# PRESS RELEASE

# Basilea presents new data on its antibiotics pipeline at ECCMID

- **Ceftobiprole phase 3 pneumonia data show rapid antibacterial effect**
- **BAL30072 synergy demonstrated with carbapenems**

***Basel, Switzerland, May 13, 2014*** – Basilea Pharmaceutica Ltd. (SIX: BSLN) reported today that new data on its antibiotics ceftobiprole and BAL30072 were presented this week at the European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) in Barcelona, Spain.

Basilea's broad-spectrum intravenous cephalosporin antibiotic ceftobiprole recently gained regulatory authorization in twelve European countries for the treatment of hospital-acquired pneumonia (HAP, excluding ventilator-associated pneumonia - VAP) and community-acquired pneumonia (CAP). Phase 3 data analyses were presented that demonstrated more rapid clinical responses in HAP and CAP patients treated with ceftobiprole than with the comparator regimen.

Ronald Scott, Basilea's Chief Executive Officer, commented: "The early clinical benefit data presented at ECCMID substantiate the potential important role of ceftobiprole in the treatment of patients with pneumonia in the hospital. Following the recent regulatory authorization of ceftobiprole, Basilea is focusing on market access and making ceftobiprole available to patients and physicians."

Results of a *post-hoc* analysis of phase 3 data including 571 HAP patients randomized on ceftobiprole or ceftazidime/linezolid were presented orally. The results show higher early clinical improvement rates at day 4 for ceftobiprole than for the comparator regimen, particularly in patients infected with methicillin-resistant *Staphylococcus aureus* (MRSA) prior to initiation of therapy. (Oral presentation O151)

Regarding CAP, a poster presentation of a *post-hoc* analysis of data from the 638-patient phase 3 study showed that, for high-risk patients hospitalized with CAP, the early clinical response rates at day 3 and the clinical cure rates at the test-of-cure visit were numerically higher for ceftobiprole than for the comparator regimen. (Poster eP431)

Further presented data demonstrated the *in-vitro* potency of ceftobiprole against over 4,000 contemporary clinically relevant Gram-positive bacteria, including methicillin-susceptible and methicillin-resistant *Staphylococcus aureus* and streptococci isolated from 17 European countries and Israel. (Poster eP187)

In addition, data of a study with pathogens isolated in 2013 from European and Israeli patients hospitalized with pneumonia showed ceftobiprole's potent broad-spectrum *in-vitro* activity against MRSA, penicillin-resistant/ceftriaxone non-susceptible *Streptococcus pneumoniae*, Enterobacteriacea and *Pseudomonas aeruginosa*. (Poster eP188)

*In-vitro* data on Basilea's investigational anti-Gram-negative antibiotic BAL30072, currently in phase 1 clinical development, were also presented, demonstrating synergy between BAL30072 and antibiotics from the carbapenem class against recent clinical isolates of difficult-to-treat Gram-negative bacteria, including those carrying the resistance-conferring NDM-1 metallo beta-lactamase gene. (Posters P0296 and P0297)



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**Ceftobiprole posters/presentations at ECCMID 2014**

- *Early clinical improvement and clinical cure in a randomised controlled phase 3 study of ceftobiprole versus ceftazidime/linezolid in patients with hospital-acquired pneumonia* – T. Scheeren, A. Rodriguez, X. Zhou, M. Saulay, M. Engelhardt; Oral presentation O151
- *Early clinical response in a randomised controlled phase 3 study of ceftobiprole versus ceftriaxone with or without linezolid in patients with community-acquired pneumonia requiring hospitalisation* – T. Welte, G. Herrera, Y.-C. Chuang, A. Demange, M. Engelhardt; Poster eP431
- *Antimicrobial activity of ceftobiprole tested against staphylococci and streptococci from European countries and Israel (2013)* – R. K. Flamm, D. J. Farrell, J. M. Streit, H. S. Sader, R. N. Jones; Poster eP187
- *Ceftobiprole activity tested against bacterial isolates from hospitalized patients with pneumonia in European hospitals and Israel (2013)* – R. K. Flamm, D. J. Farrell, J. M. Streit, H. S. Sader, R. N. Jones; Poster eP188

**BAL30072 posters at ECCMID 2014**

- *Activity of BAL30072 alone and in combination with carbapenems against Gram-negative bacteria* – I. Morrissey, C. Siegmund, E. Genet, M. Neri, S. Hawser, M. Jones, M. Page, A. Santerre Henriksen; Poster P0296
- *Determination of the effect of blaNDM-1 gene copy number on the activity of BAL30072 alone and in combination with meropenem against clinical NDM-1 positive bacteria* – L. Jones; M. G. P. Page, M. E. Jones, T. R. Walsh; Poster P0297

For further information please visit www.eccmid.org

## About Ceftobiprole

Ceftobiprole (ceftobiprole medocaril) is a broad-spectrum intravenous antibiotic from the cephalosporin class for the potential first-line treatment of severe bacterial infections. It has recently gained regulatory authorization from twelve European states through the Decentralized procedure for the treatment of hospital-acquired pneumonia (HAP, excluding ventilator-associated pneumonia, VAP) and community-acquired pneumonia (CAP) in patients 18 years of age and older, and is currently under regulatory review in Switzerland. Ceftobiprole demonstrated broad-spectrum *in-vitro* bactericidal activity against Gram-positive bacteria including methicillin-resistant and vancomycin-resistant *Staphylococcus aureus* (MRSA, VRSA) and penicillin- and ceftriaxone-resistant *Streptococcus pneumoniae* (PRSP, CRSP) as well as Gram-negative pathogens including strains of Enterobacteriaceae and *Pseudomonas*.

### Safety information

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): http://www.mhra.gov.uk/Safetyinformation/Medicinesinformation/SPCandPILs/index.htm?subsName=CEFTOBIPROLE MEDOCARIL SODIUM&pageID=SecondLevel

## About BAL30072

BAL30072 is an intravenous monosulfactam antibiotic in phase 1 clinical development with bactericidal activity against infections by multidrug-resistant Gram-negative bacteria. The investigational drug demonstrated *in-vitro* and *in-vivo* coverage of Gram-negative pathogens including multidrug-resistant *Acinetobacter baumannii and Pseudomonas aeruginosa* and has robust activity against strains that produce antibiotic-inactivating enzymes such as metallo-beta-lactamases. BAL30072 has shown synergistic or additive activity with antibiotics from the carbapenem class. Basilea entered a contract with U.S. BARDA, who may provide development funding for BAL30072 of up to USD 89 million.

## About Basilea

Basilea Pharmaceutica Ltd. is headquartered in Basel, Switzerland and listed on the SIX Swiss Exchange (SIX: BSLN). Through the fully integrated research and development operations of its Swiss subsidiary Basilea Pharmaceutica International Ltd., the company focuses on innovative pharmaceutical products in the therapeutic areas of bacterial infections, fungal infections and oncology, targeting the medical challenge of rising resistance and non-response to current treatment options.

## Disclaimer

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