

Joint Press Release



NEXTSTELLIS® ORAL CONTRACEPTIVE NOW AVAILABLE IN AUSTRALIA

26 July 2022, Adelaide, Australia and Liege, Belgium - Mayne Pharma Group Limited (ASX: MYX) and Mithra Pharmaceuticals, SA (Euronext Brussels: MITRA) are pleased to announce NEXTSTELLIS® (14.2 mg of estetrol and 3 mg drospirenone tablets), a first-of-its kind oral contraceptive with a novel estrogen is now available in Australia.

NEXTSTELLIS was approved by the Therapeutic Goods Administration (TGA) in November 2021 and is the first and only contraceptive pill containing a new low impact¹ estrogen, estetrol (E4), and a progestin, drospirenone. E4 is a natural estrogen produced by the human body during pregnancy and in NEXTSTELLIS, E4 is derived from a plant source.

NEXTSTELLIS will compete in the Australian combined (estrogen plus progestin) oral contraceptive market which is valued at A\$60 million². Combined oral contraceptives continue to be the most common method of contraception with nearly 1 million Australian women using them.

Mayne Pharma's CEO Mr Scott Richards said: "We are delighted to introduce NEXTSTELLIS to the Australian market. NEXTSTELLIS offers an effective, safe, and well-tolerated contraceptive pill with predictable cycle control and has demonstrated low impact on certain parts of the body. The launch will be supported by an expanded national GP/specialist sales team that are now educating healthcare professionals on the unique characteristics of E4."

Mithra's CEO Mr Leon Van Rompay said: "NEXTSTELLIS unlocks a new era in contraception offering women and their healthcare providers a next generation birth control pill. Every woman's body responds differently to contraceptive hormones and having a new estrogen available – E4 – opens up the possibility that more women will be able to find a combination that suits them. Mithra is excited to see the commercialisation of NEXTSTELLIS on a third continent."

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Authorised for release to the ASX by the Chair.

² IQVIA, MAT Sales December 2021

¹ Based on its selectivity, potency, pharmacokinetics, mechanism of action and impact on the liver



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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 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.

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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. 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

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 NEXTSTELLIS. 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 a predictable bleeding pattern with good safety and tolerability, as well as low rates of adverse reactions.

Mayne Pharma has a 20-year license and supply agreement in the US and Australia for NEXTSTELLIS. The full Australian prescribing information for NEXTSTELLIS can be found here.

NEXTSTELLIS is a registered trademark of Estetra SRL, a Mithra Pharmaceuticals affiliates company.