

## PRESS RELEASE

# NICE issues preliminary recommendations for Basilea's Toctino<sup>®</sup>

*Basel, Switzerland, April 30, 2009* – Basilea Pharmaceutica Ltd. (SIX:BSLN) announces that the Appraisal Committee of the National Institute for Health and Clinical Excellence (NICE) has developed preliminary positive recommendations with some limitations on the use of Toctino<sup>®</sup> (alitretinoin) within its licensed indication, as treatment for adults with severe chronic hand eczema that has not responded to potent topical corticosteroids.

The Committee's preliminary recommendations in the appraisal consultation document (ACD) does not constitute the Institute's formal guidance. A consultation period with all stakeholders will now occur and the preliminary recommendation may change after consultation. The second Appraisal Committee meeting is scheduled in June 2009 and the final guidance from NICE is anticipated by the end of August 2009.

"We continue to work together with NICE on these preliminary recommendations. Our goal is to ensure that all patients who fall within the approved indication for Toctino have access to this breakthrough treatment through the National Health Service in England and Wales," said Hans Christian Rohde, Chief Commercial Officer, Basilea Pharmaceutica International Ltd.

The preliminary recommendations (ACD) can be found on the NICE website [www.nice.org.uk](http://www.nice.org.uk)

### Chronic hand eczema – a debilitating skin disease

Hand eczema is a common inflammatory skin disease and is often chronic and relapsing. 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, causing impaired use of their hands and a considerable impact on their ability to perform everyday activities.

### Toctino<sup>®</sup> (alitretinoin), the only therapy approved for severe chronic hand eczema unresponsive to potent topical corticosteroids

Toctino<sup>®</sup> was developed by Basilea Pharmaceutica International Ltd. To date, Toctino<sup>®</sup> is launched in Denmark, Germany and the United Kingdom, and has received marketing authorization in Austria, Belgium, Finland, France, Luxemburg and the Netherlands. In addition, Toctino<sup>®</sup> has been recommended for approval in two additional EU Member States and is under regulatory review in Switzerland, Canada and 15 additional European countries.

In the largest ever phase III clinical trial program in CHE, Toctino<sup>®</sup> was the first treatment to show effective clearing of severe CHE, with clear or almost clear hands achieved in nearly 50 percent of patients treated 30 mg Toctino<sup>®</sup>. The once-daily oral therapy is given for 12 to 24 weeks, depending on patient response, and six-month post-treatment observations in patients who

responded to Toctino® indicate that treatment can provide long periods free from relapse and improve patient satisfaction.

Toctino® is a known teratogen (a substance that can cause birth defects when women are exposed during pregnancy). Strict pregnancy prevention one month before, during, and one month after cessation of treatment as well as monthly pregnancy testing are required for women of childbearing age. A comprehensive pregnancy prevention program for Toctino® has been developed and implemented.

In clinical trials, Toctino® was well tolerated and demonstrated a safety profile overall consistent with the retinoid class. Overall, the most frequently reported adverse events in the phase III clinical trials were headache and increased levels of blood lipids. Side effects were dose-dependent.

A phase III clinical trial on alitretinoin for the treatment of severe chronic hand eczema is ongoing in the U.S.

## About Basilea

Basilea Pharmaceutica Ltd. is headquartered in Basel, Switzerland, and listed on the SIX Swiss Exchange (SIX:BSLN). Basilea's integrated research and development operations are currently focused on new antibacterial, antifungal and oncology 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 in phase III (isavuconazole). Toctino® (alitretinoin) is marketed in the United Kingdom, Denmark and Germany and is approved in Austria, Belgium, Finland, France, Luxemburg and the Netherlands. Alitretinoin has been recommended for approval in two additional EU Member States and is under regulatory review in Canada, Switzerland and 15 additional European countries. Furthermore a phase III clinical trial on alitretinoin for the treatment of severe chronic hand eczema is ongoing in the U.S. Ceftobiprole is marketed in Canada and Ukraine under the brand name ZEFTERA™ and in Switzerland under Zevtera™. Marketing applications for ceftobiprole were submitted in the U.S., the EU and several other countries. The company has set up commercial organizations in UK, Denmark, Germany and Canada, while it is building sales and marketing organizations in other countries to commercialize alitretinoin and to co-promote ceftobiprole, subject to approval.

## Disclaimer

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