

## NEXTSTELLIS® ORAL CONTRACEPTIVE NOW AVAILABLE IN THE UNITED STATES

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**21 June 2021, Adelaide, Australia and Liege, Belgium:** Mayne Pharma Group Limited (ASX: MYX) and Mithra Pharmaceuticals, SA (Euronext Brussels: MITRA) are very pleased to announce the US commercial launch of NEXTSTELLIS® (3 mg drospirenone and 14.2 mg estetrol (E4) tablets), a new oral contraceptive with a novel estrogen having a unique mechanism of action.

NEXTSTELLIS was approved by the FDA in April 2021 and is the first and only pill containing E4, a natural estrogen produced during pregnancy that is now synthesised from a plant source. E4 is the first new estrogen introduced in the US in over 50 years.

NEXTSTELLIS will compete in the short-acting combination hormonal contraceptive (estrogen and progestin) market which is valued at US\$3.5 billion<sup>1</sup>. Nearly 10 million American women use combination oral contraceptives, patches or vaginal rings every day. Of these contraceptives, more than 99% contain ethinyl estradiol, a synthetic estrogen that binds widely to all estrogen receptors in the body.

E4 acts differently than other estrogens and is the first natural estrogen with selective action in tissues focusing on those needed to support contraceptive efficacy, cycle control, and other beneficial effects of estrogen. Its unique pharmacologic profile includes excellent oral bioavailability and a long half-life<sup>2</sup>.

“We are delighted to launch NEXTSTELLIS, a new birth control option for women and their healthcare providers. Every woman’s body reacts differently to hormones and so from today, American women will now have a new choice of estrogen to consider when thinking about birth control options,” **said Mayne Pharma’s CEO, Mr. Scott Richards.** “Our key priorities with this launch are to educate the market on the benefits of NEXTSTELLIS and the new estrogen E4, gain broad payor acceptance and reimbursement, and ultimately become the preferred branded oral contraceptive in the market. The launch is supported by a highly experienced national Women’s Health sales team that is now actively promoting NEXTSTELLIS to healthcare providers.”

**Mithra’s CEO Mr. Leon Van Rompay said,** “The launch of NEXTSTELLIS today represents a new era in contraception and we are proud to have played a part in helping to support women and their healthcare providers in their contraceptive choices. Mithra is excited to see the commercialisation of NEXTSTELLIS in the world’s largest pharmaceutical market.”

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<sup>1</sup> IQVIA, MAT Sales, April 2021

<sup>2</sup> Coelingh Bennink HJ, et al. *Climacteric*. 2008;11(suppl 1):47-58; Visser M, et al. *Climacteric*. 2008;11(suppl 1):31-40; Clinical study report MIT-Es0001-C103; Coelingh Bennink HJ, et al. *Climacteric*. 2008;11(suppl 1):2-14.

**About NEXTSTELLIS®**

Developed by Mithra, NEXTSTELLIS is a novel, patent-protected combined oral contraceptive pill containing 3 mg drospirenone (DRSP) and 14.2 mg estetrol (E4). E4 is an estrogen naturally produced during pregnancy that can now be made from a plant source. In two phase 3 clinical studies conducted in 3,725 women, NEXTSTELLIS was shown to be both safe and effective in meeting its primary efficacy endpoint of pregnancy prevention. It also met a variety of secondary endpoints that demonstrated favourable cycle control, bleeding pattern, safety, and tolerability.

Mayne Pharma has a 20-year exclusive license and supply agreement in the US and Australia for NEXTSTELLIS. The product has not yet been approved in Australia but is under review at the Australian Therapeutics Goods Administration (TGA). The full US prescribing information for NEXTSTELLIS can be found [here](#).

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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 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 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, 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**

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**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 (Covid-19, neuroprotection...). 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)*

**Mithra Pharmaceuticals**

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