

Very positive Clinical Phase I/IIa results for Calcipotriol AKVANO[®] formulation for the treatment of Psoriasis

We are proud to announce positive results from a Phase I/IIa study investigating the efficacy and tolerability of Lipidor's AKVANO[®]/calcipotriol spray formulation for the treatment of psoriasis vulgaris, the most common form of psoriasis.

"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.

"I am glad to see that the investment Cerbios has provided in this project has led to positive results", says Gabriel Haering, Cerbios' CEO. "Cerbios' contribution was not only directly related to the use of its API Calcipotriol, but also related to the development of the formulation at industrial scale supplying the cGMP clinical material supported by stability studies in Lugano. This is opening new opportunities to us for contract manufacturing activities in the dermatology area together with Lipidor as owner of the technology".

The outcome of the clinical trial was very successful.



The **primary objective** was met since calcipotriol in AKVANO[®] showed clear and significant ($P < 0.0001$) antipsoriatic effects, measured by sonography as a reduction in infiltrate thickness, in comparison to corresponding vehicle formulations (placebo). A **secondary objective** was also met since the antipsoriatic effects were comparable to that of the marketed product Daivonex solution.

The trial design was single-centered, randomized, vehicle- and comparator-controlled, double-blind for the novel formulations and vehicles, observer-blind for the comparators, with intra-individual comparison of treatments with 24 male and female volunteers. The trial was performed by bioskin GmbH Berlin, Germany.

The goal is to bring to market a product with equivalent/improved clinical efficacy compared to market leading calcipotriol-only topical treatments, having superior cosmetic qualities and greater ease of use, thereby, improving compliance rates and patient quality of life.

The calcipotriol project is co-developed by Cerbios-Pharma SA, Lugano, Switzerland.

A second product concept for treating psoriasis vulgaris is under evaluation. It is a sprayable AKVANO[®]-based combination product including calcipotriol and a corticosteroid.

Lipitor's AKVANO[®] delivery system can accommodate most drug substances used for topical treatment in its novel sprayable dosage form.

Cerbios' expertise and reputation in the synthesis and handling of High Potency Active Ingredients, including but not limited to Vitamin D derivatives at industrial scale, is the perfect complement to Lipidor know-how and expertise in this novel drug delivery system.

This can provide to our interested Pharma companies the possibility to immediately start development and scale-up of their target product at Cerbios, a global supplier.

About Cerbios-Pharma SA

Cerbios is a privately held company located in Lugano (Switzerland) specialized in the development and manufacturing of chemical and biological APIs for our partners world-wide. APIs made by Cerbios cover small molecules (Chemical Division), large molecules and Probiotics (Biological Division). Services for third parties under exclusive manufacturing are offered in the area of HPAs for the Chemical Division and Recombinant Proteins or monoclonal Antibodies for the Biological Division.

Full CMC support is provided to our partners world-wide in order to supply them with cGMP clinical batches, registration/validation material, and APIs from commercial manufacturing. Paramount to this is the ability to supply all the documentation required for a successful registration. Cerbios is selling commercial products mainly in Europe, USA, Japan and India.

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.

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