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ASIA EDITION

FDA approves SORILUX(R) for Adolescent Plaque Psoriasis

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Mayne Pharma Group Limited has announced 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. The most common form, plaque psoriasis affects roughly 80 percent of people who have the condition.

Scott Richards, CEO, Mayne Pharma's 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.