



PRESS RELEASE

Basilea Maintains Global Commercialization Rights for BAL8557, its Novel Broad-Spectrum Antifungal Agent and Third Compound Entering Phase III

Basel, Switzerland, 19 December 2005

Basilea Pharmaceutica Ltd. (SWX:BSLN) announced today that it maintains global marketing and manufacturing rights to BAL8557 following Roche's decision not to exercise its opt-in right. BAL8557 will be Basilea's third compound to enter phase III clinical development, planned to commence in 2006.

"We are very excited by this opportunity. Our recently announced positive phase II clinical results confirm BAL8557 as the third key product in our late-stage portfolio. Owning all rights to BAL8557, including both marketing and manufacturing rights, gives us full control to maximize product value with a partner or alone. BAL8557 will be a highly attractive and complementary product to our antibiotic ceftobiprole for the hospital anti-infectives market.

We have a solid financial position with no royalties or other payments on BAL8557 to Roche and are enthusiastic about moving this promising compound into phase III clinical development to join our other two phase III compounds; ceftobiprole, Basilea's first-in-class, broad-spectrum antibiotic effective against resistant bacteria, and alitretonin, our vitamin A derivative for refractory chronic hand dermatitis. This is a great opportunity for us to capitalize on our success and opens the possibility to add commercialization capabilities to our fully integrated research and development organization. Basilea is uniquely positioned in anti-infectives as an emerging biopharmaceutical company with a significant research base plus a late stage development portfolio of competitively profiled products", said Dr. Anthony Man, Basilea's CEO.

Positive BAL8557 Phase II Results

In September this year Basilea released positive phase II results on BAL8557. 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. 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 100 mg fluconazole. Statistical non-inferiority to comparator was confirmed for all three BAL8557 dosing regimens. 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).

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.

About BAL8557

BAL8557 is a novel extended spectrum, water-soluble anti-fungal from the azole drug class. It has in vitro activity across a wide variety of pathogenic yeasts and molds causing serious infections in immuno-compromised patients including fluconazole resistant candida strains and zygomycetes. In addition, it has activity against dermatophytes, including terbinafine resistant strains, causing chronic nail infections. BAL8557 is being developed in clinical trials with both intravenous and oral dose forms that can be administered once weekly or once daily.

About Ceftobiprole

Ceftobiprole (BAL5788), Basilea's lead antibacterial product, is the first of a new class of broad-spectrum anti-MSRA cephalosporin antibiotics that was specially designed to bind to the penicillin-resistant targets in Gram-positive cocci, resulting in potent bactericidal activity towards methicillin-resistant *Staphylococcus aureus* (MRSA) and penicillin-resistant *Streptococcus pneumoniae* (PRSP). Ceftobiprole not only has a broad-spectrum profile targeting other Gram-positive as well as Gram-negative pathogens, but has also shown a low potential to induce resistance in vitro.

The FDA granted ceftobiprole fast track designation for the treatment of complicated skin and skin structure infections due to methicillin-resistant *Staphylococcus* species and for a second indication in the treatment of nosocomial pneumonia, including ventilator-associated pneumonia due to suspected or proven methicillin-resistant *Staphylococcus aureus* (MRSA).

After successful completion of enrollment into the first phase III STRAUSS trial (Study of Resistant *Staphylococcus Aureus* Skin and Skin Structure Infections), focusing on Gram-positive infections, Basilea and its development partner Johnson & Johnson Pharmaceutical Research and Development, L.L.C. commenced a second complicated skin infection trial targeting both Gram-positive and Gram-negative bacterial infections, including patients with diabetic foot infections. Ceftobiprole is also currently in phase III clinical trials in hospital-acquired pneumonia.

Ceftobiprole is being developed through an exclusive worldwide collaboration between Basilea Pharmaceutica Ltd. and Cilag AG International, a Johnson & Johnson company. Ortho-McNeil Pharmaceutical, Inc., another Johnson & Johnson company, will market ceftobiprole in the U.S. and its affiliate company, Janssen-Cilag, will market the product in Europe, Japan and China. Basilea has retained an option to co-promote ceftobiprole in North America, major European countries, Japan and China.

About Alitretinoin

Alitretinoin, Basilea's investigational vitamin A derivative for chronic hand dermatitis refractory to conventional treatment, has recruited over two-thirds of patients needed for its European/Canadian Phase III trial. Severe chronic hand dermatitis is a common inflammatory skin disease that is often refractory to topical therapy and has a major social impact on the professional and social life of affected patients. Basilea estimates that refractory chronic hand dermatitis affects approximately one million patients in leading markets. There is no therapy with approved labeling for refractory patients who do not



benefit from topical therapies and who suffer from this disease. Alitretinoin has shown evidence of significant activity in phase II trials and the side effects seen appear typical of the retinoid class. Basilea possesses the full global marketing and manufacturing rights to alitretinoin.

About Basilea

Basilea Pharmaceutica Ltd. (SWX: 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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Conference call

Basilea invites you to participate in an investor conference call on Monday, December 19, 2005 at 4 p.m. (CET).

Dial-in numbers:

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The playback will be available 1 hour after the conference call for 48 hrs. Participants requesting the Digital Playback will be dialing:

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