

PRESS RELEASE

Basilea reports presentation of isavuconazole and ceftobiprole data at European Congress of Clinical Microbiology and Infectious Diseases (ECCMID)

- **Post-hoc analysis on clinical response of ceftobiprole in staphylococcal bacteremia**

Basel, Switzerland, April 15, 2016 – Basilea Pharmaceutica Ltd. (SIX: BSLN) announced today that a broad range of posters and oral presentations with scientific data on the antifungal isavuconazole (CRESEMBA®) and the antibiotic ceftobiprole (Zevtera®) were presented at the European Congress of Clinical Microbiology and Infectious Diseases (ECCMID). At the conference, which was held in Amsterdam, the Netherlands, starting on April 9, 2016, the company hosted symposia on new perspectives in the management of nosocomial pneumonia and current challenges and recent developments for the treatment of invasive mold infections.

The data presented on isavuconazole included further analyses from the isavuconazole SECURE phase 3 study in invasive aspergillosis and the results of the ACTIVE phase 3 study in invasive candidiasis. In addition, in-vitro data on the activity of isavuconazole against a variety of fungal pathogens, including isolates with reduced susceptibility to other azoles, were presented.

For ceftobiprole, the presentations included data from a post-hoc analysis of patients with staphylococcal bacteremia from four double-blind, randomized, phase 3 studies in complicated skin or pulmonary infections. The data demonstrated that clinical responses with ceftobiprole were similar to those for standard-of-care comparators, with a trend towards lower 30-day all-cause mortality with ceftobiprole. Bloodstream infections caused by Methicillin-susceptible and -resistant *Staphylococcus aureus* are a potentially life-threatening complication of staphylococcal infections in other sites of the body.

Isavuconazole posters and presentations at ECCMID 2016

- *Pharmacodynamics of isavuconazole in experimental invasive pulmonary aspergillosis: a virtuous cycle between bench and bedside* – L. Kovanda, R. Petraitiene, V. Petraitis, T. J. Walsh, A. Desai, P. Bonate, W. W. Hope; ePoster EP0006
- *Efficacy and safety outcomes in patients with probable or proven versus possible invasive mould disease from the phase 3 secure study, evaluating isavuconazole versus voriconazole for the primary treatment of invasive fungal disease caused by Aspergillus spp. or other filamentous fungi* – J. Maertens, D. Selleslag, W. Heinz, R. Herbrecht, G. Rahav, M. Giladi, M. Aoun, O. A. Cornely, N. Azie, A. Kaufhold, M. Engelhardt, M. Saulay, A. Ullmann; ePoster EP0010
- *In vitro activity of isavuconazole against Candida and Aspergillus* – M. C. Arendrup, R. H. Jensen, K. Astvad; Oral presentation O227
- *Isavuconazole versus caspofungin in the treatment of candidaemia and other invasive Candida infections: the ACTIVE trial* – B.-J. Kullberg, G. Thompson, P. Pappas, J. Vazquez, C. Viscoli, L. Ostrosky-Zeichner, C. Rotstein, J. Sobel, R. Herbrecht, G. Rahav, E. Van Wijngaerden, J. De Waele, S. Jaruratanasirikul, P. Chetchotisakd, L. Kovanda, C. Lademacher, M. Lee, M. Engelhardt; Oral presentation O423

- *Intra-subject variability and exposure-response relationship of isavuconazole in the phase 3 SECURE study in patients with invasive mould disease caused by Aspergillus spp. and other filamentous fungi – T. Kaindl, M. Engelhardt, R. Townsend, A. Desai, L. Kovanda, M. Saulay, A. H. Schmitt-Hoffmann; Oral presentation O424*
- *Population pharmacokinetics of isavuconazole in patients with invasive Candida infections (IC) and combined analysis of patients with IC or invasive aspergillosis – A. Desai, L. Kovanda, C. Lademacher, R. W. Townsend, S. Mujais, P. L. Bonate; Poster P1572*
- *In vitro activity of isavuconazole against azole-resistant environmental Aspergillus fumigatus isolates, cryptic Candida strains and emerging yeasts – P. Le Pape, B. Ariza, C. Loge, R. Lavergne, F. Morio, C. Picot, S. Valderrama, C. Alvarez; Poster P1584*

Ceftobiprole posters and presentations at ECCMID 2016

- *EUCAST zone diameter breakpoints and quality control criteria for ceftobiprole 5 µg – E. Matuschek, J. Åhman, A. Santerre Henriksen, G. Kahlmeter; Poster P0825*
- *A pooled analysis of clinical cure and mortality with ceftobiprole medocartil versus comparators in staphylococcal bacteraemia in complicated skin infections, and community- and hospital acquired pneumonia – J. Rello, G. Rahav, T. Scheeren, M. Saulay, M. Engelhardt, T. Welte; Oral presentation O318*
- *Pharmacokinetics and pharmacodynamics of ceftobiprole in adults who are severely obese – A. Schmitt-Hoffmann, M. Engelhardt, J. Spickermann, M. Jones, A. Kaufhold; Poster P1250*
- *Bone penetration of the new-generation cephalosporin ceftobiprole in patients following hip replacement surgery – A.-H. Schmitt-Hoffmann, M. Engelhardt, J. Spickermann, M. Jones, A. Kaufhold; Poster P1251*
- *Pharmacokinetics of ceftobiprole in paediatric patients – J. Blumer, A.-H. Schmitt-Hoffmann, M. Engelhardt, J. Spickermann, M. Jones, A. Kaufhold; Poster P1252*
- *Ceftobiprole resistance in Danish MRSA – A. Larsen, A. Petersen, F. Hansen, A. Santerre Henriksen, R. Skov; Poster P1343*
- *Comparison of MRSA susceptibility to ceftobiprole as determined by either Etest or microdilution methods – L. Galia, G. Cornaglia, A. Mazzariol; Poster P1345*

For further information please visit www.eccmid.org.

About CRESEMBA® (isavuconazole)

Isavuconazole is an intravenous and oral azole antifungal and the active agent of the prodrug isavuconazonium sulfate. The drug was co-developed with Basilea's license partner Astellas Pharma Inc. Astellas commercializes isavuconazole in the U.S. and Basilea holds full rights in markets outside the United States. Isavuconazole was approved in March 2015 by the United States Food and Drug Administration (FDA) for the use for patients 18 years of age and older in the treatment of invasive aspergillosis and invasive mucormycosis, and was launched in the U.S. by Astellas in April 2015. Isavuconazole is marketed under the trade name CRESEMBA®. The European Commission granted isavuconazole marketing authorization in October 2015 for the treatment of adult patients with invasive aspergillosis and for the treatment of adult patients with mucormycosis for whom amphotericin B is inappropriate.¹ The European marketing authorization is valid in all 28 European Union member states, as well as in Iceland, Liechtenstein and Norway. Basilea has launched CRESEMBA in the UK and Germany, and launches in additional European countries are planned throughout 2016. Isavuconazole has orphan drug designation for the treatment of invasive aspergillosis and mucormycosis in Europe and the U.S. Outside the United

States and the EU, isavuconazole is currently an investigational product and not approved for commercial use.

About Zevtera® (ceftobiprole)

Zevtera® (ceftobiprole medocaril) is a broad-spectrum antibiotic for intravenous administration with bactericidal activity against certain Gram-positive and Gram-negative bacteria, including methicillin-resistant *Staphylococcus aureus* (MRSA) and susceptible *Pseudomonas* spp.² Ceftobiprole is approved for sale in 13 European countries and Canada for the treatment of adult patients with community-acquired pneumonia and hospital-acquired pneumonia (excluding ventilator-associated pneumonia).² It has been launched in Germany, France, Italy, the United Kingdom and Austria. Ceftobiprole received Qualified Infectious Disease Product (QIDP) designation from the U.S. Food and Drug Administration for the potential treatment of community-acquired bacterial pneumonia and acute bacterial skin and skin structure infections. Ceftobiprole is not approved in the United States.

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.

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This press release can be downloaded from www.basilea.com.

References

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