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ASX Announcement

MAYNE PHARMA PROVIDES UPDATE ON WOMEN'S HEALTH PIPELINE

6 October 2020, 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, and the FDA to address the questions raised in the CRL. Following submission of the response to the CRL, Mayne Pharma will then receive a new target action date from the FDA.

Mayne Pharma's CEO Scott Richards said, "We are confident we can address the issues raised in the letter in a timely manner. Pleasingly, the FDA has indicated that Mayne Pharma and its development partner Mithra have an acceptable manufacturing process for generic NUVARING. Furthermore, the market opportunity continues to be highly attractive with only one independent generic approved and an addressable market of US$920m[1]."

The company also recently participated in a mid-cycle review meeting with the FDA regarding the New Drug Application (NDA) for NEXTSTELLIS™ to prevent pregnancy. The FDA did not raise any substantive issues at the meeting and indicated that no major safety concerns have been noted at this point in their review.

"The NEXTSTELLIS mid-cycle review meeting with the FDA provided us with some insights into the review process so far, and we are pleased that no significant issues and no major safety concerns were raised. This meeting marks the halfway point of the NEXTSTELLIS NDA review process, and with approximately six months until the PDUFA date, we continue to advance our US commercial strategy and infrastructure to support the potential launch of this novel contraceptive in the first half of calendar 2021."

The Company has also received a CRL on its potential first-to-market women's health generic product with an addressable market of US$160m[1]. Importantly, the FDA has found all key disciplines of the ANDA adequate with the exception of the packaging facility which was assessed by a desk-top audit rather than an in-person inspection due to COVID-19. Mayne Pharma is working closely with the FDA and its development partner to close out this application as soon as possible.

For further information contact:
Lisa Pendlebury (VP Investor Relations & Communications)
+61 419 548 434, lisa.pendlebury@maynepharma.com

Authorised for release to the ASX by the Chairman

[1] IQVIA MAT Sales, August 2020

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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, offering patients better and more accessible medicines. Mayne Pharma also provides contract development and manufacturing services to more than 100 clients worldwide.

Mayne Pharma has a 40-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 continue to be marketed around the world.

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

NEXTSTELLIS™ and NUVARING® are registered trademarks of third parties.