News Release

# FDA APPROVES LEXETTE® FOR ADOLESCENT PLAQUE PSORIASIS

**Raleigh, N.C., September 21, 2021:** Mayne Pharma is pleased to announce that the U.S. Food and Drug Administration (FDA) has approved LEXETTE® (halobetasol propionate) foam, 0.05% for use in adolescents.

LEXETTE, a super potent topical corticosteroid, is now approved for the treatment of plaque psoriasis in patients aged 12 years and older.

The FDA approved LEXETTE in 2018 based on evidence from two multicentre, randomized, double-blind, vehicle-controlled studies (n=560) in patients with plaque psoriasis involving between 2% to 12% body surface area. Additional data were obtained in a follow-on open label study in patients aged 12 to 17 years of age with plaque psoriasis.

Psoriasis is a chronic inflammatory disease affecting approximately 8 million Americans each year and 1% of children and adolescents in the US[1]. The most common form, plaque psoriasis, affects roughly 80 percent of people who have the condition[2].

Mayne Pharma's CEO, Mr Scott Richards said "LEXETTE has been shown to be a safe and effective treatment option, and with this approval, we're pleased to offer LEXETTE to young people living with this challenging indication."

"Traditionally, the use of halobetasol has been limited by inconvenient vehicles, which decreased patient compliance, as well as by age and duration restrictions for super potent steroids," says Dr. Neal Bhatia, Director of Clinical Dermatology at Therapeutics Clinical Research in San Diego, one of the investigators in the Phase III study, and lead author for the publication on LEXETTE. "With the versatility and tolerability of the foam, LEXETTE offers the power of a super potent steroid and the potential to treat adolescents with more affected surface areas. Favorable results were demonstrated in the adolescent trial and were comparable to the foam's previously shown safety, efficacy, and tolerability in adults."

Mayne Pharma directly markets more than twenty dermatology products in the US including four branded products - FABIOR® (tazarotene) foam, SORILUX® (calcipotriene) foam, DORYX® MPC (doxycycline hyclate) delayed-release tablets, and LEXETTE foam together with a portfolio of generic products. These products treat a range of skin conditions including acne, atopic dermatoses, actinic keratoses, psoriasis, and rosacea.

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[1] National Psoriasis Foundation, psoriasis.org/psoriasis-statistics/; American Academy of Dermatology Association; Paller AS, Singh R, Cloutier M, et al. Prevalence of Psoriasis in Children and Adolescents in the United States: A Claims-Based Analysis. J Drugs Dermatol. 2018;17(2):187-194.
[2] American Academy of Dermatology Association

## About Mayne Pharma

*Mayne Pharma is focused on commercializing novel and generic pharmaceuticals, offering patients better, safe and more accessible medicines. The Company has an extensive dermatology and women's health portfolio in the US. Its parent company, Mayne Pharma Group Limited, is an ASX-listed specialty pharmaceutical company that has a 40-year track record of innovation and success in developing oral drug delivery systems. These technologies have been successfully commercialised in numerous products that continue to be marketed around the world.*

## About LEXETTE® (halobetasol) foam, 0.05%

*LEXETTE (halobetasol propionate) foam is a potent corticosteroid indicated for the topical treatment of plaque psoriasis in patients twelve years of age and older. LEXETTE foam was evaluated for the treatment of moderate to severe plaque psoriasis in two multicentre, randomised, double-blind, vehicle-controlled studies. These studies were conducted in 560 subjects with plaque psoriasis involving between 2% and 12% body surface area. A foam vehicle can have many benefits including being absorbed quickly without residue or greasiness and being easy to apply to both hair-bearing and non-hair bearing skin.*

## About Plaque Psoriasis

*Psoriasis is a chronic (life-long) skin condition. It occurs when the immune system "speeds up" the growth cycle of skin cells. A normal skin cell matures and falls off the body in about a month. For people with plaque psoriasis, it can take only three or four days for new skin cells to develop. Instead of falling off, the cells remain on the skin and form thickened patches (lesions or plaques). While plaque psoriasis is a chronic condition, many patients experience times when their symptoms improve or worsen.*

*Plaque psoriasis is the most common form of psoriasis. It typically causes raised, red lesions covered with silvery white scales. Plaque psoriasis can occur on any part of the body, but most commonly on the scalp, knees, elbows, and torso.*

## Important Safety Information

*LEXETTE foam is a topical corticosteroid that has been shown to suppress the hypothalamic-pituitary-adrenal (HPA) axis. Systemic effects of topical corticosteroids may include reversible HPA axis suppression, with the potential for glucocorticosteroid insufficiency. This may occur during treatment or upon withdrawal of treatment of the topical corticosteroid. The potential for hypothalamic-pituitary adrenal (HPA) suppression with LEXETTE Foam was evaluated in a study of 25 adult subjects with moderate to severe plaque psoriasis involving ≥15% of their body surface area. LEXETTE Foam produced laboratory evidence of HPA axis suppression when used twice daily for two weeks in 6 out of 25 (24%) adult subjects with plaque psoriasis. Recovery of HPA axis function was generally prompt with the discontinuation of treatment.*

*Systemic effects of topical corticosteroids may also include Cushing's syndrome, hyperglycemia, and glucosuria. Use of more than one corticosteroid-containing product at the same time may increase the total systemic exposure to topical corticosteroids.*

*Local adverse reactions from topical corticosteroids may include atrophy, striae, telangiectasias, burning, itching, irritation, dryness, folliculitis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, and miliaria. These may be more likely to occur with occlusive use, prolonged use, or use of higher potency corticosteroids, including LEXETTE Foam. Some local adverse reactions may be irreversible. Use of topical corticosteroids may increase the risk of posterior subcapsular cataracts and glaucoma.*

*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 LEXETTE, please refer to the prescribing information available here.*