PRESS RELEASE

FDA Fast Track Designation for Basilea's Novel Broad-spectrum Water-soluble Antifungal BAL8557

Basel, Switzerland, May 2, 2006 - **Basilea Pharmaceutica Ltd. (SWX:BSLN) announced today that it received fast track designation from the U.S. Food and Drug Administration (FDA) for its novel broad-spectrum antifungal.**

Fast track designation is intended to expedite the availability of treatments that address unmet medical needs for serious and life-threatening diseases. Invasive fungal infections are a major cause of morbidity and mortality in patients with weakened immune systems. The overall rate of invasive fungal infections in these patients is approximately 25% and mortality ranges from 50 - 100%. The number of drugs available to treat severe infections caused by invasive fungi such as zygomyces is limited.

BAL8557's extended antifungal spectrum covers most yeasts and molds including fluconazole resistant candida strains, aspergillus and zygomyces that cause serious infections in patients with a weakened immune system. BAL8557 is water-soluble and can be given by injection or orally. It is highly bio-available and can be administered in convenient once-daily or once-weekly dosing regimens. BAL8557 also has potentially less drug-drug interactions than a number of other drugs in current use.

"We have a broad product development strategy for invasive yeast and mold infections. We also recognize that patients with such infections and impaired renal function have limited treatment options because many existing drugs can further impair kidney function. In contrast, our injectable form of BAL8557 is a water-based formulation without additives known to damage kidney function. BAL8557 is designated as a fast track product because it can provide potential benefit for the treatment of invasive fungal infections in patients with moderate to severe renal impairment. BAL8557 is our second late stage hospital anti-infective drug with fast track status, highlighting our commitment as a leading anti-infectives company to develop drugs for high medical need", commented Dr. Anthony Man, Basilea's CEO.

In September last year Basilea reported positive phase II results on BAL8557 in the treatment of esophageal candidiasis. The safety profile of BAL8557 in those patients was observed to be similar to that of fluconazole. Pivotal phase III trials in invasive fungal infections are scheduled to start in the second half of 2006.

Dr. Rienk Pypstra, Chief Development Officer indicated, "With this fast track designation, the FDA has signaled that BAL8557 has the potential to fulfill a significant therapeutic need. We will therefore integrate the needs of patients with renal impairment into our phase III program. We are pleased that this designation will allow us to accelerate the development of BAL8557 to bring this promising drug to patients with invasive fungal infections as early as possible."

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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 therapies, most importantly the gaps in the antifungal spectrum, unwanted side effects, dosing flexibility as well as the development of resistance.

About BAL8557

BAL8557, Basilea's novel broad-spectrum antifungal agent, is an investigational drug in development for the treatment of severe invasive fungal infections. Unlike other azoles, BAL8557 is a pro-drug suitable for simple intravenous administration and its excellent oral absorption allows a convenient once daily or even once weekly dosing, supporting patient-tailored treatment schemes. Basilea successfully completed its key phase II trial with both high clinical cures rates and a safety profile comparable to gold standard therapy but with potentially a more flexible dosing schedule. BAL8557 phase III trials are currently in preparation.

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 currently focused on new anti-bacterial and anti-fungal agents to fight drug resistance as well as on dermatology drugs.

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

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