PRESS RELEASE

Basilea reports presentation of new data on anti-infective drug candidates addressing drug resistance

Basel, Switzerland, April 29, 2013 – Basilea Pharmaceutica Ltd. (SIX: BSLN) reported today that new data on drug candidates from its development pipeline were presented at the European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) held in Berlin, Germany, from April 27 to 30.

The accelerating development of antibiotic resistance in Gram-positive bacteria as well as the emergence of multidrug-resistant Gram-negative pathogens are major global healthcare problems. In addition, mortality rates associated with invasive fungal disease in immunocompromized patients, such as cancer or transplant patients, remain high despite current therapies resulting in a need for novel antifungal drugs.

Prof. Achim Kaufhold, Basilea's Chief Medical Officer, commented: "Infections with drug-resistant bacteria are estimated to claim each year more than 100,000 lives in Europe and America. Basilea is one of the few companies worldwide committed to address the problem of growing resistance against currently available antibiotics and antifungals. The data presented at ECCMID on the antifungal isavuconazole and the two antibiotics ceftobiprole and BAL30072 further substantiate the promising profiles of these innovative product candidates for addressing high unmet medical need."

Isavuconazole – a novel intravenous and oral broad-spectrum antifungal for the potential treatment of severe invasive and life-threatening fungal infections, currently in phase 3 clinical testing and partnered with Astellas Pharma Inc.

In a pooled analysis of eight studies undertaken in Europe and the U.S., isavuconazole exhibited potent *in-vitro* activity against clinically relevant *Candida* isolates with reduced susceptibility to fluconazole (P 983). Fluconazole is currently recommended as first-line treatment of infections with *Candida* yeasts, which are the most common cause of invasive fungal disease in humans and a major cause of bloodstream infections in hospitalized patients associated with significant morbidity and mortality.

Other presentations further support isavuconazole's broad spectrum of activity against clinically relevant yeasts and molds. In a study of a large series of *Cryptococcus neoformans* clinical isolates causing lung infections in Asian patients, isavuconazole demonstrated the highest activity of all antifungals tested (P 1001). In addition, isavuconazole was reported to be active against recently identified emerging pathogenic yeast *Candida africana* (P 1079) as well as basidiomycete molds, which are associated with respiratory infections (O 167).

Ceftobiprole – a novel broad-spectrum anti-MRSA antibiotic under regulatory review in Europe for pneumonia treated in the hospital

To monitor the spectrum and potency of antibiotics, several European surveillance studies were conducted from 2008 through 2010. Results from *in-vitro* testing of ceftobiprole against these large collections of clinically relevant isolates were presented. Ceftobiprole was highly potent against methicillin-resistant *Staphylococcus aureus* (MRSA), including strains with decreased susceptibility to commonly used anti-MRSA antibiotics daptomycin, linezolid and vancomycin (P 1629). Furthermore, ceftobiprole was shown to be highly potent against a large collection of

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

European Gram-positive clinical isolates comprising staphylococci, streptococci and enterococci, including strains resistant to commonly used antibiotics for the treatment of Gram-positive infections (P 1628).

In addition, ceftobiprole demonstrated potent activity similar to ceftazidime and cefepime when tested against a large collection of clinically relevant Gram-negative pathogens, specifically Enterobacteriaceae and *Pseudomonas aeruginosa,* collected in Europe during 2008 to 2010 (P 1627). Cefepime and ceftazidime are two commonly used broad-spectrum cephalosporin antibiotics which, however, lack anti-MRSA activity that ceftobiprole offers in addition to its broad Gram-positive and Gram-negative spectrum.

An analysis of data from the randomized, double-blind phase 3 clinical study with ceftobiprole for the treatment of hospital-acquired pneumonia showed that clinical outcome at the test-of-cure visit was associated with exposure to the drug during treatment (P 904).

Ceftobiprole is currently under regulatory review in Europe for the treatment of pneumonia in the hospital. Data presented at ECCMID demonstrate the potent *in-vitro* activity of ceftobiprole against leading pathogens associated with community-acquired and hospital-acquired pneumonia (P 1626, P 1625). Ceftobiprole was several-fold more active against *Streptococcus pneumoniae* than ceftriaxone and cefepime, two antibiotics commonly used for the treatment of pneumonia. In addition, the drug exhibited potent activity against a broad spectrum of Gram-positive and Gram-negative pathogens associated with hospital-acquired bacterial pneumonia, including MRSA, penicillin-resistant *Streptococcus pneumoniae,* Enterobacteriaceae and *Pseudomonas aeruginosa.*

BAL30072 – a novel sulfactam antibiotic with bactericidal activity against multidrug-resistant Gram-negative bacteria that is currently in phase 1 clinical testing

The innovation of Basilea's antibiotic BAL30072 was highlighted in an oral presentation at ECCMID. BAL30072, alone or in combination with meropenem exhibited excellent *in-vitro* and *in-vivo* activity against a broad range of clinically relevant multidrug-resistant Gram-negative pathogens such as *Acinetobacter baumannii* and *Pseudomonas aeruginosa,* including isolates with resistance against meropenem or the last resort antibiotic colistin (O 182).

In an *in-vivo* infection model it was demonstrated that BAL30072 was well tolerated and highly effective against multidrug-resistant *E. coli*, *Klebsiella pneumoniae* and *Pseudomonas aeruginosa*, including isolates expressing the NDM-1 metallo-beta lactamase encoding gene. BAL30072 displayed rapid *in-vivo* bactericidal activity (P 908). BAL30072 in combination with meropenem showed strong synergistic interaction, resulting in a rapid bactericidal activity against NDM-1 positive strains expressing multiple additional beta-lactamases (P 1631).

Posters on isavuconazole

In-vitro activity of isavuconazole against Candida isolates from the EU and USA with reduced susceptibility to fluconazole: a pooled analysis from eight studies – J.I. SMART, M.E. JONES, L.L. KOVANDA; P 983

Microsatellite-typing of 458 Indian Cryptococcus neoformans var. grubii isolates and in-vitro susceptibility analysis – A. CHOWDHARY, F. HAGEN, A. PRAKASH, S. KATHURIA, C.H.W. KLAASSEN, J.F. MEIS; P 1001

Molecular characterisation of germ tube-positive Candida species with special reference to Candida africana – C. SHARMA, S. WANKHEDE, A. PRAKASH, P. KUMAR SINGH, S. KATHURIA, A. CHOWDHARY; P 1079

Molecular identification of clinically-significant non-sporulating basidiomycete moulds – P. KUMAR SINGH, S. KATHURIA, K. AGARWAL, P. ROY, G. SYBREN DE HOOG, J.F. MEIS, A. CHOWDHARY; O 167

Posters on ceftobiprole

Activity of ceftobiprole against methicillin-resistant Staphylococcus aureus including strains with reduced susceptibility to daptomycin, linezolid, and vancomycin – R.K. FLAMM, R.E. MENDES, H.S. SADER, R.N. JONES; P 1629

Activity of ceftobiprole tested against clinical isolates of staphylococci and streptococci from European surveillance (2008-2010) – R.K. FLAMM, H.S. SADER, J.M. STREIT, R.N. JONES; P 1628

Activity of ceftobiprole tested against Gram-negative clinical isolates from European medical centres – R.K. FLAMM, H.S. SADER, J.M. STREIT, R.N. JONES; P 1627

%fT>MIC (minimum inhibitory concentration) predicts probability of clinical outcome in the treatment of nosocomial pneumonia by ceftobiprole – A.E. MULLER, N. PUNT, J.W. MOUTON; P 904

Activity of ceftobiprole tested against pathogens associated with community-acquired bacterial pneumonia in Europe – R.K. FLAMM, H.S. SADER, R.N. JONES; P 1626

Activity of ceftobiprole tested against pathogens associated with hospital-acquired bacterial pneumonia in Europe – R.K. FLAMM, H.S. SADER, J.M. STREIT, R.N. JONES; P 1625

Oral presentation on BAL30072

In-vivo efficacy of the novel monosulfactam BAL30072 alone and in combination with meropenem against clinically important Gram-negative pathogens – W. WEISS, M. PULSE, P. NGUYEN, J. PIERCE, D. VALTIERRA, K. PETERSON, J. SIMECKA, W. STUBBINGS; O 182

Posters on BAL30072

Efficacy of BAL30072 in murine thigh infection models of multi-resistant Gram-negative bacteria – J.K. GOULD, A. SATTAR, P. THOMMES, L.J. PAYNE, W. STUBBINGS, J. SPICKERMANN, G. DAWS, P. WARN; P 908

BAL30072 combined with meropenem exhibits synergistic bactericidal activity against clinical New Delhi metallo beta-lactamase (NDM-1)-positive Enterobacteriaceae – J. WEEKS, W. STUBBINGS, T.R. WALSH; P 1631

For further information please visit www.congrex.ch/eccmid2013.

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

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.