

## PRESS RELEASE

# Basilea announces distribution agreement with Avir Pharma Inc. for Cresemba® (isavuconazole) and Zevtera® (ceftobiprole) in Canada

**Basel, Switzerland, June 14, 2017** – Basilea Pharmaceutica Ltd. (SIX: BSLN) announced today that Basilea Pharmaceutica International Ltd. (Basilea) has entered into a distribution and license agreement with Avir Pharma Inc. (Avir) for Basilea's antifungal Cresemba® (isavuconazole) and antibiotic Zevtera® (ceftobiprole) in Canada.

Under the terms of the agreement, Avir is granted an exclusive license to commercialize isavuconazole and ceftobiprole in the Canadian market. Basilea will receive an upfront payment and is eligible to receive milestone payments upon achievement of regulatory and commercial milestones. Avir plans to apply for a marketing authorization for isavuconazole in Canada. Zevtera is already approved by Health Canada for the treatment of adult patients with hospital-acquired pneumonia (HAP), excluding ventilator-associated pneumonia (VAP), and for the treatment of community-acquired pneumonia (CAP). Avir will be purchasing product from Basilea and be responsible for commercialization in Canada.

David Veitch, Basilea's Chief Commercial Officer, stated: "Cresemba and Zevtera are clearly differentiated hospital products potentially addressing significant medical needs of patients who are suffering from severe microbial infections. We look forward to bringing our products to patients in Canada through our partnership with Avir which has a strong presence in the specialty care market."

### 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 mold 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 cephalosporin antibiotic for intravenous administration with rapid bactericidal activity against a wide range of Gram-positive and Gram-negative bacteria, including

methicillin-susceptible and resistant *Staphylococcus aureus* (MSSA, MRSA) and susceptible *Pseudomonas* spp. The drug is approved for sale in 13 European countries (European trade name Zevtera® or Mabelio®, depending on the country) and several non-European countries, including Canada, for the treatment of adult patients with community-acquired bacterial pneumonia (CABP) and hospital-acquired bacterial pneumonia (HABP), excluding ventilator-associated bacterial pneumonia (VABP).<sup>3</sup> Basilea is currently marketing the drug in Germany, Italy, UK, France, Austria and Switzerland. Ceftobiprole received Qualified Infectious Disease Product (QIDP) designation from the US Food and Drug Administration (FDA) for the potential treatment of community-acquired bacterial pneumonia (CABP) and acute bacterial skin and skin structure infections (ABSSSI). Ceftobiprole is not approved for commercial sale in the United States.

### 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>4</sup> Methicillin-resistant *Staphylococcus aureus* (MRSA) is one of the most frequent causes of hospital-acquired pneumonia.<sup>5</sup> Community-acquired pneumonia (CAP) 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 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 the medical challenge of 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 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 Avir Pharma Inc.

Avir Pharma Inc. is a wholly-owned, privately-held Canadian pharmaceutical company whose mission is to enhance the lives of Canadians through the acquisition, in-licensing and co-development of innovative, specialty pharmaceutical products. Located in Blainville, Quebec, Avir Pharma Inc. is an affiliate of the Laboratoire Riva group, an established company with over 40 years of experience in manufacturing, distributing and promoting pharmaceutical products in the Canadian marketplace. For more information, please visit the company's web site at [www.avirpharma.com](http://www.avirpharma.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:

Peer Nils Schröder, PhD Head of Corporate Communications & Investor Relations +41 61 606 1102 media_relations@basilea.com investor_relations@basilea.com
--

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

## References

- 1 Cresemba® [US prescribing information](#) [Accessed: June 13, 2017]
- 2 European Public Assessment Report (EPAR) Cresemba®: <http://www.ema.europa.eu> [Accessed: June 13, 2017]
- 3 UK Summary of Product Characteristics (SPC) Zevtera®: <http://www.mhra.gov.uk/> [Accessed: June 13, 2017]
- 4 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
- 5 R. N. Jones. Microbial etiologies of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia. *Clinical Infectious Diseases* 2010 (51), S81-S87
- 6 W. I. Sligl et al. Severe community-acquired pneumonia. *Critical Care Clinics* 2013 (29), 563-601