



## **PRESS RELEASE**

### **Basilea Announces Positive Top-line Results on Second Pivotal Phase III Ceftobiprole Trial**

*Basel, Switzerland, January 10, 2007* – **Basilea Pharmaceutica Ltd. (SWX: BSLN)** announced today that the second pivotal ceftobiprole phase III study in complicated skin infections met its primary endpoint of statistical non-inferiority *versus* combination therapy. Ceftobiprole demonstrated high cure rates in patients with complicated Gram-positive as well as Gram-negative skin infections, including diabetic patients with foot infections. A first regulatory submission is planned this year. Ceftobiprole is an anti-MRSA, broad-spectrum cephalosporin developed in collaboration with Cilag GmbH International, a Johnson & Johnson company.

“Complicated skin infections require rapid medical intervention, typically before the causative pathogens are identified. The potent anti-MRSA activity of ceftobiprole, combined with its broad-spectrum activity, provided broad coverage of the clinically relevant pathogens in this important clinical setting. In particular, ceftobiprole, as a single agent, was clearly as effective as a combination regimen of standard broad-spectrum therapy in patients with difficult-to-treat diabetic foot infections,” commented Dr. Rienk Pypstra, Chief Development Officer of Basilea.

This second pivotal double-blind study (STRAUSS II - study of resistant *Staphylococcus aureus* in complicated skin and skin structure infections) treated 828 patients with either ceftobiprole or the combination of ceftazidime plus vancomycin in a 2:1 randomization. Almost one third of patients had diabetic foot infections of which three quarters were moderate to severe cases.

Ninety-one percent of clinically evaluable patients were cured with ceftobiprole compared to 90% of patients treated with combination therapy. The clinical response in patients with diabetic foot infections was 86% for ceftobiprole and 82% for comparator combination therapy, respectively. Over twenty percent of microbiologically evaluable patients had confirmed methicillin-resistant *Staphylococcus aureus* (MRSA) infections. The clinical cure rate for ceftobiprole in MRSA patients was 91% compared to 86% for the comparator regimen. One third of patients had infections involving a Gram-negative pathogen. The microbiologic eradication rates in these patients were similar at 84% in both treatment groups. Ceftobiprole was well tolerated. Adverse events were comparable between the two treatment groups.

“These are very strong clinical data. These results show that ceftobiprole monotherapy is non-inferior to standard combination therapy. Ceftobiprole has FDA fast track designation. With two positive phase III trials in complicated skin infections, we plan the first regulatory filing for ceftobiprole this year. We have reached another major milestone on the route to commercialization of ceftobiprole with our partner Cilag GmbH International. We are now closer to providing physicians with a new therapeutic option to treat patients with complicated bacterial skin infections,” said Dr. Anthony Man, Basilea’s CEO.



## Products About Complicated Skin Infections

Complicated skin and skin structure infections (cSSSIs) are among the most common infections in the hospital setting. *Staphylococcus aureus* is the predominant pathogen in skin infections. In recent years resistant strains (MRSA) have become increasingly common and have been associated with increased morbidity and mortality.

Patients with chronic wounds or those who have recently received antibiotics, may also be infected by Gram-negative pathogens. This is frequently the case for diabetic patients with foot infections. Adequate treatment of diabetic foot infections requires hospitalization, surgery and broad-spectrum intravenous antibiotics.

## About Ceftobiprole

Ceftobiprole is an anti-MRSA, broad-spectrum cephalosporin that has demonstrated positive results in two phase III trials in complicated skin and skin structure infections. Ceftobiprole has shown a low potential to select for resistance *in vitro* and exhibits *in vitro* activity against a wide spectrum of bacteria that cause many hospital and community-acquired infections including those due to resistant bacteria like methicillin-resistant *Staphylococcus aureus* (MRSA). Ceftobiprole has received fast track status from the FDA and is being developed through an exclusive worldwide collaboration between Basilea Pharmaceutica Ltd. and Cilag GmbH International, a Johnson & Johnson affiliate.

## About Basilea

Basilea Pharmaceutica Ltd. is an independent biopharmaceutical company headquartered in Basel, Switzerland, and listed on the SWX Swiss Exchange (SWX:BSLN). Basilea's fully integrated research and development operations are currently focused on new antibacterial and antifungal agents to fight drug resistance and on the development of dermatology drugs. Basilea's products are targeted to satisfy high medical and patient needs in the hospital and specialty care setting. The company owns a diversified product portfolio including three products in phase III clinical development for severe medical indications. Basilea is building a sustainable hospital and specialty biopharmaceutical business. The company is integrating commercialization into its organization, in a first step through co-promoting ceftobiprole in North America and major European countries.

## Disclaimer

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## Conference Call

*Basilea Pharmaceutica Ltd. invites you to participate in a conference call on Wednesday, January, 10, 2007, 4 p.m. (CET), during which the company will discuss today's press release.*

*Dial-in numbers are:*

+41 (0) 91 610 5600 (Europe and ROW)  
+1 (1) 866 291 4166 (USA)  
+44 (0) 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 (0) 91 612 4330 (Europe)  
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*and will be asked to enter the ID 485 followed by the # sign.*

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