PRESS RELEASE

Basilea reports isavuconazole and ceftobiprole data to be presented at ECCMID

Basel, Switzerland, April 24, 2015 – Basilea Pharmaceutica Ltd. (SIX: BSLN) reported today that a broad range of scientific data will be presented on the antifungal isavuconazole and the antibiotic ceftobiprole at the European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) held in Copenhagen, Denmark, from 25 - 28 April 2015.

The presentations at ECCMID will include more detailed analyses of the isavuconazole data from two phase 3 clinical trials in adult patients with invasive fungal infections: SECURE, a randomized, double-blind, active-control study of adult patients with invasive aspergillosis, and VITAL, an open-label non-comparative study of isavuconazole in adult patients with invasive aspergillosis and renal impairment or in patients with invasive fungal disease caused by other fungi, including those causing mucormycosis.

Additionally, posters and oral presentations will feature ceftobiprole, such as data on the activity spectrum of ceftobiprole against current clinical pathogens causing respiratory tract infections and its activity in community- and hospital-acquired pneumonia (CAP and HAP), including early- and late-onset HAP. In addition, pharmacokinetics, safety and tolerability of high-dose ceftobiprole in the intensive care setting are being presented.

HAP is one of the most common infectious diseases acquired in hospitals, affecting 0.5-1.7% of hospitalized patients.[1] It is caused by a wide spectrum of Gram-positive bacteria such as *Staphylococcus aureus*, particularly methicillin-resistant strains (MRSA), and Gram-negative bacteria. In MRSA pneumonia treatment failure rates are high and have been attributed to inadequate antibiotic therapy.[2]

Isavuconazole posters at ECCMID 2015

- *Safety and outcomes in invasive aspergillosis patients with renal vs. no renal impairment treated with isavuconazole: experience from the SECURE (randomized) and VITAL trials* – K. M. Mullane M. Aoun, B. Franks, N. Azie, S. Mujais, A. Kaufhold, J. Maertens,; ePoster EV0932, ePoster viewing, Saturday, April 25, 2015, ePoster area
- *Exposure response analysis of isavuconazole in patients with disease caused by Aspergillus species or other filamentous fungi* – A. Desai, L. Kovanda, W. Hope, J. Mouton, D. Andes, D. Kowalski, R. Townsend, P. L. Bonate; poster P0217, paper poster session I, Saturday, April 25, 2015, 15:30-16:30, poster area
- *Safety and outcomes in obese patients with invasive fungal disease treated with isavuconazole in the phase 3 randomised double-blind SECURE trial* – D. Goff, D. Andes, W. W. Hope, N. Azie, F. Shi, L. Kim, L. Kovanda, A.-H. Schmitt-Hoffmann, T. Gumbo; poster P0233, paper poster session I, Saturday, April 25, 2015, 15:30-16:30, poster area
- *An open-label phase 3 study of isavuconazole (VITAL): focus on patients with mixed fungal infections* – G. Rahav, I. Oren, K. M. Mullane, R. Maher, M. Lee, B. Zeiher, A.-H. Schmitt-Hoffmann, M. Giladi; poster P0230, paper poster session I, Saturday, April 25, 2015, 15:30-16:30, poster area
- *Drug interaction profiles of isavuconazole, voriconazole and posaconazole with immunosuppressants metabolized by CYP4503A4 (CYP3A4)* – R. Townsend, A. Desai, N. Azie, M. Jones, M. Engelhardt, A.-H. Schmitt-Hoffmann; poster P0216, paper poster session I, Saturday, April 25, 2015, 15:30-16:30, poster area

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- *Clinical outcomes by minimum inhibitory concentrations of baseline Aspergillus pathogens from isavuconazole phase 3 SECURE and VITAL studies* – W. Hope, M. Ghannoum, L. Kovanda, M. Jones, A. Kaufhold, M. Engelhardt, A. Santerre-Henriksen; ePoster EP016, ePoster session, Saturday, April 25, 16:06-16:12, ePoster area 3
- *A comparison of the safety profiles of isavuconazole vs voriconazole in the phase 3 SECURE study in patients with invasive mould infections* – A. J. Ullmann, D. Selleslag, W. J. Heinz, R. Herbrecht, G. Rahav, M. Giladi, M. Aoun, O. A. Cornely, N. Azie, A. Kaufhold, M. Engelhardt, J. Maertens; ePoster EP018, ePoster session, Saturday, April 25, 16:18-16:24, ePoster area 3
- *Impact of dose fractionation on the in vivo efficacy of isavuconazole in a murine model of Aspergillus fumigatus infection* – S. Seyedmousavi, R. J. M. Brüggemann, J. F. Meis, W. J. G. Melchers, P. E. Verweij, J. W. Mouton; poster P0219, paper poster session I, Saturday, April 25, 2015, 15:30-16:30, poster area
- *Successful treatment of contaminated epidural steroid associated fungal meningitis with isavuconazole* – N. Everson, J. Smith, D. Garner; poster P0231, paper poster session I, Saturday, April 25, 2015, 15:30-16:30, poster area
- *Efficacy of isavuconazole against wild-type and Cyp51 mutant isolates of Aspergillus fumigatus in a mouse infection model* – S. Seyedmousavi, R. J. M. Brüggemann, J. F. Meis, W. J. G. Melchers, P. E. Verweij, J. W. Mouton; poster P1286; paper poster session VI, , Tuesday, April 28, 2015, 12:30-13:30, poster area

Ceftobiprole posters and presentations at ECCMID 2015

- *Susceptibility of ceftobiprole and comparators against Staphylococcus aureus from hospital-acquired respiratory-tract infections in the UK and Ireland: 2011-12 & 2012-13* – I. Morrissey, S. Hawser, R. Reynolds, M. Jones, A. Santerre-Henriksen; ePoster EV0228, ePoster viewing, Saturday, April 25, 2015, ePoster area
- *In vitro activity of ceftobiprole against clinical isolates collected from blood and respiratory specimen of hospitalized patients: results of the PEG study* – M. Kresken, B. Körber-Irrgang, D. Hafner; poster P0831, paper poster session IV, Monday, April 27, 2015, 12:30-13:30, poster area
- *Clinical cure and mortality outcomes with ceftobiprole medocaril versus ceftazidime plus linezolid in patients with early versus late onset hospital-acquired pneumonia* – T. Scheeren, T. Welte, G. Capellier, M. Saulay, M. Engelhardt; oral presentation O194, Monday, April 27, 2015, 16:36-16:48, hall J
- *Pharmacokinetics, safety and tolerability of high-dose ceftobiprole medocaril administered as prolonged infusion in intensive-care-unit (ICU) patients* – A. Torres, M. Sanchez-Garcia, I. Demeyer, M. Saulay, A.-H. Schmitt-Hoffmann, M. Engelhardt, M. S. Park; oral presentation O199, Monday, April 27, 2015, 17:36-17:48, hall J
- *Comparison of ceftobiprole susceptibility testing using broth microdilution and gradient strip (Etest®)* – I. Morrissey, S. Hawser, R. Janes, M. Jones, A. Santerre-Henriksen; poster P1247, paper poster session VI, Tuesday, April 28, 2015, 12:30-13:30, poster area

BAL30072 posters at ECCMID 2015

- *Activity of BAL30072 and BAL30072 / meropenem (1:1) combination against recent clinical isolates of Klebsiella pneumoniae from urinary tract infections* – I. Morrissey, S. Magnet, S. P. Hawser, A. Santerre-Henriksen; ePoster EV0202, ePoster viewing, Saturday, April 25, 2015, ePoster area
- *Efficacy of BAL30072 in murine lung infection models of multi-resistant Gram-negative*

bacteria – A. Sattar, S. Vaddi, P. Thommes, J. Teague, A. Santerre-Henriksen, M. Jones, A.-H. Schmitt-Hoffmann, P. A. Warn; ePoster EP153, ePoster session, Monday, April 27, 2015, 13:30-13:36, ePoster area 5

- *Efficacy of BAL30072 in combination with meropenem in murine thigh infection models of multi-resistant Gram-negative bacteria* – P. Thommes, A. Sattar, E. Burgess, G. Parker, L. J. Payne, A. Santerre-Henriksen, M. Jones, A.-H. Schmitt-Hoffmann, P. A. Warn; poster P1380, paper poster session VI, Tuesday, April 28, 12:30-13:30, poster area

For further information please visit www.eccmid.org.

About isavuconazole

Isavuconazole is an azole antifungal and the active agent of the prodrug isavuconazonium sulfate (U.S. trade name CRESEMBA®). Isavuconazole is being co-developed with Astellas Pharma Inc.

Isavuconazole was approved in March 2015 by the U.S. Food and Drug Administration (FDA) for patients 18 years of age and older for the treatment of invasive aspergillosis and invasive mucormycosis. These are life-threatening fungal infections predominantly occurring in immunocompromised patients. Basilea's partner Astellas will market the drug as CRESEMBA®.

A European Marketing Authorization Application for these indications, submitted by Basilea, is currently under review by the European Medicines Agency. Outside the U.S., isavuconazole is an investigational product and currently not approved for commercial use.

The following Important Safety Information for CRESEMBA® (isavuconazonium sulfate) is applicable only to the product approved in the United States:

CRESEMBA® is contraindicated in persons with known hypersensitivity to isavuconazole.

Coadministration of strong CYP3A4 inhibitors, such as ketoconazole or high-dose ritonavir (400 mg every 12 hours), with CRESEMBA® is contraindicated because strong CYP3A4 inhibitors can significantly increase the plasma concentration of isavuconazole.

Coadministration of strong CYP3A4 inducers, such as rifampin, carbamazepine, St. John's wort, or long acting barbiturates with CRESEMBA® is contraindicated because strong CYP3A4 inducers can significantly decrease the plasma concentration of isavuconazole.

CRESEMBA® shortened the QTc interval in a concentration-related manner. CRESEMBA® is contraindicated in patients with familial short QT syndrome.

Hepatic Adverse Drug Reactions (e.g., elevations in ALT, AST, alkaline phosphatase, total bilirubin) have been reported in clinical trials and were generally reversible and did not require discontinuation of CRESEMBA®. Cases of severe hepatic adverse drug reactions including hepatitis, cholestasis or hepatic failure including death have been reported in patients with serious underlying medical conditions (e.g., hematologic malignancy) during treatment with azole antifungal agents, including CRESEMBA®. Evaluate liver tests at the start and during therapy. Monitor patients who develop liver abnormalities during CRESEMBA therapy for severe hepatic injury. Discontinue if clinical signs and symptoms consistent with liver disease develop that may be attributable to CRESEMBA®.

Infusion-related reactions including hypotension, dyspnea, chills, dizziness, paresthesia, and hypoesthesia were reported during intravenous administration of CRESEMBA®. Discontinue the infusion of CRESEMBA® if these reactions occur.

Serious hypersensitivity and severe skin reactions, such as anaphylaxis or Stevens Johnson syndrome, have been reported during treatment with other azole antifungal agents. Discontinue CRESEMBA® if a patient develops a severe cutaneous adverse reaction. Caution should be used when prescribing CRESEMBA® to patients with hypersensitivity to other azoles.

During pregnancy, CRESEMBA® may cause fetal harm when administered, and should be used during pregnancy only if the potential benefit to the patient outweighs the risk to the fetus. Women who become pregnant while receiving CRESEMBA® are encouraged to contact their physician.

Following dilution, CRESEMBA® intravenous formulation may form precipitate from the insoluble isavuconazole. Administer CRESEMBA® through an in-line filter.

The most frequent adverse events among CRESEMBA®-treated patients were: nausea (26%), vomiting (25%), diarrhea (22%), headache (17%), elevated liver chemistry tests (16%), hypokalemia (14%), constipation (13%), dyspnea (12%), cough (12%), peripheral edema (11%), and back pain (10%).

The adverse reactions which most often led to permanent discontinuation of CRESEMBA® therapy during the clinical trials were: confusional state (0.7%), acute renal failure (0.7%), increased blood bilirubin (0.5%), convulsion (0.5%), dyspnea (0.5%), epilepsy (0.5%), respiratory failure (0.5%), and vomiting (0.5%).

For full U.S. Prescribing Information, please visit here: http://astellas.us/docs/cresemba.pdf

About ceftobiprole

Ceftobiprole (ceftobiprole medocaril) is a broad-spectrum intravenous cephalosporin antibiotic with rapid bactericidal activity against Gram-positive and Gram-negative bacteria, including methicillin-resistant *Staphylococcus aureus* (MRSA) and susceptible *Pseudomonas* spp.[3]

Ceftobiprole is currently approved in thirteen European countries for the treatment of community-acquired pneumonia (CAP) and hospital-acquired pneumonia (HAP) (excluding ventilator-associated pneumonia (VAP)) in adults under the trade name of Zevtera® or Mabelio®.[4]

Safety information for ceftobiprole:

As with all beta-lactam antibacterial agents, serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported. In case of severe hypersensitivity reactions, treatment with ceftobiprole must be discontinued immediately and adequate emergency measures must be initiated. Before beginning treatment, it should be established whether the patient has a history of severe hypersensitivity reactions to ceftobiprole, to other cephalosporins or to any other type of beta-lactam agent. Caution should be used if ceftobiprole is given to patients with a history of non-severe hypersensitivity to other beta-lactam agents.

The most common adverse reactions occurring in ≥3% of patients treated with were nausea, vomiting, diarrhoea, infusion site reactions, hypersensitivity (including urticaria, pruritic rash and drug hypersensitivity) and dysgeusia.

The use of ceftobiprole may result in overgrowth of non-susceptible organisms, including fungi. Appropriate measures should be taken if evidence of super-infection occurs during therapy.

Seizures have been associated with the use of ceftobiprole. Seizures occurred most commonly in patients with pre-existing central nervous system (CNS)/seizure disorders during treatment with ceftobiprole. Therefore caution is advised when treating these patients.

Clostridium difficile-associated diarrhoea has been reported with use of ceftobiprole and may range in severity from mild to life-threatening. This diagnosis should be considered in patients with diarrhoea during or subsequent to the administration of ceftobiprole. Discontinuation of therapy with ceftobiprole and the administration of specific treatment for *C. difficile* should be considered. Medicinal products that inhibit peristalsis should not be given.

Ceftobiprole has not been shown to be effective in the treatment of patients with VAP. Ceftobiprole should not be initiated in patients with VAP. It is recommended that in patients with HAP who subsequently require ventilation, ceftobiprole should be used with caution.

See full prescribing information for ceftobiprole (UK Summary of Product Characteristics) here: http://www.mhra.gov.uk/spc-pil/?prodName=ZEVTERA%20500MG%20POWDER%20FOR%20CONCENTRATE%20FOR%20SOLUTION%20FOR%20INFUSION&subsName=&pageID=ThirdLevel&searchTerm=zevtera

About BAL30072

BAL30072 is an investigational phase 1 intravenous monosulfactam antibiotic with activity against many clinically relevant multidrug-resistant Gram-negative bacteria.

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 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.

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

References

1 R. Masterton et al. Hospital-acquired pneumonia guidelines in Europe: a review of their status and future development. Journal of Antimicrobial Chemotherapy 2007 (60), 206-213

2 C. Woods, G. Colice. Methicillin-resistant *Staphylococcus aureus* pneumonia in adults. Expert Review of Respiratory Medicine 2014 (8), 641-651

3 Y. Y. Syed. Ceftobiprole medocaril: A review of its use in patients with hospital- or community-acquired pneumonia. Drugs 2014 (74), 1523-1542

4 Ceftobiprole (European trade name Zevtera® or Mabelio®, depending on the country) has received national licenses for the treatment of CAP and HAP (excluding VAP) in adults in Austria, Belgium, Denmark, Finland, France, Germany, Italy, Luxembourg, Norway, Spain, Sweden, Switzerland and the United Kingdom. Reimbursement and pricing authorization in several countries including Spain is ongoing.