

MAYNE PHARMA ACQUIRES GENERIC EFUDEX®, COMPLEMENTING US DERMATOLOGY PORTFOLIO

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- Mayne Pharma Group Limited (“Mayne Pharma”) (ASX: MYX) has acquired generic Efudex® (fluorouracil cream 5%) from Spear Pharmaceuticals, Inc. (“Spear”) for up to US\$30.0 million
 - Product is immediately EPS accretive with an implied acquisition EBITDA multiple in the low single digits
 - Mayne Pharma will fund the acquisition from cash and undrawn debt
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Mayne Pharma is pleased to announce it has completed the acquisition of generic Efudex (fluorouracil cream 5%) from Spear Pharmaceuticals, Inc. for US\$20.0 million (comprising US\$16.0 million in cash and US\$4.0 million in Mayne Pharma equity) plus contingent payments of up to US\$10.0 million. The deferred payments are contingent upon competitive dynamics in the product market over the next three years. The transaction also comprises a long-term supply agreement with the current US-based manufacturer, ensuring supply chain continuity. Mayne Pharma will commence supply to customers immediately.

Generic Efudex is an antineoplastic topical cream indicated for the treatment of multiple actinic or solar keratoses, and for the treatment of superficial basal cell carcinomas when conventional methods of treatment are impractical. Actinic Keratoses affects approximately 60 million Americans¹ with the main cause being cumulative sun exposure. Efudex cream 5% was originally approved by the US Food and Drug Administration (FDA) in 1970 and Spear is one of only two companies with a generic approval. According to IQVIA, the annual sales for generic Efudex were US\$66 million and volumes have been growing approximately 10% per annum over the last five years². Spear’s generic Efudex net sales were US\$3.0 million in the first quarter of calendar 2018³.

Rationale for the acquisition

Commenting on the acquisition, Mayne Pharma’s CEO, Mr Scott Richards said “We are pleased to add generic Efudex to our product portfolio. Fluorouracil cream will further diversify earnings and strengthen Mayne Pharma’s position in the US dermatology market. Generic Efudex has a strong strategic fit with Mayne Pharma’s portfolio of generic and branded dermatology products and will be supported by our existing dermatology commercial capability across sales and marketing, customer service and medical affairs. Importantly, the acquisition is expected to be immediately EPS accretive with modest incremental EBITDA in FY19.”

¹ Lewis Group. Burden of Skin Diseases. Prepared for the Society of Investigative Dermatology and the American Academy of Dermatology Association.

² IQVIA, May 2018

³ Unaudited sales data as provided by Spear



“We believe the acquisition is favourably structured by way of an upfront payment comprising cash and a scrip component and three potential deferred payments contingent on competitive market dynamics over the next three years. Mayne Pharma is committed to pursuing accretive transactions, such as this one, to deliver further value to its shareholders, particularly where we can leverage our existing commercial operations and know-how.”

For further information contact:

Lisa Pendlebury +61 419 548 434, lisa.pendlebury@maynepharma.com

Important Safety Information

Fluorouracil cream may cause fetal harm when administered to a pregnant woman. Fluorouracil is contraindicated in women who are or may become pregnant during therapy. If this drug is used during pregnancy, or if the patient becomes pregnant while using this drug, the patient should be apprised of the potential hazard to the fetus.

Fluorouracil cream should not be used in patients with dihydropyrimidine dehydrogenase (DPD) enzyme activity. A large percentage of fluorouracil is catabolized by the DPD enzyme. DPD enzyme deficiency can result in shunting fluorouracil to the anabolic pathway, leading to cytotoxic activity and potential toxicities.

Fluorouracil is also contraindicated in patients with known hypersensitivity to any of its components.

Application to mucous membranes should be avoided due to the possibility of local inflammation and ulceration. Additionally, cases of miscarriage and a birth defect (ventricular septal defect) have been reported when fluorouracil cream was applied to the mucous membrane areas during pregnancy.

The most frequent adverse reactions to fluorouracil cream occur locally and are often related to an extension of the pharmacological activity of the drug. These include burning, crusting, allergic contact dermatitis, erosions, erythema, hyperpigmentation, irritation, pain, photosensitivity, pruritus, scarring, rash, soreness and ulceration.

Please see full prescribing information for fluorouracil cream [here](#).

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.



About Mayne Pharma

Mayne Pharma is an ASX-listed specialty pharmaceutical company focused on applying its drug delivery expertise to commercialize 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 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 the formulation of complex oral dose forms including potent compounds, controlled substances, modified-release products and inherently unstable compounds.

For further information, visit maynepharma.com

Efudex® is a registered trademark of ICN Pharmaceuticals, Inc.