

## PRESS RELEASE

# Basilea announces launch of antibiotic Zevtera® (ceftobiprole medocartil) in Germany

- **First commercial launch**

**Basel, Switzerland, December 5, 2014** – Basilea Pharmaceutica Ltd. (SIX: BSLN) announces today that its broad-spectrum antibiotic, Zevtera® (ceftobiprole medocartil)\* has been launched in Germany. The European Centre for Disease Prevention and Control (ECDC) estimates that every year approximately 25,000 people die from antibiotic-resistant healthcare-associated infections in the European Union.<sup>1</sup>

The new broad-spectrum antibiotic supports the treatment of bacterial lung infections. Zevtera® is the only antibiotic monotherapy that is approved in certain European countries<sup>2</sup> for the treatment of adults with community-acquired pneumonia and hospital-acquired pneumonia (excluding ventilator-associated pneumonia) with activity against methicillin-resistant *Staphylococcus aureus* (MRSA) and Gram-negative pathogens including *Pseudomonas* spp.<sup>3</sup>

Ronald Scott, Basilea's CEO, stated: "Zevtera's launch in Germany marks an important milestone for Basilea. Antibiotic resistance is a major healthcare threat throughout Europe. We are very pleased to make ceftobiprole available to doctors and their patients, starting in Germany. Ceftobiprole provides physicians and pneumonia patients with a new option to treat severe bacterial infections."

### **Focus: broad-spectrum antibiotic**

Ceftobiprole is a new generation broad-spectrum cephalosporin antibiotic with rapid bactericidal activity against Gram-positive and Gram-negative bacteria associated with pneumonia, including MRSA and *Pseudomonas* spp.<sup>4</sup> Ceftobiprole is administered intravenously and is the active moiety of the prodrug ceftobiprole medocartil.

David Veitch, Basilea's Chief Commercial Officer, added: "Zevtera provides physicians with a simplified empiric treatment option with its broad-spectrum activity reducing the need for combination treatments. This is an important advance in the empirical treatment of pneumonia." He added: "Post-hoc analyses of phase 3 study data showed a more rapid effect for ceftobiprole as compared with a standard antibiotic combination in the treatment of hospital-acquired pneumonia. An early improvement of patients' overall clinical condition may translate into additional benefits, especially in an intensive care unit setting, such as the potential for earlier mobilization or discharge of the patient to a general ward."

The state of the art in the contemporary treatment of pneumonia was presented at a symposium on "Current antibiotic therapy for pneumonia" at the annual congress of the "German Interdisciplinary Association of Intensive Care and Emergency Medicine" (*Deutsche Interdisziplinäre Vereinigung für Intensiv- und Notfallmedizin*, DIVI) in Hamburg, Germany held on December 3-5, 2014.

## Pneumonia risk

Pneumonia remains a serious and common infection especially when acquired in a hospital setting. MRSA is an important cause of pneumonia, accounting for 20–40% of hospital-acquired pneumonia.<sup>5</sup> Early initiation of appropriate antibiotic therapy is a key factor for the successful treatment of severe pneumonia. Studies have shown that inappropriate initial therapy of severe infections, including MRSA, are associated with an increased risk of mortality and morbidity, and prolonged hospital stay.<sup>6, 7, 8</sup>

Prof. Dr. med. Tobias Welte, Department of Pulmonology, Hannover Medical School (MHH), Germany, commented: “Ceftobiprole provides broad-spectrum Gram-positive and Gram-negative activity including MRSA. MRSA is associated with an increased risk of mortality and morbidity, as well as an increased length of hospital stay. As such, there is a growing need for first-line broad-spectrum antibacterial medicines that also cover resistant bacteria and we hope that ceftobiprole will help fill this gap.”

## About pneumonia

Pneumonia is a common infection<sup>9, 10</sup> and is generally classified according to the location of the patient when the infection is contracted, since this has a major bearing on the likely type of pathogen causing the disease, the treatment, and the patient’s prognosis. Frequent types are community-acquired pneumonia (CAP), hospital-acquired pneumonia (HAP) and ventilator-associated pneumonia (VAP). CAP is defined as pneumonia acquired outside hospital or extended-care facilities or occurring less than 48 hours after hospital admission.<sup>11</sup> HAP is pneumonia that occurs 48 hours or more after admission to hospital and did not appear to be incubating at the time of admission. HAP is one of the most common infectious diseases acquired in hospitals, affecting 0.5-1.7% of hospitalized patients.<sup>12</sup> The reported all-cause mortality rate for HAP varies widely, ranging from 20-70%.<sup>13, 14</sup> HAP is caused by a wide spectrum of Gram-positive bacteria such as *Staphylococcus aureus*, particularly MRSA, and Gram-negative bacteria.

## About MRSA

Methicillin-resistant *Staphylococcus aureus* (MRSA) is a Gram-positive bacterium and an important cause of pneumonia, accounting for 20–40% of HAP cases.<sup>5</sup> MRSA rates are above 25% in seven of the 30 countries of the European Union (EU) and the European Economic Area reporting to the European Centre for Disease Prevention and Control (ECDC). Based on these figures and generally high MRSA rates, the ECDC considers MRSA a public health priority.<sup>15</sup> The ECDC estimates that approximately 4 million patients acquire a healthcare-associated infection in the EU every year, resulting in at least 37,000 deaths, of which 25,000 are currently estimated to be due to the most common resistant bacteria, i.e. *Staphylococcus aureus* or *Pseudomonas aeruginosa*.<sup>1</sup>

## About Basilea

Basilea Pharmaceutica Ltd. is a biopharmaceutical company developing products that address increasing resistance and non-response to current treatment options in the therapeutic areas of bacterial infections, fungal infections and cancer. The company uses the integrated research, development and commercial operations of its subsidiary Basilea Pharmaceutica International Ltd. to develop and commercialize innovative pharmaceutical products to meet the significant medical needs of patients with serious and life-threatening conditions. Basilea Pharmaceutica Ltd. is headquartered in Basel, Switzerland and listed on the SIX Swiss Exchange (SIX: BSLN). Additional information can be found at Basilea’s website [www.basilea.com](http://www.basilea.com).

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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](http://www.basilea.com).

## References

- \* European brand name Zevtera® or Mabelio®, depending on the country
- 1 European Centre for Disease Prevention and Control. Antimicrobial resistance and healthcare-associated infections.  
[http://www.ecdc.europa.eu/en/activities/diseaseprogrammes/ARHAI/Pages/about\\_programme.aspx](http://www.ecdc.europa.eu/en/activities/diseaseprogrammes/ARHAI/Pages/about_programme.aspx)  
[Accessed November 28, 2014]
- 2 Following approval under the European decentralized procedure, ceftobiprole has received national licenses in Austria, Belgium, Denmark, Finland, France, Germany, Italy, Luxembourg, Norway, Spain, Sweden and the United Kingdom; reimbursement and pricing authorization in several countries including Spain is ongoing
- 3 Summary of Product Characteristics;  
<http://www.mhra.gov.uk/home/groups/spcpil/documents/spcpil/con1415946361819.pdf>  
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