

PRESS RELEASE

Basilea announces new data to be presented on ceftobiprole and isavuconazole at ICAAC/IDSA

Basel, Switzerland, October 20, 2008 – New data on Basilea’s late-stage anti-infectives ceftobiprole and isavuconazole will be presented at the upcoming joint meeting of the Annual Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) and the Infectious Disease Society of America (IDSA) in Washington DC.

A series of more than twenty presentations related to ceftobiprole, a broad-spectrum anti-MRSA cephalosporin antibiotic, will be discussed at ICAAC/IDSA.

The epidemiological data shown further support the noticeable absence of resistance to ceftobiprole in methicillin-resistant *Staphylococcus aureus* (MRSA) (abstract # C1-156, C1-159, C1-193, C1-1079, D-2230) and the broad-spectrum activity against Gram-negative pathogens (abstract # C1-153, C1-155, C1-157, C1-193, D-2230, D-2231). The impact of certain resistance mechanisms on ceftobiprole is discussed in abstracts # C1-154, C1-158, C1-164, C1-165, C1-3714, C1-3715.

Microbiological data from typical Gram-positive and Gram-negative baseline pathogens isolated from both hospital-acquired pneumonia (HAP) and community acquired pneumonia studies confirm the broad-spectrum activity of ceftobiprole (C1-159).

Detailed analyses from previously published top-line data of a phase III clinical study comparing clinical outcomes following the treatment with either ceftobiprole monotherapy or combination therapy of ceftazidime plus linezolid in patients with HAP including patients with ventilator associated pneumonia (VAP) are being presented. This study met the endpoint of non-inferiority (abstract # K-486). Clinical cure rates in the small VAP sub-group were lower for ceftobiprole treated patients vs. the comparator combination. Sub-group analyses indicate certain patient characteristics which may influence patient outcomes in VAP patients. The largest differences in cure rates occurred in patients below the age of 45 years and with increased renal function. In the ceftobiprole treatment group there were more male patients with underlying conditions that included severe head trauma. Incidences of adverse events, including mortality, were similar between treatment groups.

A new pharmacokinetic-population model which takes into consideration the observed altered drug distribution and elimination in the VAP sub-group is described in abstract #A-1881.

Dieter Goette, Chief Medical Officer, said: "Treatment options for VAP represent a high medical need. Therefore a pharmacokinetic/pharmacodynamic study has been initiated in ICU patients including VAP patients investigating different dosing regimen of ceftobiprole in this setting."

Ceftobiprole is currently marketed in Canada for the treatment of complicated skin and skin structure infections including diabetic foot infections under the trade name ZEFTERA™ through a co-promotion with Janssen-Ortho, Inc., a Johnson & Johnson company. Ceftobiprole is also

currently under review for treatment of cSSSI by regulatory authorities in the U.S., the European Union, Switzerland and other countries.

A series of seven abstracts discuss the preclinical and clinical properties of isavuconazole, Basilea's broad-spectrum intravenous and oral antifungal azole prodrug currently in phase III development for the treatment of invasive yeast and mold infections. Interaction studies with food showed that food had no relevant effect on absorption of isavuconazole (abstract# A-008). Isavuconazole was well tolerated and displayed predictable pharmacokinetics at doses twice as high as currently investigated in phase III clinical trials for the primary treatment of severe invasive fungal infections (abstract# M-2137). The preclinical abstracts confirm previous findings of the good broad-spectrum activity in moulds and yeasts (abstract# M-1525, M-1526, M-1531).

ICAAC/IDSA Satellite Symposium sponsored by Basilea:

MRSA and Mycoses: Tough Problems, New Solutions

Saturday, October 25; Grand Hyatt Washington.

About ceftobiprole

Ceftobiprole, Basilea's lead antibacterial product, is the first approved broad-spectrum anti-MRSA antibiotic belonging to the cephalosporin class. It is designed to bind the penicillin-resistant targets in many Gram-positive bacteria of the cocci-type, resulting in bactericidal activity towards MRSA and penicillin-resistant *Streptococcus pneumoniae*. Ceftobiprole as a single intravenous agent has demonstrated broad-spectrum activity against many other Gram-positive as well as Gram-negative bacteria, frequently associated with community and hospital-acquired infections. In the trials, ceftobiprole was generally well tolerated with a safety profile consistent with the cephalosporin class of antibiotics.

Ceftobiprole is being developed through an exclusive worldwide collaboration between Basilea Pharmaceutica International Ltd. and Cilag GmbH International. Basilea Pharmaceutica Ltd. has exercised its option to co-promote ceftobiprole in the U.S., Canada and in the major European markets together with Ortho-McNeil, Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc. in the U.S. and the respective Janssen-Cilag companies in Europe. Basilea maintains an option to co-promote the drug in Japan and China.

About isavuconazole

Isavuconazole has a potent, broad-spectrum of activity against both yeasts and molds *in vitro*. This new triazole is developed as a water-soluble prodrug to allow the potential intravenous administration in renally impaired patients. In addition, when taken as once daily or once weekly capsules, the prodrug results in rapid absorption and distribution of isavuconazole to infected tissues. Basilea successfully completed its phase II trial in esophageal candidiasis with both high clinical cure rates and a safety profile comparable to current gold standard therapy. Clinical drug interaction studies have illustrated attractive pharmacokinetic features and the potential for less drug-drug interactions than a number of broad-spectrum antifungal drugs in current use. Isavuconazole is in clinical testing with global primary-treatment phase III trials for the treatment of invasive yeast and mold infections. The clinical program includes patients with impaired renal function and patients with rare mold infections.

Isavuconazole is the only azole to-date to have been granted FDA fast track status to the company's knowledge.

About Basilea

Basilea Pharmaceutica Ltd. is headquartered in Basel, Switzerland, and listed on the SWX Swiss Exchange (SWX:BSLN). Basilea's integrated research and development operations are currently focused on new antibacterial and antifungal agents to fight drug resistance and on the development of dermatology drugs. Basilea's products are targeted to satisfy high medical and patient needs in the hospital and specialty care setting. The company owns a diversified portfolio including two commercialized drugs (alitretinoin, ceftobiprole) and one investigational drug (isavuconazole) in phase III. Alitretinoin (Toctino®) is marketed in the United Kingdom and in Denmark and is approved in Germany and Finland. Alitretinoin has been recommended for approval in seven additional EU Member States and is under regulatory review in Canada and Switzerland. Ceftobiprole is marketed in Canada and is under review by regulatory authorities in the U.S., the EU, in Switzerland and in several other countries. The company has set up commercial organizations in UK, Denmark and in Germany while it is building sales and marketing organizations to commercialize alitretinoin and to co-promote ceftobiprole in North America and in other European countries, subject to approval.

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