PRESS RELEASE

Scientific Results Presented at ECCMID Demonstrate Well-Differentiated Profile of Basilea’s Two Phase III Anti-infective Compounds

Basel, Switzerland, April 3, 2007 - New data presented at ECCMID highlight the microbiological and pharmacokinetic profiles of Basilea’s (SWX:BSLN) two late-stage drug candidates ceftobiprole and isavuconazole. Studies reported both for ceftobiprole, the first anti-MRSA broad-spectrum cephalosporin in late-stage development, and for isavuconazole, a novel azole for the treatment of invasive fungal infections, yielded further data on their respective breadths of spectrum, and pharmacokinetic properties.

Ceftobiprole is developed in collaboration with Johnson & Johnson Pharmaceutical Research & Development, L.L.C.

Eleven posters plus one oral presentation on ceftobiprole and seven posters on isavuconazole were presented at the 17th European Congress of Clinical Microbiology and Infectious Diseases (ECCMID), and highlighted the potentially attractive profiles of Basilea’s two late-stage development compounds.

With positive data reported for two pivotal trials in complicated skin and skin structure infections (cSSSI) ceftobiprole is approaching regulatory filing. Further evidence of the microbiological and pharmacokinetic profiles of this investigational compound was presented at ECCMID. Ceftobiprole has a broad in vitro spectrum, in particular activity against MRSA (Methicillin Resistant Staphylococcus aureus). In vitro susceptibility testing showed potent activity against all staphylococci collected in the first phase III cSSSI study, including MRSA and other multi-drug resistant pathogens (P2027). Testing these strains for the PVL gene, a marker for staphylococcal virulence, showed that the potential clinical efficacy of ceftobiprole is not impaired by the presence of this marker (P1321, O120). The antibacterial activity of ceftobiprole against Gram-positive organisms, including MRSA, is once more demonstrated in various in vitro studies (P710, P781, P784). Furthermore, ceftobiprole had the most potent activity of all beta-lactams tested against pneumococci that were not susceptible to ceftriaxone, selected from a recent US collection of clinical isolates (P2025), supporting the potential use of ceftobiprole in the treatment of pneumonia.

Further microbiological data illustrate that the in vitro activity of ceftobiprole against some of the most common Gram-negative pathogens such as the Enterobacteriaceae and Pseudomonas aeruginosa is comparable to that of extended-spectrum cephalosporins (P780, P2024, P2026). In one study, ceftobiprole showed greater in vitro potency than piperacillin/tazobactam against Pseudomonas aeruginosa (P2026).

The pharmacological characteristics of dosing ceftobiprole 500 mg three times daily with a 2-hour infusion were presented for the first time (P779). Ceftobiprole did not cause QT...
prolongation in a thorough QT assessment of therapeutic (500mg) and supratherapeutic (1000mg) doses (P783).

Basilea's antifungal isavuconazole for the potential treatment of invasive fungal infections is in phase III testing in a global trial program in patients with invasive candidiasis including candidemia and patients with proven or probable aspergillosis.

New microbiological surveillance data relevant for the treatment of candidemia demonstrated isavuconazole's superior coverage of different candida species and most fluconazole-resistant isolates compared to other azole drugs (P1978). Potent activity against candida is further supported by data from a thorough analysis in animal models (P1950). Additionally, Cryptococcus neoformans, a yeast species not typically covered by the candin class, is highly susceptible to isavuconazole (P1977).

In animal models of aspergillus infection, isavuconazole showed at relevant plasma concentrations potent efficacy against several strains of Aspergillus fumigatus including an itraconazole-resistant strain (P1951). Aspergillus fumigatus is the most frequent pathogen among the difficult-to-treat invasive mould infections.

Poster P987 showed that isavuconazole is completely bioavailable, supporting early switch to the oral dosage form in the clinic. Some azoles can cause cardiac disturbances. Isavuconazole showed no QT prolongation in the study presented (P1675).

List of Ceftobiprole Presentations


P779 Pharmacokinetics of ceftobiprole following single and multiple intravenous infusions administered to healthy subjects. B. Murthy, D. Skee, D. Wexler, D. Balis, I. Chang, D. Desai-Kreiger, G. Noel (Raritan, US)


P781 Activity of ceftobiprole tested against staphylococcal and streptococcal isolates recovered from patients in European medical centres (2005-2006). T. Fritsche, H. Sader, P. Strabala, R. Jones (North Liberty, US)

P784
In vitro activity of ceftobiprole, dalbavancin and tigecycline against methicillin-resistant Staphylococcus aureus strains from hospitalised patients in Belgium. O. Denis, C. Nonhoff, A. Deplano, M. Hallin, R. De Ryck, S. Rottiers, S. Crevecoeur, M.J. Struelens (Brussels, BE)

P1321

P2024

P2025
Activity of ceftobiprole against US clinical S. pneumoniae isolates that are ceftriaxone nonsusceptible. T. Davies, K. Bush, P. Appelbaum (Raritan, Hershey, US)

P2026

P2027
Ceftobiprole activity and resistance patterns in staphylococcal isolates from a recent complicated skin and skin structure infection study. K. Amsler, M. Jacobs, S. Bajaksouzian, A. Windau, M. Heep, K. Bush (Raritan, Cleveland, US; Basle, CH)

O120
Epidemiology of (CA-) MRSA (Room 13b) Characteristics of complicated skin and skin structure infections due to staphylococci and the presence of Panton-Valentine leukocidin. R. Strauss, K. Amsler, M. Jacobs, K. Bush, G. Noel (Raritan, US)

List of Isavuconazole Presentations
P987
Steady-state bioavailability of oral isavuconazole in healthy volunteers. A. Schmitt-Hoffmann, B. Roos, M. Heep (Basle, CH)

P1675
QTc measurements during a placebo- and actively controlled multiple dose study of two different dosing regimens of isavuconazole. M. Heep, B. Roos, M. Sochor, A. Schmitt-Hoffmann, S. Van Merle, D. Kappers, P. Voiriot (Basle, CH; Zuidlaren, NL; Nancy, FR)

P1676
Evaluation of isavuconazole (BAL8557/BAL4815) Etest compared to broth microdilution antifungal susceptibility testing against quality control strains and fluconazole susceptible

P1951
Dose response in neutropenic mice with disseminated infection of multiple strains of Aspergillus fumigatus with widely varying MIC and MFC values treated with isavuconazole. P.A. Warn, A. Parmar, A. Sharp, D.W. Denning (Manchester, UK)

P1950
In vivo efficacy of the triazole BAL8557 against disseminated Candida albicans in mice assessed by survival and tissue burden in temporarily and persistently neutropenic mice treated with 1-7 doses of drug over a dose range of 20-80% of Emax. P.A. Warn, A. Parmar, A. Sharp, M. Heep, J. Spickermann, D.W. Denning (Manchester, UK; Basle, CH)

P1977
In vitro activity of isavuconazole (BAL4815/8557) compared with six other antifungal agents against 180 Cryptococcus neoformans meningitis isolates from the Netherlands. I. Curfs-Breuker, M. Illnait-Zaragozi, J. Mouton, B. Janssen, F. Hagen, L. Spanjaard, T. Boekhout, J. Meis (Nijmegen, NL; Havana, CU; Utrecht, Amsterdam, NL)

P1978
In vitro activity of isavuconazole (BAL4815) compared with seven other antifungal agents against 309 prospectively collected clinical Candida isolates from the Netherlands. I. Curfs-Breuker, J. Mouton, Y. Debets-Ossenkopp, H. Endtz, P. Verweij, J. Meis (Nijmegen, Amsterdam, Rotterdam, NL)

About Ceftobiprole
Ceftobiprole is an investigational anti-MRSA, broad-spectrum cephalosporin that has demonstrated positive results in two phase III trials in complicated skin and skin structure infections. Ceftobiprole has shown a low potential to select for resistance in vitro and exhibits activity against a wide spectrum of bacteria that cause many hospital and community-acquired infections including those due to resistant bacteria like methicillin-resistant Staphylococcus aureus (MRSA). Ceftobiprole has received fast track status from the FDA and is being developed through an exclusive worldwide collaboration between Basilea Pharmaceutica Ltd. and Cilag GmbH International, a Johnson & Johnson affiliate company.

About Isavuconazole
Isavuconazole has a potent and broad spectrum of activity against both yeasts and molds. This new triazole is developed as a water-soluble pro-drug to allow intravenous administration without contraindication in renally impaired patients. In addition, taken as convenient once daily or once weekly capsules, the prodrug results in rapid and complete absorption and distribution of isavuconazole to infected tissues.

Basilea successfully completed its phase II trial with both high clinical cures rates and a safety profile comparable to gold standard fluconazole therapy and with a more flexible dosing schedule. 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 phase III testing with two global primary-treatment phase III trials for the treatment of invasive yeast and mold infections.

About Basilea
Basilea Pharmaceutica Ltd. is an independent biopharmaceutical company headquartered in Basel, Switzerland, and listed on the SWX Swiss Exchange (SWX:BSLN). Basilea’s fully 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 three investigational phase III drugs of which two have shown positive pivotal phase III results. Basilea is building a sustainable hospital and specialty pharmaceutical business. The company is integrating commercialization into its organization, in a first step through co-promoting ceftobiprole.

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