

## PRESS RELEASE

# Basilea's Toctino® (alitretinoin) receives first national marketing authorization in the UK

**Basel, Switzerland, September 8, 2008 – Basilea Pharmaceutica Ltd. announces that Toctino® (alitretinoin), a new once-daily oral treatment for adults with severe chronic hand eczema (CHE) unresponsive to potent topical corticosteroids, has been approved by the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom.**

Following the recommendation for regulatory approval under the European decentralized procedure, Toctino® received its first national regulatory approval in the UK.

Marketing applications for the use of alitretinoin in the treatment of severe chronic refractory hand eczema are also under regulatory review in Canada and in Switzerland.

### About chronic hand eczema

Hand eczema is a common inflammatory skin disease and is often chronic and relapsing. It is one of the most common occupational skin diseases and a frequent reason for patients to consult a dermatologist. Hand eczema is reported to affect up to ten percent of the general population. The more severe, chronic form of the condition is thought to affect five to seven percent of these patients. CHE causes significant economic and occupational burden with total costs alone in Europe estimated to eleven billion Euro per year. The most important patient burden is impaired use of the hands and a considerable impact on patients' quality of life.

### About Toctino® (alitretinoin)

Toctino® (alitretinoin) was developed by Basilea Pharmaceutica International Ltd.

The MHRA approved label for Toctino® indicates "*for use in adults who have severe chronic hand eczema that is unresponsive to treatment with potent topical corticosteroids.*"

Patients whose CHE is predominantly characterized by fissured, thick scaly skin are more likely to respond than those in whom the eczema is mainly characterized by blisters.

Toctino® (alitretinoin) is a convenient once-daily capsule to be taken with food. The recommended starting dose is 30 mg in most patients and a treatment course lasts up to 24 weeks depending on response.

Alitretinoin is a derivative of vitamin A and belongs to the well studied family of retinoids. All retinoids are teratogens. Therefore pregnancy is a contraindication to alitretinoin therapy and strict pregnancy prevention measures must be in place for all women of child-bearing potential who receive alitretinoin. A comprehensive pregnancy prevention program has been developed and implemented. In clinical trials alitretinoin was well tolerated and has a safety profile overall consistent with the retinoid class. Side effects were generally dose-dependent and reversible.

## 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 two commercialized drugs (alitretinoin, ceftobiprole) and one investigational drug (isavuconazole) in phase-III. Alitretinoin is approved in the United Kingdom, has been recommended for approval in ten additional EU Member States and is under regulatory review in Canada and Switzerland. Ceftobiprole is marketed in Canada and is under review by regulatory authorities in the U.S., the EU, in Switzerland and in several other countries. The company has set up commercial organizations in UK, Denmark and in Germany while it is building sales and marketing organizations to commercialize alitretinoin and to co-promote ceftobiprole in North America and in other European countries, subject to approval.

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