

PRESS RELEASE

Swissmedic approves Basilea's antibiotic Zevtera® (ceftobiprole medocaril) for the treatment of pneumonia

Basel, Switzerland, December 22, 2014 – Basilea Pharmaceutica Ltd. (SIX: BSLN) reports that the Swiss regulatory authority Swissmedic has approved the antibiotic Zevtera® (ceftobiprole medocaril) for the treatment in adults of community-acquired pneumonia (CAP) and hospital-acquired pneumonia (HAP), excluding ventilator-associated pneumonia (VAP). The license will be issued by Swissmedic following formal publication of the Product Information. Ceftobiprole for the treatment of pneumonia has already been approved in twelve other European countries.¹

Each year, approximately 70,000 hospital-acquired infections occur in Switzerland, leading to the death of about 2,000 patients, according to Swissnoso, a Swiss infectious diseases and hospital hygiene expert group.² HAP is among the most common of these hospital-acquired infections.³

Ceftobiprole is a new-generation broad-spectrum cephalosporin antibiotic with rapid bactericidal activity against Gram-positive and Gram-negative bacteria associated with pneumonia, including methicillin-resistant *Staphylococcus aureus* (MRSA) and susceptible strains of *Pseudomonas* spp.⁴ Ceftobiprole is administered intravenously and is the active moiety of the prodrug ceftobiprole medocaril.

Ronald Scott, Chief Executive Officer of Basilea, commented: "We are very pleased that Swissmedic has approved Zevtera for the treatment of pneumonia in Switzerland. Antibiotic-resistant infections are a major healthcare threat. The development of new antibiotics is part of Basilea's commitment to combat drug resistance."

Prof. Achim Kaufhold, Chief Medical Officer of Basilea, added: "The approval of ceftobiprole in Switzerland offers a new treatment option for physicians and their patients to support the treatment of pneumonia, when empiric therapy requires broad-spectrum activity against frequent Gram-positive and Gram-negative pathogens."

About pneumonia

Pneumonia is a common infection^{5, 6} 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. Common infection 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.⁷ 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.³ The reported all-cause mortality rate for HAP varies widely, ranging from 20-70%.^{8, 9} HAP is caused by a wide spectrum of Gram-positive bacteria such as *Staphylococcus aureus*, particularly MRSA, and Gram-negative bacteria. Community-acquired pneumonia is a common condition with up to 60% of the patients requiring hospital admission and intravenous antibiotics.¹⁰ Prompt empiric intervention with an appropriate broad-spectrum antibiotic treatment is accepted as best medical

practice.¹¹ The increasing incidence of bacteria resistant to many established antibiotics is a major concern.

About MRSA

Methicillin-resistant *Staphylococcus aureus* (MRSA) is a Gram-positive bacterium which is an important cause of pneumonia, accounting for 20–40% of all HAP cases.¹² 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 to be a public health priority.¹³ 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, including *Staphylococcus aureus* and *Pseudomonas aeruginosa*.¹⁴

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.

Disclaimer

This communication expressly or implicitly contains certain forward-looking statements concerning Basilea Pharmaceutica Ltd. and its business. Such statements involve certain known and unknown risks, uncertainties and other factors, which could cause the actual results, financial condition, performance or achievements of Basilea Pharmaceutica Ltd. to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Basilea Pharmaceutica Ltd. is providing this communication as of this date and does not undertake to update any forward-looking statements contained herein as a result of new information, future events or otherwise.

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 Following approval under the European decentralized procedure, ceftobiprole has received national licenses for the treatment of CAP and HAP (excluding VAP) in adults 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
- 2 Swiss Federal Office of Public Health (FOPH). 2014. 140314_FAQ_Antibiotikaresistenzen_d_updatelB.pdf. Retrieved from <http://www.bag.admin.ch/themen/medizin/14226/index.html?lang=de> [Accessed August 18, 2014]

- 3 R. Masterton et al. Hospital-acquired pneumonia guidelines in Europe: a review of their status and future development. *Journal of Antimicrobial Chemotherapy* 2007 (60), 206-213
- 4 Y. Y. Syed. Ceftobiprole medocaryl: A review of its use in patients with hospital- or community-acquired pneumonia. *Drugs* 2014 (74), 1523-1542
- 5 M. R. Loebinger, R. Wilson. Pneumonia. *Medicine* 2012 (40), 329-334
- 6 White Book. <http://www.erswhitebook.org/chapters/acute-lower-respiratory-infections/pneumonia/> [Accessed September 30, 2014]
- 7 G. B. Nair, M. S. Niederman. Community-acquired pneumonia: an unfinished battle. *Medical Clinics of North America* 2011 (95), 1143-1161
- 8 American Thoracic Society, Infectious Diseases Society of America. Guidelines for the management of adults with hospital-acquired, ventilator-associated, and healthcare-associated pneumonia. *American Journal of Respiratory and Critical Care Medicine* 2005 (171), 388-416
- 9 M. H. Kollef et al. Epidemiology and outcomes of health-care-associated pneumonia: results from a large US database of culture-positive pneumonia. *Chest* 2005 (128), 3854-3862
- 10 W. I. Sligl et al. Severe community-acquired pneumonia. *Critical Care Clinics* 2013 (29), 563-601
- 11 G. Höffken et al. Epidemiology, diagnosis, antimicrobial therapy and management of community-acquired pneumonia and lower respiratory tract infections in adults. Guidelines of the Paul-Ehrlich-Society for Chemotherapy, the German Respiratory Society, the German Society for Infectiology and the Competence Network CAPNETZ Germany. *Pneumologie* 2009 (63), e1-e68
- 12 E. Rubinstein et al. Pneumonia caused by methicillin-resistant *Staphylococcus aureus*. *Clinical Infectious Diseases* 2008 (46), Suppl 5, S378-S385
- 13 European Centre for Disease Prevention and Control. Antimicrobial resistance surveillance in Europe 2012. Annual Report of the European Antimicrobial Resistance Surveillance Network (EARS-Net). ECDC 2013
- 14 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 [Accessed November 28, 2014]