

## PRESS RELEASE

# Basilea announces that Health Canada approved ZEVTERA® for the treatment of bacterial lung infections

**Basel, Switzerland, October 12, 2015** – Basilea Pharmaceutica Ltd. (SIX: BSLN) announced today that Health Canada has approved ZEVTERA® (ceftobiprole medocartil) for the treatment of patients 18 years of age and older with hospital-acquired pneumonia (HAP), excluding ventilator-associated pneumonia (VAP), and for the treatment of community-acquired pneumonia (CAP).

ZEVTERA® is a broad-spectrum antibiotic with bactericidal activity against susceptible Gram-positive bacteria, including methicillin-resistant *Staphylococcus aureus* (MRSA), and Gram-negative bacteria associated with pneumonia.<sup>1</sup> ZEVTERA® is not yet launched in Canada.

Prof. Achim Kaufhold, Basilea's Chief Medical Officer, said: "We are very pleased that ZEVTERA has received regulatory approval in Canada. As a bactericidal cephalosporin with broad-spectrum activity against relevant pathogens causing pneumonia, ZEVTERA may potentially offer a valuable new treatment option in the empiric treatment setting for life-threatening lung infections."

David Veitch, Basilea's Chief Commercial Officer, stated: "The approval by Health Canada is a significant achievement for Basilea and demonstrates our commitment to expand the availability of ZEVTERA around the world."

### About hospital-acquired and community-acquired pneumonia

Hospital-acquired pneumonia (HAP) is one of the most common hospital-acquired infections and has been shown to have among the highest mortality rates of all hospital-acquired infections.<sup>2</sup> Methicillin-resistant *Staphylococcus aureus* (MRSA) is a frequent cause of hospital-acquired pneumonia.<sup>3</sup> In a study involving Canadian hospitals, MRSA pneumonia infections were associated with significant morbidity and an all-cause 30-day mortality of 28%.<sup>4</sup> Community-acquired pneumonia (CAP) is a common condition with up to 60% of the patients requiring hospital admission and intravenous antibiotics.<sup>5</sup> Prompt empiric intervention with an appropriate broad-spectrum antibiotic treatment is considered a best medical practice. The increasing incidence of bacteria resistant to many established antibiotics is a major concern.

### About ZEVTERA®

ZEVTERA® (ceftobiprole medocartil) is a broad-spectrum antibiotic for intravenous administration with bactericidal activity against Gram-positive and Gram-negative bacteria associated with pneumonia, including methicillin-resistant *Staphylococcus aureus* (MRSA) and susceptible *Pseudomonas* spp.<sup>6</sup>

Ceftobiprole has received national licenses in 13 European countries<sup>7</sup> for the treatment of adult patients with CAP and HAP (excluding VAP) and has been launched in Germany, France, Italy and the United Kingdom. Ceftobiprole received Qualified Infectious Disease Product (QIDP) designation from the U.S. Food and Drug Administration for the potential treatment of community-acquired bacterial pneumonia and acute bacterial skin and skin structure infections. Ceftobiprole is not approved in the United States.

## 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 discover, develop and commercialize innovative pharmaceutical products to meet the medical needs of patients with serious and potentially 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).

## 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 <a href="mailto:media_relations@basilea.com">media_relations@basilea.com</a>	Barbara Zink, PhD, MBA Head Corporate Development  +41 61 606 1233 <a href="mailto:investor_relations@basilea.com">investor_relations@basilea.com</a>

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

## References

- 1 ZEVTERA® (Ceftobiprole medocaril powder for injection) Health Canada Product Monograph. Date of Revision: September 24, 2015
- 2 C. Rotstein et al. Clinical practice guidelines for hospital-acquired pneumonia and ventilator-associated pneumonia in adults. *Canadian Journal of Infectious Diseases & Medical Microbiology* 2008 (19), 19-53
- 3 R. N. Jones. Microbial etiologies of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia. *Clinical Infectious Diseases* 2010 (51), S81-S87
- 4 M. Tadros et al. Epidemiology and outcome of pneumonia caused by methicillin-resistant *Staphylococcus aureus* (MRSA) in Canadian hospitals. *PLOS ONE* 2013 (8), e75171
- 5 W. I. Sligl et al. Severe community-acquired pneumonia. *Critical Care Clinics* 2013 (29), 563-601
- 6 Y. Y. Syed. Ceftobiprole medocaril: A review of its use in patients with hospital- or community-acquired pneumonia. *Drugs* 2014 (74), 1523-1542
- 7 Ceftobiprole (European trade name Zevtera® or Mabelio®, depending on the country) has received national licenses in 13 European countries for the treatment of adult patients with community- and hospital-acquired pneumonia (CAP, HAP), excluding ventilator-associated pneumonia (VAP): Austria, Belgium, Denmark, Finland, France, Germany, Italy, Luxembourg, Norway, Spain, Sweden, Switzerland and the United Kingdom.