Effective treatments for common skin diseases

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MOBERG DERMA REPORTS POSITIVE PHASE III RESULTS FOR K101 AGAINST NAIL FUNGUS

Moberg Derma AB reports today positive results from a phase III clinical study for K101 against nail fungus (onychomycosis). In the study, almost 500 patients were treated during six months with K101 or a placebo. The results showed that significantly more patients receiving K101 were cured of their fungal infection ($p=0.001$). The patients' subjective evaluation of the treatment effect revealed distinct benefits from treatment with K101 ($p<0.001$). Highly promising results were also observed for patients with severely infected nails.

No safety issues were identified in the trial. Patients treated with K101 had a higher frequency of localized transient irritation but only 1.7% of the patients discontinued treatment due to adverse events. No serious adverse events related to K101 were reported.

"We are very pleased with the results of the phase III study, which support that K101 is an effective and safe treatment for nail fungus. Discussions will now be initiated with authorities to determine an appropriate approach for registration," says Moberg Derma's President and CEO, Peter Wolpert.

"The results show that K101 has the capacity to become a highly competitive product, with excellent market potential. We are now intensifying our commercialization plans and discussions with potential partners," explains Peter Wolpert.

The phase III clinical study of K101 was a randomized, double-blind and placebo-controlled study conducted at 36 clinics in Sweden and Poland in 2007 and 2008. A total of 493 patients with nail fungus were treated for six months with K101 or a placebo. The main group comprised 395 patients with up to 50% infected nail surface. A subgroup comprising 98 patients with severely infected nails (51 to 75% infected nail surface) was also studied. The primary efficacy variable was mycological cure, which implies fungal culture and microscopy to be negative. A number of secondary efficacy variables were also measured, including the patients' subjective assessments of treatment effect. K101 is a topical solution that is applied to infected nails once daily.

Nail fungus is caused by dermatophytes (Trichophyton rubrum) and afflicts approximately 8% of the population. The most common treatments against nail fungus are terbinafine tablets or topical treatment with amorolfine or ciclopirox. Since many patients do not seek treatment, the untapped market potential is significant and there is a considerable need for new and efficacious topical treatments. The global market for dermatological anti-fungals is growing by an estimated 6% annually and is expected to total USD 3,9 billion by 2010.

Moberg Derma is developing several dermatological pharmaceuticals based on the company's patented Kaprolac® principle. A phase III study for K301 against seborrheic dermatitis was recently completed with promising results and a phase II study for K201 against atopic dermatitis will be initiated in January 2009.

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About Moberg Derma
Moberg Derma AB is a Swedish pharmaceutical company that develops and commercializes patented dermatological pharmaceuticals to treat common skin diseases. The company focuses on innovative products based on proven compounds and has product candidates in advanced phases of clinical development. Moberg Derma intends to market pharmaceuticals in the Nordic region and outlicense product rights to partners and distributors in other markets. The company began operations at the Karolinska Institute in 2006 and currently has 11 employees. The principal owners are Östersjösstiftelsen (the Baltic Sea Foundation), private investors and corporate management.