Basel, Switzerland – 21st March 2003

Basilea announces positive Phase II results of BAL4079 (alitretinoin) in refractory chronic hand dermatitis.

Basilea Pharmaceutica Ltd announced today that its double-blind, placebo-controlled, randomized, dose finding study of BAL4079 in patients with chronic hand dermatitis refractory to topical therapy had shown a statistically significant difference for its primary efficacy endpoint, with 53% of patients treated with 40 mg alitretinoin rated as clear or almost clear after 12-week treatment course.

"The results of this study show an unequivocal activity for BAL4079 in these patients with chronic hand dermatitis unresponsive to conventional therapies." Said Professor Thomas Ruzicka, one of the leading investigators. "A well designed, prospective, double blind, placebo controlled trial is the most stringent test to which one can submit an investigational drug. The dermatological community would welcome an effective oral therapeutic agent to treat chronic hand dermatitis, which frequently impacts the patients' social and professional life. No therapies are approved for this indication and topical steroids are often ineffective or poorly tolerated when used over extensive periods."

Three hundred and nineteen patients with chronic hand dermatitis with a median disease duration of 3 years, who had not responded to previous therapy with topical corticosteroids, were included in this multicenter European study. The patients were randomized, to treatment with placebo, 10, 20 or 40 mg of BAL4079 given orally for 12 weeks. Primary Efficacy Endpoint was the Physician Global Assessment, a static severity assessment scale that defined patients with complete or almost complete clearing of disease as responders. Other main endpoints were a Patient Global Assessment (PaGA) of improvement, a Total Lesion Symptom Score (TLSS), combining several signs and symptoms (erythema, edema, scaling, hyperkeratosis, fissuring, vesicles and pain/pruritus). The extent of disease and the Dermatology Life Quality Index (DLQI) were also assessed.

The Physician Global Assessment showed that 53% of patients on 40 mg responded vs 27% on placebo, while the 10 and 20 mg doses had response rates of 37% and 41 % respectively.A statistically significant difference with placebo was also observed for PaGA and TLSS. Consistent trends were observed for the extent of disease and the DLQI.

The safety profile of BAL4079 was consistent with the anticipated pharmacological effect of this class of retinoids. The most frequent side effects (headache, dry lips, flushing and elevated trigylcerides) were seen in the highest dose group more often than in the intermediate and placebo groups.

"We are delighted with these results", said Dr. Guenter Kinast, CEO of Basilea. "They are a clear indication of the that BAL4079 has the potential to become a significant advance for a disease in need of an effective medical therapy."

Chronic hand dermatitis is a frequent skin condition with a multifactorial etiology including irritant and allergic contact reactions, as well as an atopic background. Its diagnosis is based on clinical examination and no clear relationship has been established between etiologies and clinical aspects. Epidemiological studies, mostly conducted in Northern Europe, have indicated an overall prevalence of hand dermatitis in up to 6-11% of the adult population. Limited treatment options (such as oral corticosteroids, cyclosporin, phototherapy, or radiotherapy) have been advocated for patients who do not respond adequately to emollients and topical steroids and whose disease severely impairs professional and social life.

BAL4079 (alitretinoin; 9-cis retinoic acid) is a vitamin A derivative. Its chemical structure is related to all members of the natural and synthetic retinoids.

About Basilea

Basilea Pharmaceutica Ltd is a privately held pharmaceutical company engaged in the discovery and development of innovative drugs for the treatment of bacterial and fungal infections, and dermatological diseases. Basilea was founded with significant assets to achieve its business objective of bringing innovative medicines to the market.

Disclaimer: This press release contains forward-looking statements concerning Basilea Pharmaceutica Ltd and its prospects. Such statements are subject to certain risks and uncertainties, particularly those inherent in the process of discovering, developing, and commercializing drugs for use as human therapeutics. Actual results could differ materially from those projected in this release. As a result, the reader is cautioned not to rely on these forward-looking statements. For further information, contact

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