

## MAYNE PHARMA AND MITHRA ANNOUNCE TGA APPROVAL OF NEXTSTELLIS® ORAL CONTRACEPTIVE

---

**29 November 2021, 08:45, Adelaide, Australia and Liege, Belgium** - Mayne Pharma Group Limited (ASX: MYX) and Mithra Pharmaceuticals, SA (Euronext Brussels: MITRA) are very pleased to announce the Therapeutic Goods Administration (TGA) has approved the novel combined oral contraceptive NEXTSTELLIS® (14.2 mg of estetrol and 3 mg drospirenone tablets). Mayne Pharma anticipates the commercial launch of NEXTSTELLIS by mid-2022 supported by healthcare professional market education from January 2022.

Developed by Mithra Pharmaceuticals, NEXTSTELLIS is a first-of-its-kind contraceptive pill containing a new low impact estrogen derived from a plant source - estetrol (E4) and the proven progestin - drospirenone (DRSP). E4 is a natural estrogen produced by the human body during pregnancy. Containing a new chemical entity (NCE), NEXTSTELLIS will receive 5 years of market exclusivity.

The Australian contraceptive market is valued at circa EUR 80 million (A\$125 million) with the short-acting combined (estrogen and progestin) oral contraceptive market worth over A\$65 million<sup>1</sup>.

**Mayne Pharma's CEO Mr Scott Richards said:** *"We are pleased to be introducing NEXTSTELLIS to the Australian market. It has been 10 years since Australian women have had a new contraceptive hormone to consider with their doctor. NEXTSTELLIS offers an effective, safe and well-tolerated pill with excellent cycle control and has demonstrated low impact on certain parts of the body. Mayne Pharma is committed to women's health and launching innovative products to meet the needs of Australian and American women."*

**Sexual Health physician, Dr Terri Foran, said:** *"Combined oral contraceptives continue to be the most widely used method of hormonal birth control in Australia and every clinician knows that each woman responds differently to contraceptive hormones. This is why it is so important that we have a range of contraceptive options so we can individualise that choice. Today we have a wide range of progestins available, but the choice of estrogen has been limited to ethinylestradiol or estradiol. Having another estrogen, estetrol (E4), opens up the possibility that more women will be able to find a combination that suits them. Research indicates that estetrol is more selective in its impact on various hormonally receptive tissues in the female body. While it has the desired effects on the genital system necessary for an effective combined contraceptive, it appears to have potentially less effect on the liver and the breast."*

**Mithra's CEO Mr Leon Van Rompay said:** *"After the US, Canada and Europe, we are delighted to receive this additional approval for our innovative contraceptive, confirming a commercial launch on a third continent. This fourth major approval obtained this year, is perfectly in line with our schedule, allowing us to cover more than 80% of the targeted territory. This further demonstrates the strong expertise of our teams and the strength of our collaboration with Mayne Pharma, which makes NEXTSTELLIS' commercial launch a top priority."*

---

<sup>1</sup> IQVIA, MAT Sales December 2020

**For further information contact:****Mayne Pharma**

Lisa Pendlebury (VP Investor Relations & Communications)  
+61 419 548 434 - [lisa.pendlebury@maynepharma.com](mailto:lisa.pendlebury@maynepharma.com)

**Mithra**

Benoît Mathieu (Investor) : +32 473 35 80 18 - [investorrelations@mithra.com](mailto:investorrelations@mithra.com)  
Maud Vanderthommen (Press) : +32 473 58 61 04 – [press@mithra.com](mailto:press@mithra.com)

*Authorised for release to the ASX by the Chair.*

**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, safe 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.*

**Mayne Pharma Group Limited**

ABN 76 115 832 963

[maynepharma.com](http://maynepharma.com)

1538 Main North Road, Salisbury South, SA 5106 Australia

**About Mithra**

*Mithra (Euronext: MITRA) is a Belgian biotech company dedicated to transforming Women's Health by offering new choices through innovation, with a particular focus on contraception and menopause. Mithra's goal is to develop products offering better efficacy, safety and convenience, meeting women's needs throughout their life span. Mithra explores the potential of the unique native estrogen Estetrol in a wide range of applications in women health and beyond. Mithra also develops and manufactures complex therapeutics in the areas of contraception, menopause and hormone-dependent cancers. It offers partners a complete spectrum of research, development and specialist manufacturing at its technological platform Mithra CDMO. Active in more than 100 countries around the world, Mithra has an approximate headcount of 300 staff members and is headquartered in Liège, Belgium. [www.mithra.com](http://www.mithra.com)*

**About NEXTSTELLIS®**

*Developed by Mithra, NEXTSTELLIS is a novel, patent-protected combined oral contraceptive pill containing 14.2 mg estetrol (E4) and 3 mg drospirenone (DRSP). E4 is a naturally produced estrogen during pregnancy, that's derived from a plant source. In two phase 3 clinical studies conducted in 3,632 women, NEXTSTELLIS was shown to be both safe and effective and met its primary endpoint of pregnancy prevention. It also delivered positive results on a variety of secondary endpoints that demonstrated excellent cycle control, bleeding pattern, safety and tolerability, and low rates of adverse reactions.*

*Mayne Pharma has a 20-year license and supply agreement in the US and Australia for NEXTSTELLIS.*

*NEXTSTELLIS is a registered trademark of a third party.*