PRESS RELEASE

Basel, Switzerland, 2nd November 2004

Basilea's First-In-Class Antibiotic Ceftobiprole (BAL5788) Unaffected by Resistance and Novel Once-Daily Antifungal (BAL8557) Active Against Resistant *Aspergillus*

Basilea Pharmaceutica AG presents sixteen posters at the 44th International Conference on Antimicrobial Agents and Chemotherapy (ICAAC) held in Washington D.C., covering clinical and pre-clinical activity of ceftobiprole, its first-in-class broad–spectrum anti methicillin-resistant *Staphylococcus aureus* (MRSA) antibiotic, and BAL8557 its broad-spectrum water-soluble anti-fungal.

Poster data confirms that ceftobiprole has potent anti-MRSA activity (Ednie and Appelbaum, 2004; Sader *et al*., 2004) and is unaffected by endogenous resistance (Bogdanovich *et al*., 2004; Clark *et al.*, 2004; Rouse *et al.*, 2004; Vaudaux *et al.*, 2004) of a range of pathogens (staphylococci, pneumococci, *Haemophilius influenzae*, and Enterobacteriaceae). In addition, Kresken and Heep (2004) demonstrate that ceftobiprole has potent activity against *Pseudomonas aeruginosa*. Clinical data from Heep *et al*. (2004) confirms that ceftobiprole is a potent anti-MRSA drug for patients with complicated skin and skin structure infections.

The BAL8557 data confirms that Basilea's novel antifungal BAL8557 is active against *Aspergillus* pathogens resistant to other drugs (Warn *et al*., 2004) and has a favourable pharmacokinetic profile (Schmitt-Hoffmann *et al*., 2004).

"The sixteen posters at this year's conference highlight Basilea's position as a leader in both anti-bacterial and anti-fungal research," commented Professor Jutta Heim, Chief Scientific Officer of Basilea.

"The more we study ceftobiprole the more its potential becomes apparent as a first-choice antibiotic for severe hospital infections where MRSA is suspected. Furthermore the new data on BAL8557 shows our commitment to developing anti-infective drugs with strong competitive profiles," commented Dr. Rienk Pypstra, Chief Development Officer of Basilea.

Basilea Data at ICAAC 2004

L-361
BAL5788, the First of a New Class of Anti-MRSA Cephalosporins: Microbiological Results from a Phase II Study in Complicated Skin and Skin Structure Infections.
M. HEEP[1], S. QUERNER [1], M. HARSCH [1], W. O'RIORDAN [2]; [1]Basilea Pharmaceutica, Basel, Switzerland, [2]Paradise Valley Hospital, San Diego, CA.

A-37
Multiple Ascending Dose Pharmacokinetics of the New Antifungal BAL4815 after Intravenous and Oral Administration of its Prodrug BAL8557
A. SCHMITT-HOFFMANN[1], B. ROOS [1], J. SPICKERMANN [1], E. WEIDEKAMM [1], M. ROEHRLE [2]; [1]Basilea Pharmaceutica, Basel, Switzerland, [2]AAI, Neu-Ulm, Germany.

A-134
Monte Carlo Simulations of BAL8557: a New Watersoluble Azole with Antifungal Activity.
J. W. MOUTON[1], A. SCHMITT-HOFFMANN [2], N. PUNT [3];
[1]Canisius Wilhelmina Hospital, Nijmegen, Netherlands, [2]Basilea, Basel, Switzerland, [3]Medimatics, Maastricht, Netherlands.

B-677
Intensive Therapy with BAL5788 of Experimental Foreign Body Infection due to Methicillin-Resistant *Staphylococcus aureus* (MRSA)
BP. VAUDAUX, A. GJINOVCI, M. BENTO, D. LI, P. FRANCOIS, D. P. LEW, J. SCHRENZEL; Geneva University Hospitals, Geneva, Switzerland.

E-2021
Antistaphylococcal Activity of Ceftobiprole (BAL9141) and Comparators
L. EDNIE, P. C. APPELBAUM; Hershey Medical Center, Hershey, PA.

F-842
In Vitro Activity of a New Triazole BAL4815, the Active Component of BAL8557 (the Water-Soluble Prodrug) against *Aspergillus* spp
P. A. WARN, A. SHARP, D. W. DENNING; University of Manchester, Manchester, United Kingdom.

E-2022
In Vitro Activities of BAL9141, the Active Component of BAL5788, and Seven other Beta-Lactams against Selected Strains of *Pseudomonas aeruginosa* Susceptible or Resistant to Ceftazidime
M. KRESKEN[1], M. HEEP [2]; [1]Anti-Infectives Intelligence GmbH, Bonn, Germany, [2]Basilea Pharmaceutica Ltd., Basel, Switzerland.

E-2035
Comparative Activity of BAL9141, Daptomycin and Linezolid versus *S. aureus* from Bacteremias in the UK and Ireland
R. REYNOLDS[1], D. M. LIVERMORE [2], BSAC Working Party on Bacteraemia Resistance Surveillance; [1]British Society for Antimicrobial Chemotherapy (BSAC), Birmingham, United Kingdom, [2]Health Protection Agency, London, United Kingdom.

E-2036
Effect of Culture Conditions on MICs of BAL9141, Representing a New Class of Cephalosporins Active against MRSA
R. REYNOLDS[1], D. M. LIVERMORE [2], BSAC Working Party on Bacteraemia Resistance Surveillance;
[1]British Society for Antimicrobial Chemotherapy (BSAC), Birmingham, United Kingdom, [2]Health Protection Agency, London, United Kingdom.

E-2037
Antimicrobial Activity of BAL9141 Tested against Staphylococcal Strains with Selected Resistance Patterns
H. S. SADER, D. J. BIEDENBACH, R. N. JONES; JMI Laboratories, Inc., North Liberty, IA.

D-1920
Ceftobiprole (BAL9141): Activity Against Staphylococci and Pneumococci by Microdilution and Etest Methods
M. R. JACOBS[1], S. BAJAKSOUZIAN [1], A. WINDAU [1], P. C. APPELBAUM [2];
[1]Case Western Reserve Univ./University Hospitals, Cleveland, OH, [2]Hershey Medical Center, Hershey, PA.

E-2018
Resistance Selection Studies on Staphylococci with Ceftobiprole (BAL9141)
T. BOGDANOVICH, B. BOZDOGAN, P. C. APPELBAUM; Hershey Med. Ctr., Hershey, PA.

E-2019
Comparative Time-Kill Determination of the Antipneumococcal Activity of Ceftobiprole (BAL9141).
G. LIN, P. C. APPELBAUM; Hershey Medical Center, Hershey, PA.

E-2020
Resistance Selection of BAL9141, the Active Component of Prodrug BAL5788, against Pneumococci
C. L. CLARK, K. KOSOWSKA, K. CREDITO, P. C. APPELBAUM;
Hershey Medical Center, Hershey, PA.

B-1177
Activity of BAL5788 in *Haemophilus influenzae, Enterobacter cloacae* or *Klebsiella pneumoniae* Experimental Murine Pneumonia
M. ROUSE, P. ANGUITA-ALONSO, M. H. HEIN, J. M. STECKELBERG, R. PATEL;
Mayo Clinic, Rochester, MN.

A-1874
Pharmacodynamics of BAL4815: a New Azole Antifungal in a Mouse Model of Systemic Infection
D. TE DORSTHORST[1], P. E. VERWEIJ [2], J. F. MEIS [1], J. W. MOUTON [1];[1]Canisius Wilhelmina Hospital, Nijmegen, Netherlands, [2]University Medical Ctr. St. Radboud, Nijmegen, Netherlands.

About Ceftobiprole (BAL5788)

Ceftobiprole is the first of a new class of broad-spectrum cephalosporin antibiotics that was specially designed to bind the mutated targets in MRSA resulting in potent bactericidal activity towards MRSA and penicillin-resistant *Streptococcus pneumoniae* (PRSP). Ceftobiprole has not only maintained a broad-spectrum profile targeting other Gram-positive as well as Gram-negative pathogens, but has also shown a low potential to induce resistance *in vitro*.

In March 2003 the U.S. Food and Drug Administration granted BAL5788 Fast-Track designation for the treatment of complicated skin and skin structure infections due to methicillin-resistant *Staphylococcus* species, which has been followed by an additional designation in June 2004 for the treatment of hospital-acquired pneumonia including ventilator-associated pneumonia due to suspected or proven methicillin-resistant *Staphylococcus aureus* (MRSA). Ceftobiprole has completed phase II clinical development and is anticipated to start phase III this year.

About BAL8557

BAL8557 is a novel water-soluble azole suitable for both oral and intravenous administration for mucocutaneous and invasive fungal infections that has completed phase I clinical development and is anticipated to start phase II this year.

About Basilea

Basilea Pharmaceutica AG (BSLN) is an independent biopharmaceutical company headquartered in Basel, Switzerland that is actively engaged in the discovery and development of innovative medicines for the treatment of unmet medical needs.

The company's fully integrated research and development operations are currently focused on new anti-bacterials and anti-fungals to fight drug resistance, and dermatology drugs. Basilea was founded in October 2000 with significant resources to discover, develop and bring innovative medicines to market. Basilea is listed on the SWX Swiss Exchange.

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