

## PRESS RELEASE

Basel, Switzerland, 3 May 2004

### Basilea's Antibiotic BAL5788 — Unlikely to Induce Resistance in MRSA

Basilea Pharmaceutica AG presented *in vitro* data yesterday at the 14<sup>th</sup> European Congress on Clinical Microbiology and Infectious Diseases (ECCMID), demonstrating that BAL9141 (the active component of prodrug BAL5788) is unlikely to induce significant resistance in methicillin-resistant *Staphylococcus aureus* (MRSA). In addition, data was presented demonstrating that MRSA are less prone to develop resistance to BAL5788 than to either linezolid or moxifloxacin.

Passage data presented by Heller *et al.* (2004) showed that the minimal inhibitory concentration (MIC) of BAL5788 for MRSA strains changed much less than the MIC of either linezolid or moxifloxacin did and reached a markedly lower value that remained constant over a greater number of passages compared to those obtained with linezolid or moxifloxacin. DNA sequencing also demonstrated that there were no alterations in the penicillin-binding proteins of the MRSA exposed to BAL5788.

"These important data have elegantly demonstrated that BAL5788 exhibits a low propensity to select for endogenous resistance by methicillin-resistant staphylococci, an essential feature for any new antibiotic that may be used to treat such infections. This study, as well as the other seven posters/abstracts presented for BAL5788 at ECCMID this year, further reinforce the profile of BAL5788 as a high potential compound," said Professor Jutta Heim, Basilea's Chief Scientific Officer.

#### BAL5788 Data at ECCMID 2004

##### Sunday, 2 May 2004

P537: MIC determination of the anti-pneumococcal activity of BAL9141 compared to other agents. P. Appelbaum, D. Hoellman, M. Jacobs (Hershey, Cleveland, USA).

P536: Gram-negative bacteria producing characterised beta-lactamases: *in vitro* activities of BAL9141 and comparators. M. Kresken, M. Heep, I. Wiegand (Bonn, D; Basel, CH).

P675: Development of endogenous resistance by staphylococci to BAL9141 and comparators. S. Heller, E. Marrer, M.G.P. Page, S. Shapiro, L. Thenoz (Basle, CH).

##### Monday, 3 May 2004

P1030: Influence of gender on the pharmacokinetics of BAL9141 after intravenous infusion of Pro-drug BAL5788. A.H. Schmitt-Hoffmann, B. Roos, M. Heep, M. Schleimer, E. Weidekamm, A. Man, N. Abdou (Basle, CH; Lenexa, USA).

P1031: BAL5788 in patients with complicated skin and skin structure infections caused by Gram-positive pathogens including methicillin-resistant *Staphylococcus* species. Interim pharmacokinetic results from 20 patients. A.H. Schmitt-Hoffmann, M. Harsch, M. Heep, M. Schleimer, T. Brown, A. Man, W. O'Riordan (Basle, CH; Chula Vista, USA).

P1032: Dose adjustment in subjects with normal and impaired renal function based on the pharmacokinetics of BAL5788. A.H. Schmitt-Hoffmann, B. Roos, M. Schleimer, E. Weidekamm, T. Brown, M. Heep, A. Man, L.G. Nilsson (Basle, CH; Uppsala, S).

P1209: In vitro activities of BAL9141 and seven other beta-lactam antimicrobial agents towards clinical isolates of 12 members of the Enterobacteriaceae family. M. Kresken, M. Heep (Bonn, D; Basle, CH).

### **About BAL5788**

BAL5788 is the first of a new class of broad-spectrum cephalosporin antibiotics also active against multi-resistant Gram-positive pathogens such as methicillin-resistant *Staphylococcus aureus* (MRSA). The FDA granted BAL5788 *Fast Track* designation for the treatment of skin and skin structure infections. BAL5788 has completed phase II clinical development and is planned to start phase III in the second half of 2004.

The growing incidence of serious infections caused by antibiotic-resistant bacteria is a matter of increasing global medical concern. BAL5788 offers potent bactericidal activity against MRSA, penicillin-resistant *Streptococcus pneumoniae* (PRSP) and other major Gram-positive bacterial pathogens as well as against Gram-negative bacteria, similar to that of third-generation cephalosporins.

### **About Basilea**

Basilea Pharmaceutica AG (BSLN: SWX) 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-bacterial, anti-fungal agents and dermatology drugs. Basilea was founded in October 2000 with significant resources to discover, develop and bring innovative medicines to market.

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