



PRESS RELEASE

Efficacy and Safety Profile of Basilea's Alitretinoin for Severe Refractory Chronic Hand Eczema Confirmed by Data Shown at European Dermatology Congress

Basel, Switzerland, May 21, 2007 – **Results from phase III clinical trials and further human pharmacology studies were presented at the 16th Congress of the European Academy of Dermatology and Venereology (EADV). These data highlighted the efficacy and safety profile of alitretinoin as a potential once daily oral treatment for patients with severe refractory chronic hand eczema.**

Currently, no approved treatment exists for severe Chronic Hand Eczema (CHE) refractory or unresponsive to topical therapy. This debilitating disease can cause significant pain and functional impairment of the hands as well as considerable psychological, social and occupational impact on patients' lives. The data presented at this meeting will form part of the regulatory submissions later this year and show the potential for alitretinoin to become the first product available to treat an estimated one million patients in North America and Europe.

Eight posters on alitretinoin presented in the main conference and four oral presentations in a company sponsored satellite symposium highlighted alitretinoin as a potential treatment for severe refractory CHE.

Positive efficacy and safety data on alitretinoin were reported in posters from the pivotal BACH trial (poster number 275), the re-treatment study (280) and an open-label safety study (281). Five further posters covered aspects of the pharmacology of alitretinoin (286, 287, 288, 289 and 290).

Previously reported results for the phase III BACH study (275) confirm the efficacy and tolerability of oral alitretinoin for the treatment of CHE in patients refractory to topical corticosteroids. Once daily alitretinoin resulted in response of 48% of the patients who were treated with 30mg per day for up to six months. Response rate and time to response were dose dependent with a faster response seen with the higher dose. Alitretinoin was generally well tolerated in these clinical studies with an adverse event profile typical of the retinoid drug class.

Patients with CHE often relapse, however, approximately 70% of patients treated with alitretinoin in the BACH trial remained relapse free, as defined in the protocol, during a six month post-treatment observation period without any form of maintenance treatment.

Basilea's re-treatment study (280) demonstrated that those patients with disease recurrence remained responsive to another course of alitretinoin treatment with a response rate of 80% in the 30mg group. The primary and secondary efficacy endpoints were consistent with previously reported primary treatment studies and repeated treatment courses of alitretinoin were generally well tolerated.

An open-label study (281) provided further safety data confirming that in patients with severe refractory CHE, exposure to alitretinoin 30mg beyond six months is well tolerated.



Summary of Poster Presentations

P275 / Efficacy and safety of alitretinoin in severe refractory chronic hand eczema. Ruzicka T, Gupta A, Jemec G, Gerlach B, Maares J, Wevelsiep L.

P280 / Re-treatment study of alitretinoin (9-cis retinoic acid) in severe chronic hand eczema refractory to topical treatment. Ruzicka T, Lahfa M, Lynde Ch, Coenraads PJ, Harsch M, Maares J.

P281 / An open label study of the safety and efficacy of alitretinoin in severe refractory chronic hand eczema. Diepgen T, Maleszka R, Bissonnette R, Augustin M, Harsch M, Brown T.

P286 / Alitretinoin (BAL4079; 9-cis retinoic acid): Pharmacokinetic interactions between alitretinoin, ketoconazole, simvastatin and cyclosporine A. Schmitt-Hoffmann A, Roos B, Baumgaertner E, Maares J.

P287 / Alitretinoin (BAL4079; 9-cis retinoic acid): Pharmacokinetics after single and repeated oral dosing of 20 and 40mg in healthy volunteers. Schmitt-Hoffman A, Roos B, Brown T, Meyer I.

P288 / Alitretinoin (BAL4079; 9-cis retinoic acid): Pharmacokinetics after single and repeated oral dosing of 5, 10 and 20mg in healthy volunteers. Schmitt-Hoffman A, Roos B, Brown T, Maares J.

P289 / Alitretinoin (BAL4079; 9-cis retinoic acid): Mass-balance excretion study of oral alitretinoin in healthy volunteers. Schmitt-Hoffman A, Roos B, Brown T, van Lier JJ.

P290 / Alitretinoin (BAL4079; 9-cis retinoic acid): Low levels in seminal fluid after repeated oral dosing. Schmitt-Hoffman A, Roos B, Brown T, Meyer I.

About Chronic Hand Eczema (CHE)

Hand eczema is a common skin disease and is often chronic and relapsing. It is estimated to affect up to 10% of the general population. The more severe, chronic form of the condition is thought to affect up to 7% of these patients, many of whom do not respond, or no longer respond to topical corticosteroids. Basilea estimates there are at least one million patients in Europe and North America with severe refractory CHE for which currently no approved, effective pharmaceutical treatment is available.

About Alitretinoin

Alitretinoin is an investigational drug being developed in Phase III clinical trials by Basilea as a novel treatment for severe refractory Chronic Hand Eczema (CHE), a complex disease for which no effective treatment options are currently available. Alitretinoin has been shown to be effective in clinical studies in patients with severe refractory CHE. Alitretinoin is a teratogen and therefore pregnancy prevention measures must be in place for all women of child-bearing potential who receive alitretinoin. Within days after discontinuation of therapy, alitretinoin levels return to endogenous levels. In clinical studies the post-treatment contraceptive period was four weeks.

About Basilea

Basilea Pharmaceutica Ltd. is an independent biopharmaceutical company headquartered in Basel, Switzerland, and listed on the SWX Swiss Exchange (SWX:BSLN). Basilea's fully 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 three investigational



phase III drugs of which two have shown positive pivotal phase III results. The company is integrating commercialization into its organization, in a first step through co-promoting ceftobiprole with its partner Cilag GmbH International, a Johnson & Johnson company, in North America and major European countries.

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