

## PRESS RELEASE

Basel, Switzerland, 10th March 2003

### **FDA Fast Track Designation for Basilea's Novel Broad Spectrum Antibiotic**

Basilea Pharmaceutica Ltd announced today that it has received fast track designation from the U.S. Food and Drug Administration (FDA) for its novel broad-spectrum cephalosporin antibiotic BAL5788, for the treatment of complicated skin and skin structure infections (cSSSI). Fast track designation is designed to expedite the availability of treatments that address unmet medical needs for serious and life-threatening diseases.

Each year, more than 40 million patients undergo surgery in the United States. Infections, including skin and skin structure infections, complicate 1 to 10 percent of operations. The growing incidence of serious infections caused by antibiotic-resistant bacteria is a matter of global medical concern.

BAL5788 has a unique combination of features resulting in potent bactericidal activity towards methicillin-resistant *Staphylococcus aureus* (MRSA) and penicillin-resistant *Streptococcus pneumoniae* (PRSP), in addition to a broad-spectrum profile towards other Gram-positive and Gram-negative pathogens. Based upon BAL5788's excellent pharmacokinetic and safety profile in the Phase 1 program, Basilea has started a clinical Phase 2 trial in patients with cSSSI.

"With this fast track designation, the FDA has signaled that BAL5788 has the potential to become a significant therapeutic advance over currently approved treatment," said Dr. Anthony Man, Head of Drug Development at Basilea. "The fast track status for this indication will help accelerate the development of this potentially important treatment for patients suffering from serious hospital infections. Basilea is committed to work closely with Health Authorities in order to provide this drug to patients as early as possible and to fulfill the high potential of this innovative antibiotic in this and other indications."

Basilea Pharmaceutica Ltd is actively engaged in discovery and development programs producing novel drugs for the treatment of bacterial infections, fungal infections and skin diseases. Basilea was founded with significant assets to achieve the business objective of bringing innovative medicines to the market. Basilea was founded in 2000 as a spin-off of F. Hoffmann-La Roche.

Disclaimer: This press release contains forward-looking statements concerning Basilea Pharmaceutica Ltd and its prospects. Such statements are subject to certain risks and uncertainties, particularly those inherent in the process of discovering, developing, and commercializing drugs for use as human therapeutics. Actual results could differ materially from those projected in this release. As a result, the reader is cautioned not to rely on these forward-looking statements.

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