

PRESS RELEASE

Basilea's antibiotic ceftobiprole obtains regulatory approval in Europe for pneumonia

Basel, Switzerland, October 23, 2013 – Basilea Pharmaceutica Ltd. (SIX: BSLN) announced today the approval of its antibiotic ceftobiprole in Europe. Ceftobiprole is indicated for the treatment of hospital-acquired pneumonia (excluding ventilator-associated pneumonia) and community-acquired pneumonia in adults. Ceftobiprole has broad-spectrum activity against many pathogens that cause pneumonia including Gram-positive pathogens such as penicillin-resistant *Streptococcus pneumoniae* (PRSP), methicillin-resistant *Staphylococcus aureus* (MRSA) and various Gram-negative pathogens including *Pseudomonas* species.

Basilea submitted the ceftobiprole Marketing Authorization Application under the Decentralized Procedure (DCP) initially in 12 European Union Member States including the major markets in Europe. In accordance with the DCP, each of the involved Member States are expected to grant national authorizations within the coming months.

"Basilea is committed to develop new medicines that fight the increasing threat of resistance," stated Basilea's Chief Executive Officer Ronald Scott. "The European approval of ceftobiprole in pneumonia marks another significant milestone for our company. Ceftobiprole has the broadest spectrum of activity of any approved anti-MRSA agent. It is the first broad-spectrum anti-MRSA cephalosporin monotherapy for both hospital- and community-acquired pneumonia. We will work with authorities, hospital formularies, clinicians and potential partners to bring this new antibiotic to patients as soon as possible."

Basilea's Chief Medical Officer Prof. Achim Kaufhold added: "Ceftobiprole has broad-spectrum activity against many pathogens that cause pneumonia. Its spectrum extends to isolates resistant to other commonly used antibiotics like penicillin-resistant *Streptococcus pneumoniae* (PRSP), methicillin-resistant *Staphylococcus aureus* (MRSA) or *Staphylococcus aureus* strains resistant to vancomycin or linezolid. In the phase 3 pneumonia studies ceftobiprole was comparable to a standard-of-care regimen consisting of two drugs. Ceftobiprole may simplify physicians' treatment choice when the causative organism of an infection is not known and offers coverage over a broad range of bacteria right from the start of empiric therapy."

The European authorities' positive decision will support additional regulatory submissions in many markets around the world. In Switzerland, a ceftobiprole Marketing Authorization Application for the treatment of hospital- and community-acquired pneumonia in adults is currently under review by the regulatory authority Swissmedic.

About ceftobiprole

Ceftobiprole medocaril (ceftobiprole) is a broad-spectrum intravenous antibiotic from the cephalosporin class for the treatment of hospital-acquired pneumonia (excluding ventilator-associated pneumonia) and community-acquired pneumonia. Ceftobiprole has demonstrated broad-spectrum activity against Gram-positive bacteria including methicillin-resistant and vancomycin-resistant *Staphylococcus aureus* (MRSA, VRSA) and penicillin- and ceftriaxone-resistant *Streptococcus pneumoniae* (PRSP, CRSP) as well as Gram-negative pathogens including strains of Enterobacteriaceae and *Pseudomonas* species.

About hospital-acquired and community-acquired pneumonia

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.^{1, 2} Community-acquired pneumonia is a common condition with up to 60% of the patients requiring hospital admission and intravenous antibiotics.³ Prompt empiric intervention with an appropriate broad-spectrum antibiotic treatment is accepted as best medical practice. The increasing incidence of bacteria resistant to many established antibiotics is a major concern.

Conference call

Basilea Pharmaceutica Ltd. invites you to participate in a conference call on Wednesday, October 23, 2013, 4 p.m. (CEST), during which the company will discuss today's press release.

Dial-in numbers are:

+41 (0) 58 310 50 00 (Europe and ROW)
+1 (1) 631 570 5613 (USA)
+44 (0) 203 059 5862 (UK)

A playback will be available 1 hour after the conference call until Friday, October 25, 2013, 6 p.m. (CEST). Participants requesting a digital playback may dial:

+41 (0) 91 612 4330 (Europe and ROW)
+1 (1) 866 416 2558 (USA)
+44 (0) 207 108 6233 (UK)

and will be asked to enter the ID 15072 followed by the # sign.

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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For further information, please contact:

Media Relations	Investor Relations
Peer Nils Schröder, PhD Head Public Relations & Corporate Communications +41 61 606 1102 media_relations@basilea.com	Barbara Zink, PhD, MBA Head Corporate Development +41 61 606 1233 investor_relations@basilea.com

This press release can be downloaded from www.basilea.com.

References

- 1 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.
- 2 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.
- 3 Sligl WI, Marrie TJ. Severe community-acquired pneumonia. *Critical Care Clinics* 2013; 29: 563-601.