PRESS RELEASE

Basilea’s Toctino® included in guidelines for management of hand eczema in Canada

Basel, Switzerland, November 24, 2010 - Basilea Pharmaceutica Ltd. (SIX:BSLN) confirms the inclusion of alitretinoin (Toctino®) in the “Canadian Hand Dermatitis Management Guidelines”. These expert guidelines recommend alitretinoin as the systemic treatment of choice when clinical signs of severe chronic hand eczema persist or recur under treatment with potent topical corticosteroids.

The guidelines, developed by a panel of leading experts, provide practice recommendations for managing hand dermatitis to dermatologists and other health care professionals in Canada. Intervention with oral alitretinoin is recommended as a treatment of choice for severe chronic hand eczema (CHE) that is unresponsive to potent topical corticosteroids. Alitretinoin is the first and only treatment approved for this condition. The document is published in the Journal of Cutaneous Medicine and Surgery (C. Lynde, L. Guenther, T.L. Diepgen, D. Sasseville, Y. Poulin, W. Gulliver, T. Agner, K. Barber, R. Bissonnette, V. Ho, N.H. Shear, J. Toole; Vol 14, No 6 (November/December), 2010: pp 267-284).

“The evidence-based recommendation of Toctino as systemic treatment of choice for severe chronic hand eczema by a panel of leading Canadian and European experts indicates that Toctino has an important role to play in the management of this very debilitating and painful skin disease,” said Prof. Achim Kaufhold, Chief Medical Officer of Basilea. “This condition severely impacts patients’ quality of life as well as their ability to perform everyday activities. The publication of Canadian guidelines now that Toctino is available in Canada is good news for hand eczema patients as it supports physicians in identifying and implementing the optimal treatment.”


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 treatments

Toctino® was developed by Basilea Pharmaceutica International Ltd. Basilea markets Toctino® in France, Germany, the United Kingdom, Switzerland and Denmark for the treatment of severe CHE. The company has appointed Actelion Pharmaceuticals Canada Inc. as its distributor for Toctino® in Canada and Almirall, SA, as its distributor in selected European markets and Mexico. Health Canada approved Toctino® for the treatment of severe chronic hand eczema refractory to high potency topical corticosteroids in adults.
In the largest ever phase III clinical trial program in CHE, Toctino® 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 with 30 mg Toctino®. The once-daily oral therapy for adults 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 and reversible.

About Basilea

Basilea Pharmaceutica Ltd. is headquartered in Basel, Switzerland, and listed on the SIX Swiss Exchange (SIX:BSLN). Its fully integrated research and development operations are currently focused on antibiotics, antifungals and oncology drugs, as well as on the development of dermatology drugs, targeting the medical challenge of resistance and non-response to current treatment options in the hospital and specialty care setting.

Basilea is currently marketing Toctino® (alitretinoin), the only approved treatment for severe chronic hand eczema unresponsive to potent topical corticosteroids, in Denmark, France, Germany, Switzerland and the United Kingdom and has appointed distributors for Toctino® in other selected European markets, Canada and Mexico. Furthermore, a phase III clinical program on alitretinoin for the treatment of severe chronic hand eczema is ongoing in the U.S. The company has entered into a global partnership with Astellas Pharma Inc. for its phase III compound isavuconazole, a potential best-in-class azole antifungal, for the treatment of life-threatening invasive fungal infections. Full rights to ceftobiprole for the treatment of potentially life-threatening resistant bacterial infections, are being transferred from Cilag GmbH International, a Johnson & Johnson company, back to Basilea.

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