ASX Announcement

E4/DRSP PRESENTED AT THE EUROPEAN SOCIETY OF GYNECOLOGY

23 October 2019, Adelaide Australia: Mayne Pharma Group Limited (ASX: MYX) is pleased to announce that Mithra Pharmaceuticals, SA (Mithra) has presented its phase 3 trial results for E4/DRSP oral contraceptive at the 13th Annual Meeting of the European Society of Gynecology (ESG) in Vienna, Austria. In addition, there were several oral presentations and poster presentations at the ESG conference relating to Estetrol (E4) a new and novel estrogen.

E4/DRSP is a next generation combined oral contraceptive composed of 15 mg Estetrol (E4) and 3 mg drospirenone (E4/DRSP). Top-line results for the phase 3 studies in Europe/Russia and US/Canada were announced August 2018 and January 2019 respectively. A total of 3,725 women were included in the two studies and showed positive top-line results against primary efficacy and safety endpoints and achieved positive secondary endpoints including good bleeding profile, cycle control, and tolerability. On 2 October 2019, Mayne Pharma announced signing a 20-year exclusive supply and license agreement with Mithra to commercialise E4/DRSP in the US in the field of oral contraception.

Estetrol (E4) is a native estrogen produced by the human foetal liver during pregnancy and is also present in the mother at growing concentrations during the gestation period. Mithra can now produce Estetrol at scale through a complex plant-based production process. If approved, Estetrol (E4) will be the first native estrogen approved in a contraceptive product in the US and the first new estrogen introduced in the US in approximately 50 years.

There was one opening symposium with four presentations, one oral presentation and three poster presentations related to Estetrol (E4) at the ESG conference.

Abstracts:

- Contraceptive efficacy and bleeding pattern of a new combined oral contraceptive containing Estetrol 15 mg and drospirenone 3 mg – phase 3 trial results – Abstract ID 8840;
- Estetrol 15 mg combined with drospirenone 3 mg is an effective oral contraceptive: results from the E4Freedom EU/RU phase 3 trial - Abstract ID 9027;
- Excellent cycle control of an Estetrol 15 mg and drospirenone 3 mg combined oral contraceptive in the E4Freedom EU/RU phase 3 trial - Abstract ID 9030; and
- E4Relief: a phase 2b study with Estetrol (E4), the next generation hormone therapy for menopausal symptoms - Abstracts ID 9049.

Mayne Pharma CEO, Mr Scott Richards said, “The data presented at the ESG conference in Vienna showcases the strong efficacy and safety profile of E4/DRSP as a novel, next generation combined hormonal contraceptive. I am excited about this innovative contraceptive product with its unique mode of action that phase 2 and phase 3 studies suggest could result in improved patient outcomes. Estetrol (E4) is the first native estrogen with selective actions in tissues and has potential application in various fields including contraception and menopause. E4/DRSP oral contraceptive is expected to be commercialised in the first half of calendar 2021, subject to US FDA approval.”

President of the European Society of Gynecology, Professor Andréa Genazzani commented, "Clinical results are excellent and were eagerly awaited by the scientific community here in Vienna. Estetrol is a major innovation potentially offering an improved benefit-risk profile."

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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.