

Lipidor reports positive clinical Phase I/II data in psoriasis

STOCKHOLM – August 27, 2013. Today Lipidor announced positive results from a Phase I/IIa study investigating the efficacy and tolerability of its AKVANO®/calcipotriol spray formulation for the treatment of psoriasis vulgaris, the most common form of psoriasis. Karolinska Development owns 50% of Lipidor.

“The positive study results represents an important milestone for Lipidor in its efforts to develop a product with equivalent clinical efficacy compared to market leading calcipotriol-only topical treatments, and with superior cosmetic qualities and greater ease of use, thereby, improving compliance rates and patient quality of life”, concludes Anders Carlsson, CEO of Lipidor.

Various kinds of ointments, creams and lotions are commonly prescribed treatments for psoriasis, but they also show low compliance rates. This is largely due to their greasiness and inability to absorb into the skin and therefore be present on the skin for a long time after application. This causes personal discomfort as well as staining of clothes.

Lipidor is developing AKVANO®/calcipotriol, a water-free spray formulation containing calcipotriol, a vitamin D derivative that is one of the cornerstones in the treatment of mild to moderate psoriasis vulgaris. The AKVANO® technology enables efficient delivery of the pharmaceutical ingredient. After application the carrier compounds evaporates quickly, leaving a pleasant feeling on the skin and a cosmetically appealing result.

Data from the recently concluded Phase I/IIa clinical study in 24 psoriasis vulgaris patients revealed that the AKVANO®/calcipotriol spray formulation had clear and significant antipsoriatic effects compared to placebo, comparable to a marketed formulation of calcipotriol. This means that the primary objective of the trial was met. In the study, the patients received 10 topical treatments over 12 days. No safety issues were noted in the study.

Approximately 125 million patients suffer from psoriasis worldwide. While the disease varies in its manifestation, psoriasis vulgaris that affects 80-90% of the patients typically causes plaques of rapid skin accumulation at certain areas of the skin. One of the measures of disease severity is the body surface area covered by affected skin plaques or lesions, from distinctly localized to widespread. Psoriasis can cause itching and pain, scaling of skin and bleeding lesions. Quality of life aspects, including self-consciousness and social withdrawal are important factors in the management of the disease including treatment compliance.

For further information, please contact:

Anders Carlsson, CEO, Lipidor AB

Phone: +46 (0)73 778 06 43, e-mail: anders.carlsson@lipidor.se

Torbjörn Bjerke, CEO, Karolinska Development AB

Phone: +46 (0)72 744 41 23, e-mail: torbjorn.bjerke@karolinskadevelopment.com

Benjamin Nordin, IRO, Karolinska Development AB

Phone: +46 (0)73 093 60 80, e-mail: benjamin.nordin@karolinskadevelopment.com

TO THE EDITORS

About Lipidor

Lipidor is a drug delivery company focusing on topical treatment. Its proprietary AKVANO[®] technology can accommodate most drug substances used for topical treatment in its novel sprayable dosage form. The lead product concept is a sprayable AKVANO[®]-based product concept with calcipotriol being developed for psoriasis vulgaris. The company is also evaluating a similar AKVANO[®]-based product concept with a combination of calcipotriol and a corticosteroid for the same indication.

About the clinical trial

The primary objective of the Phase I/IIa clinical trial was met since AKVANO[®]/calcipotriol showed clear and significant antipsoriatic effects, measured by sonography as a reduction in infiltrate thickness, in comparison to corresponding vehicle formulations. A secondary objective was also met since the antipsoriatic effects were comparable to that of the marketed product Daivonex[®] solution. 24 patients (male and female) were included in the study.

About Karolinska Development AB

Karolinska Development aims to create value for patients, researchers, and investors by developing innovations from world class science into products that can be sold or out-licensed with high returns. The business model is to: SELECT the most commercially attractive medical innovations; DEVELOP innovations to the stage where the greatest return on investment can be achieved; and COMMERCIALIZE the innovations through the sale of companies or out-licensing of products. An exclusive deal flow agreement with Karolinska Institutet Innovations AB, along with other cooperation agreements with leading universities, delivers a continuous flow of innovations. Today, the portfolio consists of 35 projects, of which 16 are in clinical development. For more information, please visit www.karolinskadevelopment.com.

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