PRESS RELEASE

Basilea's U.S. phase III HANDEL study with investigational compound oral alitretinoin meets study endpoints

- **40% of alitretinoin-treated severe refractory chronic hand eczema patients achieved "clear" or "almost clear" hands compared to 15% of patients receiving placebo**
- **Topline safety data consistent with established profile of oral alitretinoin**

Basel, Switzerland, March 12, 2012 – Basilea Pharmaceutica Ltd. (SIX:BSLN) announced today topline results from its U.S. phase III HANDEL study with its investigational compound oral alitretinoin in severe chronic hand eczema (CHE) refractory to potent topical corticosteroids. The results cover observations made during the treatment period and the first six-month post-treatment observation period.

In this randomized, double-blind, placebo-controlled multicenter study, 596 adult patients with severe chronic hand eczema unresponsive to potent topical corticosteroids were randomized either to a once-daily dose of 30 mg alitretinoin or placebo for a treatment duration of up to six months. Since alitretinoin belongs to a pharmaceutical class that is known to be teratogenic and contraindicated in pregnancy, strict pregnancy risk management measures were required for women of childbearing potential who participated in the study.

Patients included in the study had a long history of disease, for an average of seven years, and had a pre-treatment run-in period of up to four months to confirm the refractory nature of the disease towards potent topical corticosteroids. Patients are being followed for twelve months post treatment in total to assess sustainability of response and safety.

At the end of treatment, 40% of patients treated with alitretinoin achieved "clear" or "almost clear" hands compared to 15% treated with placebo ($p<0.001$) based on the primary outcome measure Physician Global Assessment (PGA) in the intent-to-treat population, thereby achieving the primary study objective. Consistent with the physicians' assessment, the secondary outcome measure of the Patient's Global Assessment (PaGA) demonstrated that 39% of patients treated with alitretinoin scored themselves as "cleared" or "almost cleared", compared to 14% of patients treated with placebo ($p<0.001$). In another secondary measure of treatment effect, the modified Total Lesion Symptom Score (mTLSS), the mean reduction in score values was 54% in patients treated with alitretinoin compared to 30% for patients treated with placebo ($p<0.001$).

Analysis of the topline data indicates that alitretinoin exhibited a safety profile consistent with that reported in previously conducted clinical studies. During therapy the most common adverse events considered as related to alitretinoin were headache, followed by flushing, nausea and increased blood triglycerides.

End-of-treatment data and currently available 12-month follow-up data did not show an impact of alitretinoin on bone mineral density. Final bone mineral density analyses will be performed after completion of the one-year post-treatment observation period. These data are expected to be available around mid-year.

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Dr. Anthony Man, Chief Executive Officer of Basilea Pharmaceutica International Ltd., said, "This is an important development milestone for alitretinoin. The topline results of this large prospective randomized trial in patients in the U.S. are consistent with previous randomized international studies. We plan to discuss the final study results and the requirements for a risk evaluation and mitigation strategy (REMS) with the FDA in the second half of 2012 in the context of a potential filing of a New Drug Application in the U.S."

For additional information on the HANDEL study please refer to
http://www.clinicaltrials.gov/ct2/show/NCT00817063

Conference call

Basilea Pharmaceutica Ltd. invites you to participate in a conference call on Monday, March 12, 2012, 4 p.m. (CET), during which the company will discuss today's press release.

Dial-in numbers are:
+41 (0) 91 610 56 00 (Europe and ROW)
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A playback will be available 1 hour after the conference call until Wednesday, March 14, 2012, 6 p.m. (CET). Participants requesting a digital playback may dial:
+41 (0) 91 612 4330 (Europe and ROW)
+1 (1) 866 416 2558 (USA)
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and will be asked to enter the ID 13412 followed by the # sign.

About chronic hand eczema

Hand eczema is a common disease that tends to run a persistent, relapsing course.[1] Hand eczema are estimated to affect up to ten percent of the general population.[2] Approximately five to seven percent of patients with hand eczema are estimated to suffer from severe, chronic hand eczema.[2] Chronic hand eczema can be defined as hand eczema that last for at least three months despite adequate dermatological treatment or when the patient has suffered at least two relapses within a year. It is usually characterized by a combination of signs and symptoms of thick scaly skin that gives rise to painful fissures, blisters and abrasions, erythema, itching and edema.

About Toctino® (oral alitretinoin)

In the U.S., oral alitretinoin is an investigational drug and not approved by the U.S. Food and Drug Administration (FDA).

Toctino® was developed by Basilea Pharmaceutica International Ltd. It is marketed in nine European countries as well as Canada and approved in another 17 European countries and Israel as a once-daily capsule for the treatment of adults with severe CHE that is refractory to treatment with potent topical corticosteroids.

Alitretinoin belongs to a class of medicines (retinoids) known to cause severe birth defects if used in pregnant women. This means that if alitretinoin is taken during pregnancy there is a very high risk that the baby will be born with very severe and serious malformations. For this reason strict pregnancy prevention for one month before, during, and one month after treatment as well as monthly pregnancy testing is required for women of childbearing potential who take alitretinoin. Other side effects that have been reported with variable frequency in association with use of the retinoid class of drugs (including alitretinoin) are psychiatric effects, depression, mood changes, suicidal ideation; inflammatory bowel disease; alterations in serum lipids, thyroid

function, liver and muscle enzymes; mucocutaneous effects; impaired vision and hearing as well as benign intracranial hypertension.

About Basilea

Basilea Pharmaceutica Ltd. is headquartered in Basel, Switzerland, and listed on the SIX Swiss Exchange (SIX:BSLN). Through the fully integrated research and development operations of its Swiss subsidiary Basilea Pharmaceutica International Ltd. the company focuses on innovative pharmaceutical products in the therapeutic areas of bacterial infections, fungal infections, oncology and skin diseases, targeting the medical challenge of resistance and non-response to current treatment options in the hospital and specialty care setting.

Disclaimer

This communication expressly or implicitly contains certain forward-looking statements concerning Basilea Pharmaceutica Ltd. and its business. Such statements involve certain known and unknown risks, uncertainties and other factors, which could cause the actual results, financial condition, performance or achievements of Basilea Pharmaceutica Ltd. to be materially different from any future, anticipated results, performance or achievements expressed or implied by such forward-looking statements. Basilea Pharmaceutica Ltd. is providing this communication as of this date and does not undertake to update any forward-looking statements contained herein as a result of new information, future events or otherwise.

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This press release can be downloaded from www.basilea.com.

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2. Diepgen TL, Agner T, Aberer W, et al. Management of chronic hand eczema. Contact Dermatitis 2007: 57: 203-10