News Release

FDA APPROVES SORILUX® FOR ADOLESCENT PLAQUE PSORIASIS

22 May 2019, Adelaide Australia: Mayne Pharma Group Limited (ASX: MYX) is pleased to announce that the US Food and Drug Administration (FDA) has approved SORILUX® (calcipotriene) Foam, 0.005% in adolescents.

SORILUX is now approved for treating plaque psoriasis of the scalp and body in patients aged 12 years and older.

The FDA approved SORILUX in 2010 based on evidence from two 8-week placebo controlled clinical trials in patients with mild to moderate plaque psoriasis of the body and one 8-week placebo controlled clinical trial in patients with moderate plaque psoriasis of the scalp. Further data was obtained in a follow-on open label study in patients aged 12 to 17 years of age with psoriasis.

SORILUX Foam contains calcipotriene, a synthetic vitamin D analog that has a similar receptor binding affinity as natural vitamin D. The exact mechanism of action contributing to the clinical efficacy is unknown.

Psoriasis is a chronic disease of the immune system affecting approximately 7.5 million Americans each year[1]. The most common form, plaque psoriasis affects roughly 80 percent of people who have the condition.

Mayne Pharma's CEO, Mr Scott Richards said "SORILUX is an elegant foam formulation that is marketed by Mayne Pharma's Specialty Brands sales team alongside recently launched LEXETTE™ (halobetasol propionate) Foam, a potent topical corticosteroid also used to treat plaque psoriasis in adult patients. Topical products are the mainstay of treatment for plaque psoriasis patients and the foam delivery platform has a well-established reputation with dermatologists due to ease of application and lack of greasiness and stickiness, especially in hair-bearing areas and under clothing."

Mayne Pharma directly markets more than 60 products in the US including four branded dermatology products FABIOR® (tazarotene) Foam, SORILUX Foam, DORYX® MPC (doxycycline hyclate) delayed-release tablets and LEXETTE Foam. The Company also markets TOLSURA® (SUBA®-itraconazole) capsules used to treat certain fungal infections which was recently approved and launched this year.

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[1] American Academy of Dermatology

About Mayne Pharma

At Mayne Pharma we believe that everyone deserves medicines that are better, safe and more affordable. That's why our people are determined to create innovative products and services for our changing world.

Mayne Pharma is an ASX-listed specialty pharmaceutical company focused on applying its drug delivery expertise to commercialize branded and generic pharmaceuticals. Mayne Pharma also provides contract development and manufacturing services to more than 100 clients worldwide.

Mayne Pharma has a 30-year track record of innovation and success in developing new oral drug delivery systems and these technologies have been successfully commercialized in numerous products that have been marketed around the world.

Mayne Pharma has two product development and manufacturing facilities based in Salisbury, Australia and Greenville, USA with expertise in formulation of complex oral and topical dose forms including potent compounds, modified-release products and inherently unstable compounds.

About SORILUX® (calcipotriene) Foam, 0.005%

SORILUX Foam contains calcipotriene, a synthetic vitamin D3 analogue. It is indicated for the topical treatment of plaque psoriasis of the scalp and body in patients aged 12 years and older.

Plaque psoriasis is a chronic, non-contagious, inflammatory skin condition that appears as red patches covered with silvery flakes often found on the elbows, scalp and knees but can also affect other parts of the body.

Important Safety Information

A thin layer of SORILUX Foam should be applied twice daily to the affected areas, and rubbed in gently and completely. SORILUX Foam is for topical use only, and is not for oral, ophthalmic, or intravaginal use. SORILUX Foam should not be used by patients who have elevated blood calcium levels (hypercalcemia).

The propellant in SORILUX Foam is flammable. Instruct the patient to avoid fire, flame, and smoking during and immediately following application. Transient, rapidly reversible elevation of serum calcium has occurred with use of calcipotriene. If elevation in serum calcium outside the normal range should occur, discontinue treatment until normal calcium levels are restored.

To report SUSPECTED ADVERSE REACTIONS, contact at Mayne Pharma at 1-844-825-8500 or FDA at 1 800-FDA-1088 or www.fda.gov/medwatch.

For more information about SORILUX, please refer to the prescribing information available here and SORILUXFoam.com.