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DermaGen Reports Successful Phase I/IIa Clinical Trial for Atopic Dermatitis

LUND – December 2, 2009. DermaGen AB – part of the Karolinska Development dermatology and wound healing company “Pergamum” – today announced that DermaGen AB has received promising results from a clinical Phase I/IIa study. DermaGen AB is developing a novel antimicrobial peptide (AMP) treatment for atopic dermatitis. Atopic dermatitis is a chronic inflammatory skin disease where dry skin and the skin’s weakened barrier function make patients susceptible to colonization by microorganisms, a triggering or exacerbating factor of the disease. The AMP has shown a broad spectrum of activity and is both bactericidal and fungicidal. In the clinical trial, the company’s candidate drug clearly reached its primary objective, demonstrating a significant reduction of total microbes in eczemas compared to placebo. In addition to good safety and tolerability performance, the candidate drug also showed a trend towards improved eczema status. This is the first time a study has shown efficacy of AMPs for atopic dermatitis in man.

Commenting on the study, DermaGen’s Managing Director, Jan Alenfall, said, “Achieving such promising results from a first-time-in-man trial is very pleasing. The observed trend towards improvement of the disease condition provides particular encouragement. We will now initiate further clinical studies to substantiate this. Skin infection is recognized as an aggravating factor of atopic dermatitis. The development of a new class of treatment, capable of eradicating microbes with limited risk of microbial resistance development, is likely to have significant market appeal within this and other dermatological indications.”

Jørgen Thorball, Pergamum’s Chairman, stated, “DermaGen is a very exciting company with a strong technology platform. These promising clinical results go a long way towards establishing proof of concept within atopic dermatitis. They also strengthen the company’s position as it explores additional, first-in-class opportunities for the candidate drug and other compounds for the topical treatment of dermatological infections, such as impetigo and infected wounds and burns.”

The rapid resistance development by microbes limits the use of classical antibiotics for indications such as atopic dermatitis, especially for topical applications. DermaGen’s AMP is derived from natural endogenous human proteins and there is low probability that it will induce resistance as it lack a specific molecular target on bacteria and other microbes. Anti-infective treatments represent the most important component of the global dermatology market, accounting for 31% of total market value, approximately USD 4 billion.

Conny Bogentoft, CEO of Karolinska Development, said, “Pergamum and its Operating Units form an important part of the Karolinska Development portfolio. They represent a strong offering in dermatology and wound healing markets with products targeting indications with significant unmet medical needs. It is encouraging to see the progress they are making in their clinical development programs.”

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About DermaGen

DermaGen AB is a specialty pharmaceutical company and world leader in the research and development of endogenous antimicrobial peptides. Founded in 2004, DermaGen focuses on the development of topically applied products for the prevention and treatment of bacterial and fungal skin infections. Novel antimicrobial peptides are modified to increase their potency and stability, facilitating the development of pharmaceutical products that fulfill unmet medical needs and significantly improve quality of life for patients. DermaGen partners with leading international pharmaceutical companies in the dermatological field to ensure rapid and cost-efficient development. The company is based in Lund, Sweden and is part of the Pergamum group of companies.

www.dermagen.se



About Pergamum

Pergamum AB is a new kind of biopharmaceutical company focusing solely on dermatology and wound healing markets. The company currently has four Operating Units, which it supports with strategic management, business development, drug development and operational assistance as required. Pergamum is a Karolinska Development AB company.

www.pergamum.com



About Karolinska Development

Karolinska Development manages one of the largest portfolios of life science companies in Europe. Using a unique, highly cost-efficient business model, the management team guides the commercialization of world-class life science innovations, helping to shape the next-generation pharma industry. Since 2003, Karolinska Development has built a portfolio of some 40 companies; among the company's projects 12 compounds are undergoing clinical trials. The portfolio also includes a total of 19 potential first-in-class products.

www.karolinskadevelopment.com

About Atopic Dermatitis

Atopic dermatitis (AD) is a chronic inflammation of the skin that occurs in persons of all ages but is more common in children. AD is a chronic, itching, inflammatory skin disease, which is associated with asthma and/or hay fever and a familial occurrence of these conditions.

The prevalence of AD has risen 3-4-fold over the last 30 years and is now a major public health problem in the seven major markets, with 3% of the US population suffering from AD. It has been reported to affect 10 % of children and accounts for between 10 and 20 % of all visits to dermatologists.

There is considerable evidence that colonization or infection with *S. aureus* is a triggering or exacerbating factor in AD. Superantigens produced by the bacteria stimulate keratinocytes and T-lymphocytes, and trigger the inflammatory process. The inflammation leads to an impaired skin barrier function. Furthermore, endogenous antimicrobial peptides are low in patients with AD, leading to a vicious cycle of *S. aureus* involvement in the disease. Superantigens also act as potent inhibitors of steroid action, possibly leading to steroid resistance.

The use of topically administered AMPs for control and normalization of the bacterial and fungal flora is therefore a logical and attractive method for interfering with the pathogenesis of AD. It is well established that treatment of AD with steroids in combination with antibiotics is more effective than use of steroids alone. In the light of current therapies, endogenous AMPs will add an important new and significant therapeutic modality to current treatments with a very low probability of inducing bacterial resistance.

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