ASX Announcement

NEW DATA SHOW NEXTSTELLIS™ HAS SELECTIVE IMPACT ON ENDOCRINE MARKERS COMPARED WITH COMMON COMBINED ORAL CONTRACEPTIVES

Results presented at the annual meeting of the International Society for the Study of Women's Sexual Health

8 March 2021, Adelaide Australia: Mayne Pharma Group Limited (ASX: MYX) announced today new data showing treatment with NEXTSTELLIS™, [1] a novel, investigational combined oral contraceptive (COC) containing estetrol (E4) and drospirenone (DRSP), resulted in limited changes in endocrine markers, including lower increases in hormone binding globulins, compared with COCs based on ethinyl-estradiol (EE), the synthetic estrogen used in all but one of the marketed COCs. The data was presented at the annual meeting of the International Society for the Study of Women's Sexual Health (ISSWSH), held virtually in the U.S. from March 5-7.

"When prescribing COCs, practitioners must have a good understanding of how these therapies may impact other hormones in the body in order to make an informed prescribing decision for their patients," said Andrew London, M.D., Assistant Professor of OB/GYN, at The Johns Hopkins School of Medicine. "Based on our findings, treatment with E4/DRSP has limited effects on some of these endocrine parameters compared to the tested EE-containing products, giving E4/DRSP a different and potentially favorable endocrine profile compared to those EE-based COCs ."

"This exciting new data adds to the solid safety and tolerability profile of NEXTSTELLIS and the growing body of clinical evidence that this unique combination with a new form of estrogen, may be a promising novel oral contraceptive option for women," said Scott Richards, CEO, Mayne Pharma.

Abstract

Estetrol Combined with Drospirenone: An Investigational Oral Contraceptive With A Selective Impact on Endocrine Parameters – Abstract ID 013.

About NEXTSTELLIS™

Developed by Mayne Pharma's development and manufacturing partner Mithra Pharmaceuticals SA, NEXTSTELLIS™ is a novel, investigational combined oral contraceptive pill containing 15 mg estetrol (E4) and 3 mg drospirenone (DRSP). E4 is a naturally occurring estrogen that is produced by the human fetal liver during pregnancy and can now be produced from a plant source. In June 2020, the U.S. Food and Drug Administration (FDA) accepted for review a New Drug Application (NDA) submitted by Mayne Pharma for NEXTSTELLIS to prevent pregnancy. The NDA submission included results from two phase 3 clinical studies conducted in more than 3,725 women aged 16 to 50 years. If approved, NEXTSTELLIS would be the first contraceptive product containing E4 and the first new estrogen introduced in the U.S. for contraceptive use in approximately 50 years.

[1] NEXTSTELLIS™ trade name conditionally accepted by the FDA

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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 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™ is a registered trademark of a third party.