PRESS RELEASE

Positive Results for Basilea's (SWX:BSLN) Novel Broad Spectrum Antifungal Agent

Basel, Switzerland, September 8, 2005

Basilea Pharmaceutica Ltd. announced today positive results from its phase II clinical trial evaluating BAL8557, Basilea's broad-spectrum antifungal. The trial was conducted in patients with esophageal candidiasis, a common infection in immunocompromised patients.

The phase II study compared three dosing regimens of BAL8557 to fluconazole in the treatment of esophageal candidiasis, to demonstrate antifungal efficacy in patients. All three BAL8557 dosing regimens were highly effective for the stringent primary endpoint of endoscopically confirmed complete clinical cure. Excellent activity was also confirmed in secondary endpoints, including microbiological cure, therapeutic responses and follow-up assessments at two and four weeks. In the trial, BAL8557 was safe and well tolerated with an adverse event profile comparable to fluconazole. Planned phase III trials will target severe invasive yeast (candida) and mold infections (including aspergillus and zygomycetes).

BAL8557's extended antifungal spectrum covers most yeasts and molds causing serious infections in immunocompromised patients including fluconazole resistant candida strains and zygomycetes. BAL8557 is designed as a water-soluble prodrug that is suitable for both oral and intravenous administration. Furthermore, the study results confirm the possibility to develop convenient once-daily and once-weekly dosing regimens.

"These clinical results confirm our view of BAL8557 as a key product in our portfolio. We look forward to move our third promising compound into phase III clinical development. Basilea is uniquely positioned in anti-infectives as an emerging biopharmaceutical company with a significant research base plus our late stage anti-infectives: ceftobiprole, our first-in-class anti-MRSA cephalosporin and BAL8557, our extended spectrum antifungal", said Dr. Anthony Man, Basilea's CEO.

Clinical Trial Results Summary

The double-blind, multi-center, randomized phase II trial studied three oral dose levels of BAL8557 (100 mg daily, 50 mg daily and 400 mg weekly) versus a 100 mg daily dose of fluconazole in 160 patients with endoscopically confirmed esophageal candidiasis. All groups received a loading dose on treatment day one. Patients received treatment for 14 or 21 days. The primary endpoint was endoscopically confirmed clinical cure, requiring complete absence of subjective and objective symptoms of esophageal candidiasis.

Endoscopically confirmed clinical cure at the end of therapy was achieved in 95%, 95% and 98% of patients treated with BAL8557 for the 100 mg daily, 50 mg daily and 400 mg weekly doses, respectively, and in 95% of patients treated with fluconazole. Statistical non-inferiority to comparator was confirmed for all three BAL8557 dosing regimens.

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BAL8557 was generally well tolerated, with a profile comparable to fluconazole in the trial. Most adverse events were intercurrent infectious diseases, due to the immunocompromised status of the patients in the study.

The Need for New Antifungal Therapies
The expansion of the immunocompromised patient population including cancer patients with chemotherapy induced neutropenia, transplant recipients receiving immunosuppressive therapy and HIV infected patients has led to an increased incidence of invasive fungal infections. In major markets alone, an estimated nine million patients are at risk for invasive fungal infection with more than two million patients treated.

Currently available antifungal drugs are reported to fail in more than 50% of patients with acute invasive aspergillosis and in 20-30% of patients with candidemia. There is a high medical need to address the limitations of current therapy, most importantly the gaps in the antifungal spectrum, unwanted side effects, dosing flexibility as well as the development of resistance.

“Basilea’s novel antifungal BAL8557 has the potential to address a high medical need because of its extended spectrum covering fluconazole resistant yeast and mold infections, including aspergillus and zygomycetes. We are pleased to reach another milestone in the development of our new medicines for severely ill patients and are eager to move intravenous and oral BAL8557 into phase III”, stated Dr. Rienk Pypstra, Chief Development Officer.

About Basilea

Basilea Pharmaceutica Ltd. (BSLN) is a biopharmaceutical company headquartered in Basel, Switzerland, and listed on the SWX Swiss Exchange. Basilea was founded in October 2000 to discover, develop and bring innovative medicines to the market. The company's fully integrated research and development operations are focused on new anti-bacterial and anti-fungal agents to fight drug resistance, as well as on dermatology drugs.

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