomedical Advanced Research and Development Authority (BARDA) within the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response. The contract may provide development funding for BAL30072 of up to USD 89 million.

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

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

oncology, targeting the medical challenge of rising resistance and non-response to current treatment options.

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:

Media Relations	Investor Relations
Peer Nils Schröder, PhD Head Public Relations & Corporate Communications +41 61 606 1102 media_relations@basilea.com	Barbara Zink, PhD, MBA Head Corporate Development +41 61 606 1233 investor_relations@basilea.com

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

References

1 A. Y. Peleg et al. Hospital-acquired infections due to gram-negative bacteria. New England Journal of Medicine 2010 (362), 1804-1813

2 C. Torres. Up against the wall. Nature Medicine 2010 (16), 628-631

3 I. Morrissey et al. Activity of BAL30072 alone and in combination with carbapenems against Gram-negative bacteria. European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) 2014, poster P0296