

## **PRESS RELEASE**

# Ceftobiprole, a new anti-MRSA broad-spectrum antibiotic, receives its first marketing authorization by Health Canada

Basel, Switzerland, June 30, 2008 - Basilea Pharmaceutica Ltd. announces that ceftobiprole (ZEFTERA<sup>™</sup>), the first-in-class anti-MRSA broad-spectrum cephalosporin, has obtained regulatory approval from Health Canada authorizing the marketing of ceftobiprole for the treatment of complicated skin and soft tissue infections including diabetic foot infections. In addition, Basilea announces further organizational changes in preparation of product commercialization.

Dr. Anthony Man, CEO of Basilea said, "The availability of ZEFTERA<sup>™</sup> is an important advance in the fight against infections due to potentially deadly bacteria, including MRSA and we are delighted by this first regulatory approval in Canada. The labeling reflects our conviction that ZEFTERA<sup>™</sup> is an innovative broad-spectrum, first-line treatment which may be used before knowing the exact bacteria causing the infection. This marketing authorization signals the start of a new era for Basilea as we commercialize the first of a number of innovative compounds in our pipeline."

Basilea Pharmaceuticals Corp. will co-promote the drug in Canada under the trade name ZEFTERA<sup>™</sup> with its local partner Janssen-Ortho, Inc. Ceftobiprole is currently under review by regulatory authorities in the U.S., the European Union, Australia, Russia, South Africa and Switzerland.

### About ZEFTERA™

ZEFTERA<sup>™</sup> (ceftobiprole medocaril for injection) is the first approved broad-spectrum anti-MRSA antibiotic belonging to the cephalosporin class. It is specially designed to bind the penicillinresistant targets in many Gram-positive bacteria of the cocci-type, resulting in bactericidal activity towards MRSA and penicillin-resistant *Streptococcus pneumoniae*. Ceftobiprole as a single intravenous agent has demonstrated broad-spectrum activity against many other Grampositive as well as Gram-negative bacteria, frequently associated with community and hospitalacquired infections.

Health Canada has indicated ZEFTERA<sup>™</sup> for: "The treatment of the following infections when caused by susceptible strains of the designated microorganisms in patients 18 years of age and older: Complicated skin and skin structure infections (cSSSI), including non-limb threatening diabetic foot infections without concomitant osteomyelitis caused by: Enterobacter cloacae, Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, Staphylococcus aureus (including methicillin-resistant isolates), and Streptococcus pyogenes."

Ceftobiprole is being developed through an exclusive worldwide collaboration between Basilea Pharmaceutica International Ltd. and Cilag GmbH International. Basilea Pharmaceutica Ltd. has also exercised its option to co-promote ceftobiprole in the U.S. and in the major European markets together with Ortho-McNeil, Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc. in

Page 1 of 3



the U.S. and the respective Janssen-Cilag companies in Europe. Basilea maintains an option to co-promote the drug in Japan and China.

## About Complicated Skin Infections

Complicated skin and soft tissue infections are among the most common infections in the hospital setting. *Staphylococcus aureus*, a Gram-positive microbe, is the predominant germ in skin infections. In recent years methicillin resistant strains of *S. aureus* (MRSA) have become increasingly common and have been associated with increased morbidity and mortality. Patients with chronic wounds or those who have recently received antibiotics may also be infected by Gram-negative microbes. This is frequently the case for diabetic patients with foot infections. Treatment of diabetic food infections requires broad-spectrum intravenous antibiotics and may include hospitalization and surgery. Broad-spectrum antibiotics that cover resistant bacteria are often needed for the treatment of more severe skin infections.

### Organizational Changes

Basilea Pharmaceutica Ltd. also announces organizational changes in preparation of anticipated international product commercialization including expansion of Drug Safety, Medical Information, Medical Affairs, Market Access, Supply Chain Distribution, and Global Quality Management.

To support Basilea's transition to a fully integrated company, Dr. Dieter Götte joins as Chief Medical Officer and replaces Dr. Rienk Pypstra on the Basilea Management Committee. Dr. Götte has over twenty years of industry experience with Hoechst, Aventis and Novartis across multiple therapeutic areas including anti-infectives and dermatology. His previous senior management roles have included Vice President of Regulatory & Medical Affairs including Drug Safety at Aventis Pharma and Global Head of Corporate Medical Services at Hoechst. Dr. Götte also was Chief Scientific Officer with Novartis Germany and Chairman of the Novartis Foundation for Therapeutic Research.

Dr. Rienk Pypstra takes on the role of Head of Portfolio Development to focus on expansion and consolidation of Basilea's R&D portfolio.

#### About Basilea

Basilea Pharmaceutica Ltd. is headquartered in Basel, Switzerland and listed on the SWX Swiss Exchange (SWX:BSLN). Basilea's 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 one approved product (ZEFTERA<sup>™</sup>), one pre-registration drug (alitretinoin) and one phase-III investigational drug (isavuconazole). The company is currently building its sales and marketing organization to commercialize alitretinoin and to co-promote ZEFTERA<sup>™</sup> in North America and major European countries, subject to approval.

#### Disclaimer

This communication expressly or implicitly contains certain forward-looking statements concerning Basilea Pharmaceutica Ltd. and its business. Such statements involve certain known and unknown risks, uncertainties and other factors, which could cause the actual results, financial condition, performance or achievements of Basilea Pharmaceutica Ltd. to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Basilea Pharmaceutica Ltd. is providing this communication as of this date and does not undertake to update any forward-looking statements contained herein as a result of new information, future events or otherwise.

Page 2 of 3



For further information, please contact:

Media Relations	Investor Relations
Jean-Christophe Britt, Ph.D. Corporate Communication & Public Relations	Barbara Zink, Ph.D. Head Corporate Development
+41 61 606 1354	+41 61 606 1233
media_relations@basilea.com	investor_relations@basilea.com

This press release can be downloaded from <u>www.basilea.com</u>