

## PRESS RELEASE

# Basilea announces supply, distribution and license agreement with Grupo Biotoscana for CRESEMBA® (isavuconazole) and Zevtera® (ceftobiprole) in Latin America

*Basel, Switzerland, September 13, 2016* – Basilea Pharmaceutica Ltd. (SIX: BSLN) announced today that Basilea Pharmaceutica International Ltd. (Basilea) has entered into a supply, distribution and license agreement with Grupo Biotoscana S.L., (GBT) for Basilea's antifungal CRESEMBA® (isavuconazole) and antibiotic Zevtera® (ceftobiprole) in 19 countries in Latin America including Brazil, Mexico, Argentina and Colombia.

Under the terms of the agreement, GBT holds an exclusive license to commercialize isavuconazole and ceftobiprole in key Latin American countries. In total, Basilea will receive upfront payments of CHF 11 million for both drugs and will be eligible to receive payments upon achievement of regulatory and commercial milestones. GBT will be responsible for marketing authorization applications, market access, commercialization and distribution of isavuconazole and ceftobiprole in the countries covered by the agreement.

David Veitch, Basilea's Chief Commercial Officer, stated: "We are pleased to have signed a distribution agreement with GBT, a leading biopharmaceutical company in Latin America. Latin America is one of the fastest growing markets in the world. With its presence in more than 90% of the Latin America market, GBT has the capability to successfully commercialize isavuconazole and ceftobiprole in this important region."

### 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 available 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 Grupo Biotoscana

Grupo Biotoscana (GBT) is a biopharmaceutical group that operates in the fast growing Latin American region and focuses on rapidly growing market segments such as oncology, hematology, high-complexity genetic disorders, rare disease, infectious disease, HIV and other specialty treatments. GBT operates throughout Latin America under its companies Biotoscana, United Medical and LKM. GBT's strong portfolio combines world-class licenses and proprietary products with annual revenues of USD 250 million. GBT is controlled by the global private equity firm Advent International, with other significant shareholders including Essex Woodlands and a number of private investors. To find out more about Grupo Biotoscana, please go to [www.grupobiotoscana.com](http://www.grupobiotoscana.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.

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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 12, 2016]
- 2 European Public Assessment Report (EPAR) CRESEMBA®: <http://www.ema.europa.eu> [Accessed: September 12, 2016]
- 3 UK Summary of Product Characteristics (SPC) Zevtera®: <http://www.mhra.gov.uk/> [Accessed: September 12, 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