

## Calcipotriol Spray for Psoriasis

Lipidor has developed a sprayable formulation consisting of calcipotriol formulated in AKVANO® for treatment of mild to moderate psoriasis vulgaris (plaque psoriasis). The product is a hybrid generic to the originator Dovonex®/Daivonex® ointment and cream, a topical vitamin D derivative which reduces excessive skin cell production and therefore reduces the symptoms of psoriasis.

The positive results of the Phase I/IIa clinical trial resulted in a partnership with Cadila Pharmaceuticals who will perform the clinical Phase III study, with First Patient In in October 2018 and an estimated end of trial in Q3 2019.

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

### Phase III Study: First Patient In in October 2018

The clinical trial is designed to demonstrate therapeutic equivalence to the comparator product. The study is conducted at 10 centers in India involving 266 patients, with First Patient In in October 2018 and an estimated end of trial in Q3 2019. The protocol has been designed to enable market authorization in Europe and in the US.

The Calcipotriol Spray project is a cooperation between:

- Lipidor/Sweden: owner of product and the AKVANO delivery system
- Cerbios Pharma/Switzerland: API supplier, cGMP manufacturer of clinical material and cGMP stability testing
- Cadila Pharmaceuticals/India: Pharmaceutical company with CRO capability, responsible for the clinical phase III study.

### Facts

#### Product

A topical antipsoriatic AKVANO/Calcipotriol Spray

#### Indications

Mild to moderate psoriasis vulgaris (plaque psoriasis)

#### Active substance

Calcipotriol anhydrous 50 µg/g

#### Physical appearance

Sprayable clear liquid

#### Volume

20 or 30 ml

#### Container

Spray bottle (pump)

## Product Benefits

Benefits of Calcipotriol Spray compared to marketed products are mainly:

### Clinical benefits

- ✓ Dose accuracy and consistency
- ✓ Minimized risk of infection by non-touch application and inherently antiseptic properties
- ✓ Reduced skin irritation
- ✓ No need for additional creams/emollients
- ✓ Skin dehydration can be prevented
- ✓ Avoid getting the formulation on other parts of the body, e.g. finger tips, nails etc.

### Patient benefits

*Excellent cosmetic and convenience qualities for patients mean Calcipotriol Spray is likely to be preferred by patients ahead of ointments and creams:*

- ✓ Quick and simple to use, dries very quickly, invisible once dry.
- ✓ Has a pleasant feeling on the skin, non-greasy and non-sticky.
- ✓ No risk of greasy stains on clothes or bed clothes after evaporation.
- ✓ Allows non-touch application for sensitive skin.
- ✓ Allows for easy administration of the formulation on the back which may be inaccessible for self-treatment for some patients
- ✓ Antipsoriatic calcipotriol mono products are appreciated by patients seeking to avoid the systemic effects, as well as the skin atrophy effects, coming from the steroids present in Calcipotriol/Betamethasone combination products.
- ✓ AKVANO formulations do not require preservatives or other additional components that may cause skin irritation.
- ✓ Furthermore, AKVANO formulations reinforce the skin barrier function which render the skin less susceptible for irritation. Non-touch application also minimizes irritation for sensitive skin.
- ✓ The preferred properties of Calcipotriol Spray mean that it has the potential to increase compliance rates – leading to better efficacy outcomes and increasing the willingness of physicians to prescribe the treatment to new patients.

## The Market

Psoriasis is a chronic inflammatory skin disease, with a global prevalence of 2-4%. It is estimated that there are about 15 million patients diagnosed with psoriasis (mild, moderate or severe) in the US, Japan, and EU5 markets. The drug treated population in these markets is estimated to 8.2 million patients, of which about 6.9 million receive topical drug treatment. The vast majority of topical treatments contain calcipotriol, either as a mono product or as a combination product together with a corticosteroid.

Calcipotriol is a topical vitamin D derivative which reduces excessive skin cell production and therefore reduces the symptoms of psoriasis. It is manufactured as an ointment, cream or gel for psoriasis plaques on the body and as a lotion (solution) for scalp psoriasis. Dovonex® has historically been the most popular topical vitamin derivative in the psoriasis market thanks to proven efficacy and safety and is still considered the gold standard for topical treatments. Its market share has declined since 2007 due to generic entrants

consisting of lotions, creams and foam formulations, and the strategic launch by Leo Pharma of a newer product Dovobet®/ Daivobet®, a combination of calcipotriol and betamethasone.

Sales of Calcipotriol mono products amounted to about USD 204 million in 2015, while sales of Calcipotriol combination products amounted to about USD 530 million. For Calcipotriol mono products, US is the largest market with about 128 MUSD, followed by Europe, China and Japan. In Europe, sales have been affected by the fact that LEO Pharma has withdrawn Daivonex from several markets.

Dermatologists score Calcipotriol mono products highly and patients often receive such in combination with other treatments. Furthermore, Calcipotriol products are considerably less expensive than systemic and biologic therapies,

## Licensing Opportunity

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### 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 areas like pharmaceuticals, biocides, cosmetics and medical devices.

### About Lipidor AB

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.

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