

PRESS RELEASE

Basilea's Toctino® receives marketing authorization in Spain

Basel, Switzerland, May 5, 2009 – 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 Spanish Drugs and Health Products Agency (Agencia Española de Medicamentos y Productos Sanitarios, AEMPS).

Following the recommendation for regulatory approval under the European decentralized procedure, Toctino® has received national regulatory approval in Spain. Basilea will submit a pricing and reimbursement dossier to the Spanish authorities based on the approval.

"We are pleased by the AEMPS approval of Toctino, the first authorized oral treatment for patients suffering from severe chronic hand eczema who do not respond to potent steroid therapy," said Hans Christian Rohde, Chief Commercial Officer, Basilea Pharmaceutica International Ltd. "The disease heavily burdens patients' ability to perform day-to-day activities and their psychological well-being. We look forward to bring this novel and effective treatment to patients and physicians in Spain."

Toctino® has been launched in Denmark, Germany and the United Kingdom for the treatment of adults with severe chronic hand eczema unresponsive to potent topical corticosteroids. Launches in other European countries are expected during 2009. Toctino® has also received marketing authorization in Austria, Belgium, Finland, France, Luxemburg and Netherlands. Further, Toctino® has been recommended for approval in Italy. Alitretinoin is under regulatory review in Canada, Switzerland and 15 additional European countries.

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® (alitretinoin), the only therapy approved for severe chronic hand eczema unresponsive to potent topical corticosteroids

Toctino® was developed by Basilea Pharmaceutica International Ltd.

The AEMPS approved Toctino® for the use in adults who have severe CHE 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 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 naturally occurring, physiologic retinoid that is thought to work in CHE through anti-inflammatory and immunomodulatory effects.

Alitretinoin 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 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.

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, the Netherlands and Spain. Alitretinoin has been recommended for approval in Italy 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.

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