

## PRESS RELEASE

# Swissmedic accepts for review Basilea's ceftobiprole Marketing Authorization Application for the treatment of pneumonia

**Basel, Switzerland, September 16, 2013** – Basilea Pharmaceutica Ltd. (SIX: BSLN) announced today that the Swiss regulatory authority Swissmedic has accepted the ceftobiprole Marketing Authorization Application for review. Ceftobiprole is an investigational broad-spectrum anti-MRSA (methicillin-resistant *Staphylococcus aureus*) antibiotic. The intended indication of ceftobiprole is for the treatment of hospital-acquired (nosocomial) pneumonia and community-acquired pneumonia in adults.

Ronald Scott, Chief Executive Officer of Basilea, stated: "We are very pleased that Swissmedic will begin its review of our Marketing Authorization Application for ceftobiprole in pneumonia. Severe pneumonia is a condition associated with morbidity and mortality which is significantly increased when MRSA is a causative organism. Data has shown that ceftobiprole provides broad antibacterial coverage including MRSA and Gram-negative pathogens such as *Pseudomonas*. We are focused on working with Swissmedic to support their review of ceftobiprole."

Basilea's submission dossier includes data from two international double-blind, randomized, controlled phase 3 studies in hospital-acquired pneumonia and community-acquired pneumonia. These studies compared the efficacy and safety of empiric ceftobiprole use versus standard-of-care single or combination antibiotic therapy.

Ceftobiprole in pneumonia is currently under review with European regulatory authorities, with a decision anticipated in the second half of 2013.

### About ceftobiprole

Ceftobiprole is an investigational broad-spectrum intravenous antibiotic for the potential first-line empiric treatment of severe bacterial infections. Ceftobiprole has demonstrated broad-spectrum activity against Gram-positive bacteria, including methicillin-resistant and vancomycin-resistant *Staphylococcus aureus* (MRSA, VRSA) and penicillin-resistant *Streptococcus pneumoniae* (PRSP) as well as Gram-negative pathogens, including Enterobacteriaceae and *Pseudomonas aeruginosa*.

### About pneumonia treated in the hospital

Community-acquired pneumonia is a common condition with up to 60% of the patients requiring hospital admission and intravenous antibiotics.<sup>1</sup> Hospital-acquired pneumonia is one of the most common infections in the hospital, accounting for approximately 25% of all intensive care unit (ICU) infections, and is associated with significant mortality.<sup>2,3</sup> Prompt empiric intervention with an appropriate broad-spectrum antibiotic treatment is accepted as best medical practice. The increasing incidence of bacteria resistant to many antibiotics is a major concern.

### About Basilea

Basilea Pharmaceutica Ltd. is headquartered in Basel, Switzerland, and listed on the SIX Swiss Exchange (SIX: BSLN). Through the fully integrated research and development operations of its Swiss subsidiary Basilea Pharmaceutica International Ltd., the company focuses on innovative pharmaceutical products in the therapeutic areas of bacterial infections, fungal infections and

oncology, targeting the medical challenge of rising resistance and non-response to current treatment options.

## Disclaimer

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This press release can be downloaded from [www.basilea.com](http://www.basilea.com).

## References

- 1 Sligl WI, Marrie TJ. Severe community-acquired pneumonia. *Critical Care Clinics* 2013; 29: 563-601.
- 2 Torres A, Ferrer M and Badia JR. Treatment guidelines and outcomes of hospital-acquired and ventilator-associated pneumonia. *Clinical Infectious Diseases* 2010; 51: S48-S53.
- 3 Barbier F, Andremont A, Wolff M, Bouadma L. Hospital-acquired pneumonia and ventilator-associated pneumonia: recent advances in epidemiology and management. *Current Opinion in Pulmonary Medicine* 2013; 19: 216-228.