

## NEXTSTELLIS® RECEIVES FDA MARKETING EXCLUSIVITY AND PHASE III DATA PUBLISHED

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**27 May 2021, 07:30 CEST - Adelaide, Australia and Liege, Belgium** - Mayne Pharma Group Limited (ASX: MYX) and Mithra Pharmaceuticals, SA (Euronext Brussels: MITRA) are very pleased to announce that the novel oral contraceptive Estelle® - under the trademark Nextstellis®<sup>1</sup> (3 mg drospirenone and 14.2 mg estetrol (E4) tablets) - has been granted marketing exclusivity as a new chemical entity (NCE) from the US Food and Drug Administration (FDA). The exclusivity runs for five years from FDA approval of the New Drug Application for Nextstellis.

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 made from a plant source. E4 is the first new estrogen introduced in the US in more than 50 years.

A [new article](#) has been published in *Contraception* – an international, peer-reviewed reproductive health journal - with the results of the Nextstellis North American Phase III clinical study involving nearly 2,000 women. The publication concluded that Nextstellis is an effective oral contraceptive with a predictable bleeding pattern for most women and has low rate of adverse events.

In addition to efficacy and safety, a predictable bleeding pattern is another key consideration for women and their healthcare providers. Bothersome breakthrough bleeding is a common side effect of hormonal contraception and can often lead to discontinuation of contraceptives. Unscheduled bleeding occurred in less than 2% of patients after cycle 2 (bleeding only) with less than 1 day of unscheduled bleeding or spotting on average per cycle after cycle 1.

*“Nextstellis demonstrated contraceptive efficacy regardless of age or contraceptive history with low adverse events and favourable body-weight control. Most noticeable was the lack of venous thromboembolic (VTE) events among the 1,864 women who participated in this study<sup>2</sup>,” said Dr. Mitchell Creinin, M.D., Professor and Director of Family Planning at the University of California, Davis. “For women taking birth control, unscheduled bleeding is one of the main reasons cited for stopping or switching to an alternate contraceptive. The bleeding pattern seen with Nextstellis was regular and predictable for most women - with low rates of unscheduled bleeding even at cycle 1 - providing clinicians with another important option when patients are concerned about breakthrough bleeding.”*

**Mayne Pharma’s CEO, Mr. Scott Richards said:** *“We are pleased to see the clinical trial results for Nextstellis being reported in the renowned journal Contraception. This data validates Nextstellis as being a new and innovative oral contraceptive which is safe and effective and that combines a natural estrogen (E4) with selective tissue actions together with the proven progestin drospirenone. Women now have the option of using a contraceptive pill that offers the anti-androgenic, anti-mineralocorticoid, and long half-life benefits of drospirenone together with an estrogen that also has a long half-life and has*

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<sup>1</sup> NEXTSTELLIS® is a registered trademark of a third party.

<sup>2</sup> Large phase 4 studies will be needed to confirm the phase 3 findings that suggest NEXTSTELLIS use is associated with low clinical thrombosis risk.

a low impact on hemostasis and endocrine biomarkers, as well as on lipids, and glucose<sup>3</sup>."

**Mithra's CEO Mr. Leon Van Rompay said:** "The publication of these pivotal data is a testament to the extraordinary efforts of the Mithra team to develop a novel and effective contraceptive with a favourable safety profile. Sharing this data in a renowned peer-reviewed journal ensures clinicians have the most comprehensive information about Nextstellis and underlines our commitment to transparency and scientific rigor."

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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, 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.

### 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)

### About Estelle®

Developed by Mithra, Estelle® is a novel patent protected combined oral contraceptive pill containing 3 mg drospirenone (DRSP) and 15 mg estetrol (E4). E4 is a naturally produced estrogen during pregnancy, which can now be made from a plant source. In two phase 3 clinical studies conducted in 3,725 women, Estelle® was shown to be both safe and effective and met its primary efficacy endpoint of pregnancy prevention. It also delivered excellent results on a variety of secondary endpoints that demonstrated outstanding cycle control, bleeding control, safety, and

<sup>3</sup> Mawet M, et al. Eu J Contra Rep Hlth Care. 2015; 20, 463-475; Douxfils, J et al. Contraception. 2020; 102, 396-402; Klipping C et al. Contraception. 2021; 103, 213-221



## Joint Press Release



*tolerability. Mithra has signed 15 licensing deals for Estelle® with a number of leading women's health companies covering more than 100 countries in the world.*