



## MAYNE PHARMA EXPANDS AUSTRALIAN DERMATOLOGY PORTFOLIO

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**21 June 2021, Adelaide Australia:** Mayne Pharma Group Limited (ASX: MYX) is pleased to announce it has licensed the Australian rights to SOLARAZE® (diclofenac sodium 3%) gel, and ACTIKERALL® (fluorouracil and salicylic acid, 0.5% / 10%) topical solution from Almirall, SA. Both products are approved by the Australian Therapeutic Goods Administration (TGA). In addition, Mayne Pharma has filed FABIOR® (tazarotene) foam, 0.1% with the TGA. FABIOR was acquired from GlaxoSmithKline and re-launched into the US dermatology market in 2016.

SOLARAZE and ACTIKERALL are indicated for the treatment of actinic keratosis (AK, also known as solar keratosis) which affects approximately 40-60% of Australians over the age of 40<sup>1</sup>. Australia has the highest incidence of AK globally with the main cause being long-term sun exposure<sup>2</sup>. SOLARAZE was launched in Australia in 2007 and has captured around 5% share of the \$18 million topical prescription AK market<sup>3</sup>. ACTIKERALL was approved in 2019 and is yet to be launched in Australia. The transfer of SOLARAZE full distribution rights has commenced and is expected to be completed by 1 July 2021 with ACTIKERALL transfer and launch planning already complete.

Associate Professor Peter Foley, Director of Research at Skin Health Institute said, “AKs are precancerous lesions that have the potential to transform into skin cancers. SOLARAZE is an effective therapy for multiple thin lesions of AK, whilst ACTIKERALL is effective for the treatment of palpable and/or moderately thick hyperkeratotic AK. Both products have been shown in clinical trials to be highly effective and well tolerated causing less irritation and inflammation of the skin compared with other currently available AK treatments.”

FABIOR is a topical retinoid indicated in the US for the treatment of acne in patients aged 12 years or older. Acne affects 2.5 million Australians or 12% of the population over the age of 20<sup>4</sup> and is common in teenagers with prevalence peaking at 93% of people aged 16-18 years<sup>5</sup>. The annual sales of topical prescription acne products in Australia were \$12m in 2020<sup>3</sup>.

Mayne Pharma’s CEO Scott Richards said, “We are pleased to partner with Almirall, a global biopharmaceutical company focused on skin health and expand our Australian portfolio with these new differentiated dermatology products. SOLARAZE and ACTIKERALL will be promoted by the existing Australian sales team focusing on dermatologists and general practitioners that specialise in skin cancer. Mayne Pharma looks forward to further broadening the Australian specialty portfolio in calendar 2022 with the potential commercialisation of FABIOR foam and NEXTSTELLIS® (E4/DRSP) an oral contraceptive, both pending at the TGA.”

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<sup>1</sup> Frost CA, Green AC. Epidemiology of solar keratoses. Br J Dermatol. 1994

<sup>2</sup> Chetty, P. et al. Dermatol. Ther. (Heidelb) 2015, 5: 19-35

<sup>3</sup> IQVIA, MAT sales, Dec 2020

<sup>4</sup> Plunkett A et al. Int J Dermatol 1999; 38: 901-908

<sup>5</sup> Kilkenny M, Merlin K, Plunkett A, Marks R. The prevalence of common skin conditions in Australian school students: 3. Acne vulgaris. Br J Dermatol 1998

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*Authorised for release to the ASX by the Chairman*

**About Mayne Pharma**

*Mayne Pharma is an ASX-listed specialty pharmaceutical company focused on commercialising novel and generic pharmaceuticals, offering patients better, safe and more accessible medicines. Mayne Pharma also provides contract development and manufacturing services to clients worldwide.*

*Mayne Pharma has a 40-year track record of innovation and success in developing new oral drug delivery systems. These technologies have been successfully commercialised in numerous products that continue to be marketed around the world.*

*Mayne Pharma has two facilities based in Salisbury, Australia and Greenville, NC, US with expertise in the formulation of complex oral and topical dose forms including potent compounds, modified-release products and poorly soluble compounds.*

*ACTIKERALL<sup>®</sup>, SOLARAZE<sup>®</sup> and NEXTSTELLIS<sup>®</sup> are registered trademarks of third parties.*

**About SOLARAZE<sup>®</sup>**

*SOLARAZE (diclofenac sodium) topical gel, 3%, contains the active ingredient, diclofenac sodium indicated for the management/treatment of AK.*

**About ACTIKERALL<sup>®</sup>**

*ACTIKERALL (fluorouracil and salicylic acid, 0.5% / 10%) is a patent protected topical solution indicated for the treatment of AK.*

**About Actinic Keratosis (AK)**

*AKs often appear as small, dry, scaly or crusty patches of skin found on sun-damaged skin. They may be red, light or dark tan, white, pink, flesh-toned or a combination of colours and are sometimes raised. The lesions frequently arise on sun-exposed areas of the face, lips, ears, scalp, shoulders, neck and the back of the hands and forearms. It is estimated around 10% of AKs turn into skin cancer. If detected early, AKs can be treated before they develop into skin cancer. The use of high sun protection factor sunscreen and sun protection measures is the most important preventative measure for AKs.*