



Press Release

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Lipidor gets go-ahead for Phase III Clinical Study of new Calcipotriol Spray treatment for psoriasis

India's CDSCO (Central Drugs Standard Control Organization) has approved Phase III Trials of a new topical anti-psoriatic spray developed by Swedish company Lipidor. The new spray is expected to overcome patient non-compliance, a major problem for traditional psoriasis creams and ointments. It is exceptionally fast-drying and easy to apply.

Calcipotriol Spray consists of the generic Vitamin D analogue, Calcipotriol, formulated in Lipidor's patented lipid-based drug delivery technology, AKVANO®. Lipidor has developed the clinical trial material (CTM) in cooperation with Swiss API supplier Cerbios-Pharma SA, while Cadila Pharmaceuticals, one of India's largest privately held pharma companies, is responsible for the clinical phase III study. The study will be carried out at 13 centers in India, with 266 patients with mild to moderate psoriasis.

Increased comfort = increased compliance

Non-compliance has been a major problem for topical psoriasis treatments. Creams and ointments being sticky or greasy, and unpleasant or time-consuming to apply have all been frequently reported by patients as reasons to stop taking treatment. Calcipotriol Spray delivers an exceptionally comfortable experience to patients, drying cleanly and very quickly on the skin, compared to ointments, creams and gels.

The active ingredient is the generic Vitamin D analogue Calcipotriol, which reduces psoriasis symptoms by reducing excessive skin cell production. Calcipotriol Spray contains no steroids, and is formulated with AKVANO®, Lipidor's patented lipid-based drug delivery technology based on skin barrier enforcing lipids.

Olle Holmertz, Lipidor AB Acting CEO: "We are delighted to get the green light to begin Phase III trials of this important new treatment. Combining efficient pharmaceutical delivery with excellent cosmetic qualities and improved comfort and convenience, we believe Calcipotriol Spray is a truly global medical opportunity, treating a condition, psoriasis, which affects 2-3% of the world's population."

Dr. Rajiv Modi, CMD, Cadila Pharmaceuticals Ltd., said: "We are driven by research-based innovations that provide care and affordable solutions to our customers. Our partnership with Lipidor will help to bring forward a superior solution for psoriasis which will ensure greater compliance and efficacy."

AKVANO® and Calcipotriol Spray are protected by granted patents and patent applications. Lipidor will be looking for licensing partners for all countries for registration and market introduction of Calcipotriol Spray.

About Psoriasis

Psoriasis Vulgaris is a long-lasting (chronic) autoimmune disease that affects 2-3% of the world's population. It is characterized by patches of abnormal and inflamed skin. Quality of life aspects, including self-consciousness and social withdrawal, are important factors in the disease, also affecting treatment compliance. Various kinds of topical ointments, creams and lotions are commonly prescribed treatments, but all show low compliance rates, largely due to their greasiness and inability to absorb into the skin, staying present on the skin for a long time after application.

About AKVANO

AKVANO® technology represents a new sprayable dosage form that creates a lipid layer on the skin surface for effective topical delivery of drugs and skin care treatment. AKVANO® is available to companies wishing to innovate, develop or improve new and existing products in pharmaceuticals, biocides and medical devices.

About Lipidor AB (www.lipidor.se)

Lipidor is a Swedish lipid technology company offering unique lipid based formulation opportunities across dermatology, wound and skin care markets. The company was established in 2009. Research and development is conducted at Stockholm University and Karolinska Institutet Science Park in Stockholm.

About Cadila Pharmaceuticals Ltd (www.cadilapharma.com)

Cadila Pharmaceuticals Ltd. is one of the largest privately held pharmaceutical companies in India. Over the last six decades, the company has been developing and manufacturing pharmaceutical products in India and selling and distributing these in over hundred countries around the world. The company is present in more than forty-five therapeutic areas spread across twelve specialties. A pioneer in providing affordable care, this company has developed many first-in-the-world innovations for the treatment of cardiovascular diseases, tuberculosis, lung cancer and seasonal influenza.

About Cerbios-Pharma SA (www.cerbios.ch)

Cerbios is a privately held company located in Lugano, Switzerland, that specializes in the development and manufacturing of both chemical and biological APIs for its partners worldwide. Cerbios' is a global leading supplier of a portfolio of Generic APIs primarily used for the treatment of Respiratory and Dermatological disorders as well as in Oncology. Exclusive, CDMO services are offered for the development and manufacturing of HPAs as well as for Biological products including monoclonal antibodies, recombinant proteins, Antibody Drug Conjugates (ADCs) and pharma probiotics.

FOR FURTHER INFORMATION, PLEASE CONTACT:

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