ASX Announcement

MAYNE PHARMA PROVIDES FDA UPDATE ON GENERIC NUVARING®

7 October 2021, Adelaide Australia: Mayne Pharma Group Limited (ASX: MYX) has received a complete response letter (CRL) from the US Food and Drug Administration (FDA) in relation to its abbreviated new drug application (ANDA) for a generic version of NUVARING®.

Mayne Pharma is working closely with its development partner, Mithra Pharmaceuticals, SA (Mithra) and the FDA to address the questions raised in the CRL. Following submission of the response to the CRL, Mayne Pharma will receive a new target action date from the FDA.

Mayne Pharma's CEO Scott Richards said, "We are now one step closer to approval and are confident that we can address the few remaining outstanding questions raised by the FDA in a timely manner. Pleasingly, the FDA had no questions around Mithra's facility, the drug product manufacturing process, drug substance or bioequivalence. The market opportunity continues to be attractive with two independent generics approved and an addressable market of US$670m[1].

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Authorised for release to the ASX by the Chair

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.

[1] IQVIA MAT Sales, August 2021