

## PRESS RELEASE

# Basilea reports presentation of 19 posters at ICAAC on investigational anti-infectives isavuconazole, ceftobiprole, and BAL30072

**Basel, Switzerland, September 13, 2013** – Basilea Pharmaceutica Ltd. (SIX: BSLN) announced today that 19 posters are being presented on the anti-infectives isavuconazole, ceftobiprole, and BAL30072 at the 53rd Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC). The conference is taking place from September 10 to 13, 2013 in Denver, USA.

Basilea's Chief Scientific Officer Dr. Laurenz Kellenberger commented: "Drug resistance is a major global healthcare concern with patients facing potentially life-threatening infections with few to no therapeutic options. The wealth of data presented on the activity of isavuconazole, ceftobiprole, and BAL30072 against resistant pathogens further substantiates the promising profiles of these innovative product candidates in addressing this unmet medical need. We expect topline data from two isavuconazole phase 3 studies to be available in the second half of 2013. In the same timeframe, we anticipate a regulatory decision on the European Marketing Authorization Application for ceftobiprole for the potential treatment of pneumonia in the hospital."

Presentations on isavuconazole further substantiate its broad antifungal coverage. Isavuconazole demonstrated potent activity against global collections of contemporary, clinically relevant pathogens causing invasive fungal disease. Activity against invasive pulmonary aspergillosis and mucormycosis was demonstrated in neutropenic animal models. In addition, synergistic action between isavuconazole and micafungin was observed *in-vitro* against *Aspergillus* spp.

A presentation showing a genotypic characterization of methicillin-resistant *Staphylococcus aureus* (MRSA) strains collected during the ceftobiprole pneumonia phase 3 studies confirmed that the isolates were representative of MRSA strains causing nosocomial infections worldwide. Additional posters highlight the potent synergistic activity of ceftobiprole with daptomycin *in-vitro*; against vancomycin-intermediate or daptomycin-resistant MRSA isolates; and against daptomycin-susceptible and vancomycin resistant enterococci.

Susceptibility data presented at ICAAC highlight the activity of Basilea's novel anti-Gram-negative antibiotic BAL30072 against important potential biodefense pathogens. In June, Basilea announced its contract with the U.S. Biomedical Advanced Research and Development Authority (BARDA) for the development of BAL30072.

#### Posters on isavuconazole

*Pharmacodynamics (PD) of Isavuconazole (Isav) in a Murine Invasive Pulmonary Aspergillosis (IPA) Model Against Wildtype (WT) and Cyp51 Mutants – A. Lepak, K. Marchillo, J. Van Hecker, D.R. Andes; A-291*

*No Effect on Pharmacokinetic and Pharmacodynamic Parameters of Warfarin after Coadministration with Isavuconazole – T. Yamazaki, A. Desai, H. Pearlman, D. Kowalski, C. Lademacher, R. Townsend; A-448*

*Effect of Multiple Doses of Isavuconazole on the Pharmacokinetics of CYP3A4 Substrate Atorvastatin in Healthy Subjects – T. Yamazaki, H. Pearlman, D. Kowalski, C. Lademacher, A. Desai, R. Townsend; A-449*

*Effect of Multiple Doses of Isavuconazole on the Pharmacokinetics of CYP2B6 Substrate Bupropion in Healthy Subjects – A. Desai, H. Pearlman, T. Yamazaki, C. Lademacher, D. Kowalski, R. Townsend; A-450*

*Impact of Candida species on the Isavuconazole (ISA) Pharmacodynamic (PD) Target in an in vivo Neutropenic Murine Model of Invasive Candidiasis (IC) – A. Lepak, K. Marchillo, J. Van Hecker, D. Diekema, D.R. Andes; A-451*

*Pharmacokinetics and Efficacy of Isavuconazole for Treatment of Experimental Invasive Pulmonary Aspergillosis – R. Petraitiene, V. Petraitis, P.W. Moradi, G.E. Strauss, B.T. Huertas, A. Katragkou, E. Petraityte, L.L. Kovanda, J. Smart, W.W. Hope, T.J. Walsh; M-759*

*Isavuconazole Protects Immunosuppressed Mice from Rhizopus oryzae Infection – G. Luo, T. Gebremariam, H. Lee, J.E. Edwards, A.S. Ibrahim; M-787*

*In Vitro Activity of Antifungal Drugs against a Global Collection of 28 Clinical and Environmental Exserohilum Species Isolates – J.F. Meis, H. Madrid, I. Breuker, F. Hagen, G.S. De Hoog, A. Chowdhary; M-1350*

*Intra- and Interlaboratory Study of Antifungal Susceptibility Testing of Isavuconazole against Aspergillus Strains – M.A. Ghannoum, V. Chaturvedi, A. Espinel-Ingroff, A. Fothergill, R. Jones, L. Ostrosky-Zeichner, R. Rennie, T. Walsh; M-1351*

*In Vitro Interaction Between Isavuconazole and Micafungin or Amphotericin B against Medically Important Moulds – V. Petraitis, J. Meletiadis, P.W. Moradi, G.E. Strauss, L.L. Kovanda, R. Petraitiene, T.J. Walsh; M-1362*

*Isavuconazole Susceptibility in Triazole Resistant Aspergillus fumigatus – L. Gregson, J. Goodwin, A. Johnson, L. McEntee, C.B. Moore, M. Richardson, W.W. Hope, S.J. Howard; M-1365*

*Activity of Isavuconazole, Amphotericin B, and Micafungin Alone and in Combination against Exserohilum rostratum – P.W. Moradi, V. Petraitis, R. Petraitiene, G.E. Strauss, D.H. Larone, Y. Zhao, A. W. Forthergill, M. Ghannoum, M. Simitsopoulou, E. Rollides, D.P. Kontoyiannis, D.S. Perlin, T. J. Walsh; M-1372*

*In Vitro Activity of Isavuconazole compared with Itraconazole, Voriconazole, and Posaconazole in azole-resistant Aspergillus fumigatus – S. Seyedmousavi, A.J. Rijs, W.J. Melchers, J.W. Mouton, P.E. Verweij; M-1377*

*Activity of Isavuconazole and Comparator Antifungals Tested Against Contemporary (2012) Fungal Clinical Isolates Collected Worldwide – M. Castanheira, S.A. Messer, P.R. Rhomberg, R. Dietrich, R.N. Jones, M.A. Pfaller; M-1378*

#### Posters on ceftobiprole

*%fT>MIC Predicts the Microbiological Eradication at End of Treatment with Ceftriaxon or Ceftobiprole in Patients with Community Acquired Pneumonia – A.E. Muller, N. Punt, J.W. Mouton; A-472*

*Genotypic Characterization of Methicillin-resistant Staphylococcus aureus Strains Recovered from Pneumonia Clinical Trials for Ceftobiprole – R.E. Mendes, L.M. Deshpande, A.J. Costello, R.K. Flamm, R.N. Jones; C2-558*

*Ceftobiprole (BPR) and Ampicillin (AMP) Increase Daptomycin (DAP) Susceptibility in DAP Susceptible and Resistant and Vancomycin Resistant Enterococci (VRE) – B.J. Werth, K.E. Barber, K. Tran, M.J. Rybak; E-132*

*Activity of Ceftobiprole (BPR) Combination Regimens Against Multiple Strains of Staphylococcus aureus with Differing Resistance Phenotypes; K.E. Barber, B.J. Werth, C.E. Ireland, N.E. Stone, M.J. Rybak; E-138*

#### Poster on BAL30072

*In vitro Activity of BAL30072 against Biodefense Pathogens – J.R. Hershfield, L.L. Miller, S.A. Halasohoris, M.G. Page; F-1203*

For further information please visit [www.icaac.org](http://www.icaac.org).

#### About isavuconazole

Isavuconazole is an investigational intravenous and oral broad-spectrum antifungal, partnered with Astellas Pharma Inc., for the potential treatment of severe invasive and life-threatening fungal infections. It is currently in phase 3 of clinical development. Isavuconazole demonstrated *in-vitro* and *in-vivo* coverage of a broad range of yeasts (such as *Candida* species) and molds (such as *Aspergillus* species) as well as *in-vitro* activity against emerging and often fatal molds including those that cause mucormycosis. In clinical studies isavuconazole achieved predictable drug levels in patients, supporting reliable once-daily dosing and a switch from intravenous to oral administration. Isavuconazole received U.S. FDA fast-track and U.S. orphan drug designation.

#### About ceftobiprole

Ceftobiprole is an investigational broad-spectrum intravenous antibiotic for the potential first-line empiric treatment of severe bacterial infections. It is currently under regulatory review in Europe for the potential treatment of pneumonia in the hospital. Ceftobiprole has demonstrated broad-spectrum activity against Gram-positive bacteria including methicillin-resistant and vancomycin-resistant *Staphylococcus aureus* (MRSA, VRSA) and penicillin-resistant *Streptococcus pneumoniae* (PRSP) as well as Gram-negative pathogens, including Enterobacteriaceae and *Pseudomonas aeruginosa*.

#### About BAL30072

BAL30072 is an intravenous bactericidal sulfactam antibiotic against multidrug-resistant Gram-negative bacterial infections, currently in phase 1 of clinical development. BAL30072 demonstrated *in-vitro* and *in-vivo* coverage of Gram-negative pathogens including multidrug-resistant *Acinetobacter baumannii* and *Pseudomonas aeruginosa*. It has robust activity against common strains of resistant bacteria that produce antibiotic-inactivating enzymes including carbapenemases and metallo-beta-lactamases such as the New Delhi metallo-beta-lactamase 1

(NDM-1). In addition, BAL30072 has shown additive or synergistic activity with antibiotics from the carbapenem class. Basilea entered a contract with BARDA for up to USD 89 million in funding for the development of BAL30072.

## 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.

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