Joint Press Release

MAYNE PHARMA AND MITHRA ANNOUNCE FDA APPROVAL OF NEW ORAL CONTRACEPTIVE NEXTSTELLIS®

16 April 2021, 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 US Food and Drug Administration (FDA) has approved the New Drug Application (NDA) for the novel combined oral contraceptive NEXTSTELLIS® (3 mg drospirenone (DRSP) and 14.2 mg of estetrol (E4) tablets). Mayne Pharma anticipates the commercial launch of NEXTSTELLIS by the end of June 2021.

Developed by Mithra, NEXTSTELLIS is the first and only contraceptive pill containing estetrol, a native estrogen, now produced from a plant source. Estetrol is the first new estrogen introduced in the US in more than 50 years.

Nearly 10 million American women use short-acting combination (estrogen and progestin) contraceptives. The US market for combined hormonal contraceptives generated US$3.6 billion in sales according to IQVIA for the 12-month period ending January 2021[1].

Mitchell Creinin, Professor and Director of Family Planning at the University of California said "When speaking with patients about their contraceptive options, one of the most common concerns is side effects. NEXTSTELLIS is a new innovative contraceptive that has been shown in clinical trials to be not only safe and effective but also well tolerated with a desirable bleeding profile and minimal impact on triglycerides, cholesterol and glucose, as well as weight and endocrine markers."

Mayne Pharma's CEO, Scott Richards said "The approval of NEXTSTELLIS represents an important milestone, providing women with a new choice for their reproductive health. We are delighted to be introducing a new estrogen and bringing to market this novel, safe and effective option for women to consider with their healthcare providers."

As a result of receiving FDA approval for NEXTSTELLIS, Mayne Pharma will pay Mithra US$11m in cash and issue 85.8m ordinary Mayne Pharma shares. Mithra is also entitled to a Mayne Pharma Board position. The new appointment will be subject to shareholder approval at the next Annual General Meeting in November 2021.

Mithra's CEO Leon Van Rompay said "We are very proud that our teams achieved this important milestone for the commercialisation of NEXTSTELLIS in the world's largest pharmaceutical market. We look forward to working closely with our partner Mayne Pharma to make this commercial launch a success. The approval of NEXTSTELLIS represents a huge achievement for a biotech company such as Mithra and all the teams who made this ambitious project come to fruition. This is a critical step in Mithra's journey to bring innovative medicines to the US women's health market. We believe the approval of NEXTSTELLIS represents a new era in contraception and demonstrates the potential of our E4 portfolio."

[1] IQVIA, MAT Sales January 2021

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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 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, NEXTSTELLIS 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 tolerability.

Mayne Pharma has a 20-year exclusive license and supply agreement in the US and Australia for NEXTSTELLIS. The product is under active review at the Australian Therapeutics Goods Administration (TGA).

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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 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.

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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

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