



MAYNE PHARMA ADDS GENERIC ABSORICA® TO US DERMATOLOGY PORTFOLIO

29 September 2021, Adelaide Australia: Mayne Pharma Group Limited (ASX: MYX) is pleased to announce it has begun distribution of isotretinoin capsules, 10 mg, 20 mg, 30 mg and 40 mg in the United States. Isotretinoin capsules are a generic version of ABSORICA® indicated for the treatment of severe recalcitrant nodular acne.

According to IQVIA, the annual US market sales for isotretinoin capsules were US\$157 million for the twelve months ending July 2021¹. There is currently one other approved and marketed AB2-rated generic equivalent.

Mayne Pharma entered into a Private Label Supply and Distribution Agreement with Upsher-Smith Laboratories, LLC (Upsher-Smith) to distribute in non-retail channels isotretinoin capsules manufactured under the Upsher-Smith ANDA. Under the terms of this agreement, Mayne Pharma has access to the Upsher-Smith iPLEDGE REMS program supporting the fulfilment of product to patients.

Mayne Pharma's CEO Scott Richards said, "We are pleased to partner with Upsher-Smith, a trusted US based specialty pharmaceutical company with more than 100 years of history in formulating and manufacturing generic medicines. Implementing strategic partnerships and bringing specialty brands and generic products to the US market are fundamental to our company's continued growth."

"This dermatology partnership leverages our established commercial capabilities across sales and marketing, medical affairs and patient access and support. Mayne Pharma has extensive experience in launching new dermatology products, re-launching brands, transitioning brand franchises through genericisation and optimising market share. With more than a dozen branded and generic dermatology products we are proud to offer patients more affordable and accessible options to treat their skin conditions."

"Mayne Pharma continues to have active discussions with a number of third parties around potential future product collaborations that will continue to add breadth to our offering in our therapeutically aligned markets in dermatology, women's health and infectious disease."

Upsher Smith's President and CEO, Rusty Field said, "The launch of isotretinoin capsules marks an important milestone as we continue to grow and diversify our product portfolio. Our supply and distribution agreement with Mayne Pharma has the potential to significantly impact this market given the company's established network of healthcare professionals and vast experience in this market."

¹ IQVIA, MAT Sales



ASX Announcement

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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.

ABSORICA® is a registered trademark of a third party.

About isotretinoin oral capsules

Isotretinoin capsules is a prescription medicine used in patients 12 years of age and older, who are not pregnant, for the treatment of severe acne (nodular acne) that cannot be cleared up by any other acne treatments, including antibiotics.

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 isotretinoin capsules, please refer to the prescribing information available [here](#).

