



## **PRESS RELEASE**

### **Phase III Community-Acquired Pneumonia Study Opens for Basilea's Novel Broad-spectrum anti-MRSA Antibiotic Ceftobiprole to Broaden Indications**

**Basel, Switzerland, May 17, 2006 - Basilea Pharmaceutica Ltd. (SWX:BSLN) announced today the initiation of a community-acquired pneumonia trial further expanding the development program for ceftobiprole in collaboration with Johnson & Johnson Pharmaceutical Research and Development, L.L.C.**

In addition to an ongoing clinical program in complicated Skin and Skin Structure Infections (cSSSI) and hospital-acquired pneumonia (HAP), Basilea Pharmaceutica Ltd. and Johnson & Johnson Pharmaceutical Research and Development, L.L.C. have initiated a study in patients with community-acquired pneumonia (CAP).

"Each year, approximately five million patients are treated worldwide for community-acquired pneumonia in hospitals. With the rising incidence of drug-resistant *Streptococcus pneumoniae* (DRSP) and threat of community-acquired methicillin-resistant *Staphylococcus aureus* (cMRSA), an increasing number of patients with pneumonia may no longer respond to traditional antibiotic treatment. We are expanding the clinical trial program for ceftobiprole to cover both hospital and community-acquired respiratory infections," commented Rienk Pypstra, Chief Development Officer at Basilea.

Community-acquired pneumonia remains a major cause of mortality worldwide. A significant number of patients with severe community-acquired pneumonia require hospitalization and intravenous antibiotic treatment. Cephalosporins are a mainstay of treatment in pneumonia. Ceftobiprole has shown a broad, promising cephalosporin spectrum that includes antibacterial activity against resistant pathogens such as drug-resistant *Streptococcus pneumoniae* (DRSP) and methicillin-resistant *Staphylococcus aureus* (MRSA), and was highly effective in animal models of pneumonia.

"By broadening the development program for ceftobiprole to include emerging resistant infections arising from the general community we intend to maximize the potential of this novel antibiotic. The first regulatory filing for ceftobiprole is planned for 2007," commented Dr. Anthony Man, CEO of Basilea.

#### **About Ceftobiprole**

Ceftobiprole (BAL5788), Basilea's lead antibacterial product, is the first of a new class of broad-spectrum anti-MRSA cephalosporin antibiotics. It is specially designed to bind the penicillin-resistant targets in Gram-positive cocci, resulting in potent bactericidal activity towards methicillin-resistant *Staphylococcus aureus* (MRSA) and penicillin-resistant *Streptococcus pneumoniae* (PRSP). Ceftobiprole has demonstrated a broad-spectrum profile targeting other Gram-positive as well as Gram-negative pathogens. In addition it has shown a low potential to induce resistance *in vitro*.



The FDA granted ceftobiprole fast-track designation for the treatment of complicated skin and skin structure infections due to methicillin-resistant *Staphylococcus* species and for a second indication in the treatment of hospital-acquired (nosocomial) pneumonia, including ventilator-associated pneumonia due to suspected or proven methicillin-resistant *Staphylococcus aureus* (MRSA). Ceftobiprole showed positive, top-line phase III results in a first complicated skin infection study (STRAUSS1). The drug is currently also being studied in a second complicated skin infection trial (STRAUSS 2) targeting both Gram-positive and Gram-negative bacterial infections, including patients with diabetic foot infections and in phase III clinical trials in nosocomial pneumonia (CHOPIN studies).

Ceftobiprole is being developed through an exclusive worldwide collaboration between Basilea Pharmaceutica Ltd. and Cilag GmbH International, a Johnson & Johnson company. Ortho-McNeil, Inc., another Johnson & Johnson company, will market ceftobiprole in the U.S. and its affiliate Janssen-Cilag companies will market the product in Europe and Asia. Basilea has maintained an option to co-promote ceftobiprole in North America, major European countries, Japan and China.

### About Basilea

Basilea Pharmaceutica Ltd. (BSLN) is an independent biopharmaceutical company headquartered in Basel, Switzerland, and listed on the SWX Swiss Exchange. Basilea's fully integrated research and development operations are currently focused on new antibacterial and antifungal agents to fight drug resistance in the hospital market and on the development of dermatology drugs. Basilea's products are targeted to satisfy high medical and patient needs in the hospital setting. The company owns a diversified product portfolio including three products for severe medical indications in late stages of clinical development.

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