



## **PRESS RELEASE**

### **Basilea (SWX: BSLN) announces positive phase III results for ceftobiprole, its first-in-class anti-MRSA cephalosporin**

*Basel, Switzerland, March 2, 2006* - **Basilea Pharmaceutica Ltd. announces today positive results for its first comparative phase III trial with ceftobiprole. Ceftobiprole showed a high cure rate and was safe and well tolerated. This first-in-class anti-MRSA broad-spectrum cephalosporin is partnered with Cilag AG International, a Johnson & Johnson company.**

"These exciting results are a very important and a positive step forward for Basilea and our partner, Cilag AG International. Ceftobiprole has performed consistently in line with our expectations to date. This positive trial is the first of a series of ongoing registration studies designed to demonstrate the effectiveness of ceftobiprole. Our goal is to bring this product to market as soon as possible because patients with serious hospital infections are in need of new treatment options," said Dr. Anthony Man, Basilea's CEO.

The phase III STRAUSS study (Study of resistant *Staphylococcus aureus* in skin and skin structure infections) demonstrated a high cure rate. In this study targeting Gram-positive infections 397 patients were treated with 500mg ceftobiprole and 387 patients with 1g vancomycin; both groups were treated twice daily for 7-14 days. Statistical non-inferiority was achieved with 93.3% of patients clinically cured on ceftobiprole, and 93.5% of patients treated with vancomycin. Over 25% of microbiologically evaluable patients were confirmed with methicillin-resistant *Staphylococcus aureus* (MRSA) infections. The ceftobiprole response rate in infections caused by MRSA was 91.9% compared with 90.0% for vancomycin. Adverse events were comparable between the two treatment groups.

"MRSA is a major cause of mortality and morbidity in severe hospital infections and is of increasing concern in the community. While ceftobiprole has a broad spectrum of activity, this study was specifically designed to highlight the Gram-positive activity, including MRSA. The positive results of this first, large-scale study are an important milestone toward registration of ceftobiprole," commented Dr. Rienk Pypstra, Chief Development Officer 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 that was specially designed to bind to 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 not only has 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*.



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 is currently also 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 AG International, a Johnson & Johnson company. Ortho-McNeil, Inc., another Johnson & Johnson company, will market ceftobiprole in the U.S. and its affiliate company, Janssen-Cilag, will market the product in Europe, Japan and China. Basilea has retained an option to co-promote ceftobiprole in North America, major European countries, Japan and China.

### **Basilea's additional late-stage development compounds:**

#### About BAL8557

BAL8557 is Basilea's novel broad-spectrum antifungal agent for patients with severe invasive fungal infections. Unlike the other azoles, BAL8557 is a pro-drug suitable for simple intravenous administration and its excellent oral absorption allows a convenient once daily or even once weekly dosing, supporting patient-tailored treatment schemes. Basilea successfully completed its key phase II trial with both high clinical cures rates and a safety profile comparable to gold standard therapy but with potentially a more flexible dosing schedule. BAL8557 is in preparation for phase III.

#### About Alitretinoin (BAL4079)

Alitretinoin is a novel vitamin A analog that is developed for patients with chronic hand eczema that is refractory to conventional topical treatments. Chronic hand dermatitis is a disabling condition for which there is currently no approved prescription treatment available. Patient accrual into the European/Canadian phase III trial is well advanced.

### **About Basilea**

Basilea Pharmaceutica Ltd. (BSLN) is a biopharmaceutical company headquartered in Basel, Switzerland, and listed on the SWX Swiss Exchange. Basilea was founded in October 2000 to discover, develop and bring innovative medicines to the market. The company's fully integrated research and development operations are currently focused on new anti-bacterial and anti-fungal agents to fight drug resistance as well as on dermatology drugs.

### **Disclaimer**

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**NOTE**

*Basilea Pharmaceutica Ltd. invites you to participate in a conference call on Thursday, March 2, 2006, 4 p.m. (CET), during which the company will discuss today's press release:*

*Dial-in numbers are:*

*+41 91 610 5600 (Europe and ROW)*

*+1 866 291 4166 (USA)*

*+44 20 7107 0611 (UK)*

*The playback will be available 1 hour after the conference call for 48 hrs. Participants requesting a digital playback may dial:*

*+41 91 612 4330 (Europe)*

*+1 866 416 2558 (USA)*

*+44 20 7108 6233 (UK)*

*and will be asked to enter the ID 422 followed by the # sign.*

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