

## PRESS RELEASE

# Basilea reports isavuconazole (Cresemba®) and ceftobiprole (Zevtera®) presentations at European Congress of Clinical Microbiology and Infectious Diseases (ECCMID)

**Basel, Switzerland, April 12, 2019** – Basilea Pharmaceutica Ltd. (SIX: BSLN) announced today that a broad range of posters and presentations on the antifungal isavuconazole (Cresemba®) and the antibiotic ceftobiprole (Zevtera®) will be presented at the 29<sup>th</sup> European Congress of Clinical Microbiology and Infectious Diseases (ECCMID), held in Amsterdam, the Netherlands, from April 13 to 16, 2019.

One of the oral presentations with isavuconazole will report data from a phase 1 study in pediatric patients. The study is part of the pediatric investigation plan that was agreed with the U.S. and European regulatory authorities, FDA and EMA. Upon completion of this plan, isavuconazole may receive an additional two years of market exclusivity in the European Union and six months in the U.S. Another oral presentation will report on an open-label trial of isavuconazole prophylaxis against invasive fungal infection in adult patients undergoing allogeneic haematopoietic stem cell transplantation.

The details of the presentations are as follows:

### Isavuconazole at ECCMID 2019

**Saturday, 13 April 2019 – 10:00-12:00 CEST, Hall H**

#### **Oral Session OS017– Issues in antifungal treatment**

- *A single-centre, open-label trial of isavuconazole prophylaxis against invasive fungal infection in patients undergoing allogeneic haematopoietic stem cell transplantation – A. Stern, Y. Bogler, S. Seo, M. Perales, Y. J. Lee, G. Papanicolaou; O0107*
- *An open-label, phase I, multi-centre study to evaluate the pharmacokinetic, safety and tolerability profile of intravenous isavuconazonium sulfate in paediatric patients – A. Arrieta, H. Frangoul, W. Steinbach, W. Muller, P. Sue, D. Yin, L. Danziger-Isakov, J. Chu, S. Rheingold, V. Statler, T. Chen, K. Hamed, C. Lademacher, A. Desai, J. Akin, D. L. Phillips, L. Kovanda, T. J. Walsh; O0110*

**Saturday, 13 April 2019 – 15:30-16:30 CEST, Paper Poster Arena**

#### **Paper Poster Session PS007 – Clinical pharmacokinetics, treatment strategies and prescribing of antifungals**

- *Isavuconazole clearance during in vitro and in vivo continuous renal replacement therapy – D. Butler, M. Biagi, S. Qasmieh, X. Tan, E. Wenzler; P0120*

**Monday, 15 April 2019 – 11:00-12:00 CEST, Arena 2**

#### **Mini-oral ePoster Session OE151 – Antifungals: novel drugs, novel dosing?**

- *Isavuconazole kinetic exploration for clinical practice –L. Darnaud, F. Lamoureux, C. Godet, S. Pontier, A. Debard, N. Venisse, P. Martins, D. Concordet, P. Gandia; O0737*
- *Comparative evaluation of isavuconazonium sulfate, voriconazole, and posaconazole for the management of invasive fungal infections in an academic medical centre – E. Van Matre, S. Evans, S. Mueller, R. MacLaren, D. Fish, T. Kiser; O0739*

**Monday, 15 April 2019 – 12:30-13:30 CEST, Paper Poster Arena**

**Paper Poster Session PS099 – MIC testing various species**

- EUCAST susceptibility testing of isavuconazole: MIC data for contemporary Danish clinical mould isolates – K. M. Jørgensen, R. K. Hare, K. M. T Astvad, M. C. Arendrup; P1767

**Monday, 15 April 2019 – 13:30-14:30 CEST, Paper Poster Arena**

**Paper Poster Session PS114 – Current issues in clinical pharmacokinetics**

- Achievement of clinical isavuconazole serum and plasma trough concentrations in seven patients with isavuconazonium capsules administered via an enteral feeding tube – E. McCreary, M.-H. Nguyen, L. Sacha, J. Borlagdan, R. Shields, R. Marini, R. Rivosecchi, F. Silveira, D. Andes, A. Lepak; P1984

**Tuesday, 16 April 2019 – 12:30-13:30 CEST, Paper Poster Arena**

**Paper Poster Session PS126 – Conventional approaches in fungal diagnostics**

- Comparison of azoles and amphotericin B MICs against Mucorales obtained after visual inspection or by spectrophotometric reading according to EUCAST 9.3.1. – P. Escribano, S. Lopez<sup>1</sup>, J. Diaz-Garcia, P. Munoz, E. Bouza Santiago, J. Guinea Ortega; P2216

**Ceftobiprole at ECCMID 2019**

**Monday, 15 April 2019, 13:30-14:30 CEST, Paper Poster Arena**

**Paper Poster Session PS107– In vitro activity of newer antibacterial agents**

- In vitro activity of ceftobiprole against Gram-positive isolates from clinical samples from a tertiary hospital – F. J. Candel, C. Rico-Luna, I. Diaz De La Torre, A. Ruedas, B. Laguna, J. Martinez, C. Visiedo, M. Peñuelas Martinez, A. Arribi, A. Suárez; P1863
- In vitro activity of ceftobiprole against isolates of common involved pathogens in nosocomial pneumonia from a tertiary hospital – F. J. Candel, I. Diaz De La Torre, A. Ruedas, C. Rico-Luna, C. Lejarraga, T. Emilov, C. Visiedo, J. Martinez, J. M. Viñuela-Prieto, A. Arribi, A. Suárez; P1864
- Susceptibility of ceftobiprole and other beta-lactams against Gram-negative pathogens from hospital-acquired pneumonia in the UK and Ireland since 2011 – B. Ritz, N. Redder, N. Dunkel; P1865
- Susceptibility of ceftobiprole and comparators against methicillin-resistant *Staphylococcus aureus* from respiratory tract infections – S. Hawser, N. Kothari, M. Gueni, S. Magnet, T. Wiktorovicz, K. Hamed, I. Morrissey; P1866
- Activity of ceftaroline and ceftobiprole against staphylococci and *Streptococcus pneumoniae* in the UK and Ireland – C. Horner, S. Mushtaq, D. Livermore; P1867

**Paper Poster Session PS110 – Clinical efficacy studies for antimicrobial agents**

- 18 months of real-life use of ceftobiprole: clinical experience in an internal medicine ward – G. Russo, F. Casu, R. Franceschini; P1911

**Tuesday, 16 April 2019, 12:30-13:30 CEST, Paper Poster Arena**

**Paper Poster Session PS161 – Resistance mechanisms in Gram-positive cocci**

- PBP2a mutations do not affect bactericidal activity to ceftaroline and ceftobiprole in clinical MDR-MRSA isolates – F. Campanile, G. Mongelli, D. Bongiorno, M. Rizzo, S. Stefani; P2849

For further information please visit [www.eccmid.org](http://www.eccmid.org).

## About isavuconazole (Cresemba®)

Isavuconazole is an intravenous (i.v.) and oral azole antifungal, commercialized under the trade name Cresemba. In the 28 European Union member states, as well as in Iceland, Liechtenstein and Norway, isavuconazole is approved 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>1</sup> Cresemba is also approved in the United States and several additional countries in and outside of Europe. It has U.S. and European orphan drug designation for its approved indications. Basilea has entered into several license and distribution agreements for isavuconazole covering the United States, Europe, China, Japan, Latin America, Asia-Pacific, the Middle East and North Africa (MENA) region, Canada, Russia, Turkey and Israel.<sup>2</sup>

## About ceftobiprole (Zevtera®)

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.<sup>3</sup> Ceftobiprole is approved in major 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</sup> It is commercialized under the trade names Zevtera and Mabelio. Basilea has entered into license and distribution agreements for the brand in Europe, Latin America, China, Canada, Israel, and the Middle East and North Africa (MENA) region. Ceftobiprole is currently in a phase 3 clinical program for registration in the U.S.

## About Basilea

Basilea Pharmaceutica Ltd. is a commercial stage biopharmaceutical company, focused on the development of products that address the medical challenges in the therapeutic areas of oncology and anti-infectives. With two commercialized drugs, the company is committed to discovering, developing and commercializing 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).

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

## References

- 1 European Public Assessment Report (EPAR) Cresemba: <http://www.ema.europa.eu>  
[Accessed: April 11, 2019]
- 2 The registration status and approved indications may vary from country to country.
- 3 U.K. Summary of Product Characteristics (SPC) Zevtera: <http://www.mhra.gov.uk/>  
[Accessed: April 11, 2019]