

PRESS RELEASE

Basel, Switzerland, 4th November 2004

Basilea's First-In-Class Antibiotic Ceftobiprole (BAL5788) Moves into Phase III

Basilea Pharmaceutica AG announces the start of its international phase III program for ceftobiprole (BAL5788), a novel broad spectrum, first-in-class anti methicillin resistant *Staphylococcus aureus* (MRSA) antibiotic, in complicated skin and skin structure infections.

"MRSA infections are an important and an increasingly prevalent global healthcare problem causing increased hospital mortality and morbidity while placing a significant burden on hospital resources. Today, in Southern and Western Europe approximately forty percent of *S. aureus* bloodstream infections are MRSA, while in the U.S. over fifty percent of *S. aureus* isolates in intensive care units are now resistant, and there is a disturbing pattern of community-acquired resistant infections emerging, predominantly in the U.S.," commented Dr. David Livermore, Director of the Antibiotic Resistance Monitoring Reference Laboratory at the Health Protection Agency, U.K.

Basilea has started enrollment into its randomized controlled phase III study in complicated skin and skin structure infections. The STRAUSS study (Study of Ceftobiprole in Resistant *Staphylococcus aureus* Skin and Skin Structure Infections), investigates the efficacy and safety of ceftobiprole versus vancomycin in approximately 700 patients recruited from over 100 centres. The primary efficacy endpoint for STRAUSS is clinical outcome at the test-of-cure visit which occurs between 7–14 days after end of therapy.

In addition to its study in complicated skin and skin structure infections, Basilea plans to initiate other studies in severe infection indications.

"We are committed to provide patients with new drugs for serious diseases. Infections due to resistant bacteria are a major global problem. The launch of the ceftobiprole phase III program is our second phase III program launched this year. It marks another significant corporate milestone in bringing high potential products to the market and once again confirms the ability of our organization to execute our business plans," commented Anthony Man MD, CEO of Basilea.

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).

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.

Disclaimer

This communication expressly or implicitly contains certain forward-looking statements concerning Basilea Pharmaceutica AG 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 AG to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Basilea Pharmaceutica AG 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 the following:

Contact

| | |
|-------------------------|--|
| General Information | Investor Relations |
| information@basilea.com | Sean Wells investor_relations@basilea.com |

Basilea Pharmaceutica AG
Corporate Information
P.O. Pox
CH-4005 Basel
Switzerland