

## PRESS RELEASE

# Basilea to launch Zevtera®/Mabelio® (ceftobiprole medocaril) in Europe through a commercial services provider

**Basel, Switzerland, July 21, 2014** – Basilea Pharmaceutica Ltd. (SIX: BSLN) reports that it has entered into an agreement with Quintiles (NYSE: Q) for the commercialization of Zevtera®/Mabelio® (ceftobiprole medocaril) in Europe.

Under the agreement, Quintiles will provide commercial services including a dedicated field force, medical science liaisons, and market access support in selected countries.

“At a time when antibiotic resistance is a major healthcare threat throughout Europe, we are very pleased to be launching Zevtera/Mabelio, a new broad-spectrum antibiotic also covering MRSA and providing physicians with a new option to treat severe bacterial infections,” said Ronald Scott, Basilea’s Chief Executive Officer. “Basilea has the potential opportunity to launch two hospital products in Europe; ceftobiprole followed by isavuconazole in the event of regulatory approval. This could afford the company significant commercialization synergies. We have initially opted to commercialize our products in Europe through Quintiles in order to retain flexibility and to more fully participate in the economic upside of our products. The agreement with Quintiles allows us to scale and optimize our resources during the launch of Zevtera/Mabelio on a country-by-country basis.”

He added: “We have made significant progress on national pricing and reimbursement and anticipate launching Zevtera in Germany in the second half of 2014, followed by launches in other key European markets in 2015. In parallel, we continue to assess opportunities for distribution and licensing partnerships in other parts of the world.”

Basilea’s financial guidance for 2014 remains unchanged, with total operating expenses estimated at CHF 8 to 9 million per month and operating loss estimated at CHF 4 to 5 million per month.

### About Ceftobiprole

Ceftobiprole (ceftobiprole medocaril, trademarks Zevtera®, Mabelio®) is a broad-spectrum intravenous cephalosporin antibiotic for the potential empiric treatment of severe bacterial infections where Gram-positive bacteria, such as methicillin-resistant *Staphylococcus aureus* (MRSA) and Gram-negative pathogens, such as *Pseudomonas* are suspected. It has gained regulatory authorization from twelve European states<sup>1</sup> for the treatment of hospital-acquired pneumonia (HAP, excluding ventilator-associated pneumonia, VAP) and community-acquired pneumonia (CAP) in patients 18 years of age and older, and is currently under regulatory review in Switzerland. Ceftobiprole demonstrated broad-spectrum *in-vitro* bactericidal 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*.<sup>2, 3</sup>

## 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.<sup>4, 5</sup> Community-acquired pneumonia is a common condition with up to 60% of the patients requiring hospital admission and intravenous antibiotics.<sup>6</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 established 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 Ceftobiprole has received national licenses in Austria, Belgium, Denmark, Finland, France, Germany, Norway, Spain, Sweden and the United Kingdom; national authorization in Luxembourg and Italy is ongoing.
- 2 A. Walkty et al. In vitro activity of ceftobiprole against frequently encountered aerobic and facultative Gram-positive and Gram-negative bacterial pathogens: results of the CANWARD 2007–2009 study. *Diagnostic Microbiology and Infectious Disease* 2011 (69), 348-355
- 3 D. J. Farrell et al. Ceftobiprole activity against over 60,000 clinical bacterial pathogens isolated in Europe, Turkey and Israel from 2005 to 2010. *Antimicrobial Agents and Chemotherapy* 2014 (58), 3882-3888
- 4 A. Torres et al. Treatment guidelines and outcomes of hospital-acquired and ventilator-associated pneumonia. *Clinical Infectious Diseases* 2010 (51), S48-S53
- 5 F. Barbier et al. Hospital-acquired pneumonia and ventilator-associated pneumonia: recent advances in epidemiology and management. *Current Opinion in Pulmonary Medicine* 2013 (19), 216-228
- 6 W. I. Sligl et al. Severe community-acquired pneumonia. *Critical Care Clinics* 2013 (29), 563-601