

## PRESS RELEASE

# Basilea announces distribution agreement with Unimedic for CRESEMBA® (isavuconazole) and Zevtera® (ceftobiprole) in the Nordic countries

**Basel, Switzerland, September 20, 2016** – Basilea Pharmaceutica Ltd. (SIX: BSLN) announced today that Basilea Pharmaceutica International Ltd. (Basilea) has entered into a license and distribution agreement with Unimedic Pharma AB (Unimedic) for Basilea's antifungal CRESEMBA® (isavuconazole) and antibiotic Zevtera® (ceftobiprole) in the Nordic countries, including Sweden, Denmark and Norway, and Finland.

Under the terms of the agreement, Unimedic is granted an exclusive license to import and commercialize isavuconazole and ceftobiprole in the region. Basilea will be eligible to receive an upfront and sales milestone payments. Basilea will remain the marketing authorization holder and Unimedic will be responsible for commercialization and distribution of isavuconazole and ceftobiprole in these countries.

David Veitch, Basilea's Chief Commercial Officer, stated: "We are pleased to have entered into this partnership with Unimedic. The Nordic countries are traditionally early adopters of innovative medicines. Unimedic focuses on hospital anti-infectives and is well positioned for the commercialization of both isavuconazole and ceftobiprole. With this partnership we are further broadening the availability of our products to patients and physicians within Europe."

### About isavuconazole

Isavuconazole is an intravenous (i.v.) and oral azole antifungal and the active agent of the prodrug isavuconazonium sulfate. It is approved in the United States for patients 18 years of age and older in the treatment of invasive aspergillosis and invasive mucormycosis.<sup>1</sup> In Europe, isavuconazole received marketing authorization for the treatment of adult patients with invasive aspergillosis and for the treatment of adult patients with mucormycosis for whom amphotericin B is inappropriate.<sup>2</sup> Isavuconazole has orphan drug designation for the approved indications in Europe and the US. Basilea commercializes isavuconazole as CRESEMBA® in Germany, Italy, the UK and Austria and is seeking national pricing and reimbursement in additional EU countries. In the US, the drug is commercialized by Basilea's license partner Astellas Pharma US. Outside the US and the EU, isavuconazole is currently not approved for commercial use.

### About invasive aspergillosis and mucormycosis

Invasive aspergillosis and mucormycosis are life-threatening fungal infections that predominantly affect immunocompromised patients, such as patients with cancer. Invasive aspergillosis is known for high morbidity and mortality. Mucormycosis (also known as zygomycosis) is a rapidly progressing and life-threatening invasive fungal infection, known for high morbidity and mortality.

### About ceftobiprole

Ceftobiprole is a broad-spectrum antibiotic from the cephalosporin class for i.v. administration with bactericidal activity against certain Gram-positive and Gram-negative bacteria, including methicillin-resistant *Staphylococcus aureus* (MRSA) and susceptible *Pseudomonas* spp. Ceftobiprole is approved for sale in 13 European countries and several non-European countries for the treatment of adult patients with community-acquired pneumonia (CAP) and hospital-

acquired pneumonia (HAP), excluding ventilator-associated pneumonia (VAP).<sup>3,4</sup> The drug is currently commercialized in Germany, Italy, the United Kingdom, France, Austria and Switzerland.

### 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>5</sup> Methicillin-resistant *Staphylococcus aureus* (MRSA) is one of the most frequent causes of hospital-acquired pneumonia.<sup>6</sup> Community-acquired pneumonia (CAP) is a common condition with up to 60% of the patients requiring hospital admission and intravenous antibiotics.<sup>7</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 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).

### About Unimedic

Unimedic Pharma AB is a Swedish based specialty care company, focusing on developing and commercializing specialty care pharmaceuticals mainly in the Nordics but also in other parts of Europe. The company is primarily focused towards Intensive care, Anti-infectives, and the Addiction therapeutic areas. The company is today one of the fastest growing pharmaceutical companies within the Nordic market and has, over the past three years, increased the turnover from MSEK 100 to MSEK 600. Unimedic Pharma is owned by MedCap AB, listed on the Stockholm stock exchange.

### 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.

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

## References

- 1 CRESEMBA® [US prescribing information](#) [Accessed: September 19, 2016]
- 2 European Public Assessment Report (EPAR) CRESEMBA®: <http://www.ema.europa.eu> [Accessed: September 19, 2016]
- 3 UK Summary of Product Characteristics (SPC) Zevtera®: <http://www.mhra.gov.uk/> [Accessed: September 19, 2016]
- 4 European trade name Zevtera® or Mabelio®, depending on the country. The drug 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.
- 5 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
- 6 R. N. Jones. Microbial etiologies of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia. *Clinical Infectious Diseases* 2010 (51), S81-S87
- 7 W. I. Sligl et al. Severe community-acquired pneumonia. *Critical Care Clinics* 2013 (29), 563-601