



MAYNE PHARMA ACQUIRES FDA-APPROVED HALOBETASOL FOAM, COMPLEMENTING US DERMATOLOGY PORTFOLIO

26 October 2018, Adelaide, South Australia

- Mayne Pharma Group Limited ("Mayne Pharma" or "Company") (ASX: MYX) has acquired the FDA approved halobetasol foam 0.05% for an investment of up to US\$32.0 million and an ongoing earn out payment
 - Halobetasol foam is a highly complementary dermatology product treating plaque psoriasis that will be marketed through Mayne Pharma's existing Specialty Brands sales team
 - Expected to be accretive to earnings in the first full year following commercialisation (FY20)
 - New leadership talent on board to further drive and grow Specialty Brands
 - Mayne Pharma will fund the acquisition from cash and undrawn debt
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Mayne Pharma is pleased to announce it has acquired the US and Australian rights to halobetasol foam 0.05% for an investment of up to US\$32.0 million (comprising US\$10.0 million in cash up front, US\$5.0 million at commercial launch plus contingent payments of up to US\$17.0 million based on reaching cumulative net sales targets, patent issuance and potential capital spend to support the project). In addition, there is an ongoing earn-out payment based as a percentage of net sales over a 10-year period. Under the terms of the asset purchase, license and commercialisation agreement, Mayne Pharma has also acquired the approved US regulatory filing, medical and technical data, and a portfolio of pending US patent applications.

The product received US Food and Drug Administration approval in May 2018 and Mayne Pharma is planning for the commercial launch of this product in early 2019. The product received three years of marketing exclusivity and has four pending patent applications with the US Patent and Trademark Office.

Halobetasol foam is a potent corticosteroid used to treat plaque psoriasis. Plaque psoriasis affects approximately 7.5 million Americans with potent topical corticosteroids prescribed to approximately 80% of psoriasis patients diagnosed¹. The market for potent topical corticosteroids is estimated at US\$600m with approximately 10 million units sold per annum, of which halobetasol dosage forms (cream, ointment and lotion) account for US\$64 million and 0.8 million units². The halobetasol market has been growing 10% per annum over the last three years².

¹ American Academy of Dermatology Association, Company sponsored primary research

² IQVIA, Aug MAT 2018

Rationale for the acquisition

Commenting on the acquisition, Mayne Pharma's CEO, Mr Scott Richards said "Halobetasol foam is a new formulation that provides a highly desirable treatment option for patients in the management of plaque psoriasis. Adding halobetasol foam to our dermatology product portfolio is a major step forward in supporting psoriasis patients. We can now offer a potent steroid along with steroid-free Sorilux® for psoriasis treatment giving our patients more treatment options with the benefits of an elegant foam formulation."

"The acquisition broadens our pipeline of innovative dermatology products with strong growth potential, further diversifies earnings and strengthens Mayne Pharma's position in the US dermatology market. Halobetasol foam will be supported by our existing psoriasis focused sales team, leveraging existing commercial infrastructure across market access, customer service, medical affairs and supply chain."

In Australia, the Company will be seeking to register halobetasol foam with the Therapeutic Goods Administration (TGA) in 2019. In addition, the Company recently acquired the rest of world rights to Sorilux (calcipotriene) foam from GlaxoSmithKline and will also seek to file this product with the TGA in 2019 expanding further the portfolio of specialty products marketed in Australia.

Mayne Pharma anticipates spending approximately US\$4 million in FY19 to launch halobetasol foam and expects the product to be accretive to earnings in the first full year following commercialisation (FY20). Mayne Pharma expects peak sales potential to exceed US\$25 million.

New leadership talent on board to drive Specialty Brands

Brant Schofield has joined Mayne Pharma as Executive Vice President (EVP) of Specialty Brands. Brant brings more than 25 years of pharmaceutical industry experience including more than 15 years at Galderma Laboratories, a leading global dermatology and skin health company.

Previously, he was Vice President and General Manager Dermatology at Sandoz US where he was responsible for the brand and generic product portfolio with revenues of approximately US\$500m. Prior to Sandoz, he was Vice President of New Business for Nestlé Skin Health (parent entity of Galderma) and he was also Vice President of Sales and Marketing for Galderma US, where he led a 300+ person sales and marketing team and was responsible for more than US\$1.0b of sales across prescription, over-the-counter and aesthetic dermatology markets.

"I am extremely pleased that Brant Schofield has joined the leadership team at Mayne Pharma. Brant will be a valuable addition to our business, bringing a proven track record of success in commercialising and growing specialty product portfolios. Brant brings a wealth of experience across sales and marketing, strategy, finance, supply chain and business development activities. Our specialty product portfolio is poised for growth with the pipeline of products under development including the New Drug Application for SUBA®-Itraconazole capsules which the Company filed with the US Food and Drug Administration earlier this year as well as our on-market portfolio of dermatology products which have significant untapped potential."



ASX Announcement

Further information

Shareholders are advised to refer to the 'Acquisition of FDA-approved Halobetasol foam' presentation released to the ASX this morning for further details of the acquisition.

For further information contact:

Scott Richards +61 3 8614 7777
Lisa Pendlebury +61 419 548 434, lisa.pendlebury@maynepharma.com

About Mayne Pharma

Mayne Pharma is an ASX-listed specialty pharmaceutical company focused on applying its drug delivery expertise to commercialise branded and generic pharmaceuticals, providing patients with access to better and more affordable medicines. 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 commercialised 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 the formulation of complex oral dose forms including potent compounds, controlled substances, modified-release products and inherently unstable compounds.

About halobetasol foam

Halobetasol propionate topical foam is a corticosteroid indicated for the topical treatment of plaque psoriasis in patients eighteen years of age and older. Halobetasol 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 aqueous-based, absorbed quickly without residue or greasiness and 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.