Joint Press Release

MAYNE PHARMA AND MITHRA ANNOUNCE FDA APPROVAL OF HALOETTE®, A GENERIC VERSION OF NUVARING®

8 August 2022, Adelaide, Australia and Liege, Belgium: Mayne Pharma Group Limited (ASX: MYX) and Mithra Pharmaceuticals, SA (Euronext Brussels: MITRA) are pleased to announce that the US Food and Drug Administration (FDA) has granted approval of the Abbreviated New Drug Application (ANDA) for HALOETTE® (etonogestrel and ethinyl estradiol) vaginal hormonal contraceptive ring. Mayne Pharma anticipates the commercial launch of HALOETTE® ring by early calendar year 2023.

HALOETTE® contraceptive is a generic version of NUVARING®, a combined hormonal contraceptive flexible ring that combines etonogestrel and ethinyl estradiol and is indicated for the prevention of pregnancy. According to IQVIA, NUVARING® US brand and generic sales were approximately US$580 million for the 12 months ended June 2022[1].

Under the terms of the long-term license and supply agreement, Mayne Pharma will pay Mithra EUR 6 million as a result of receiving FDA approval and EUR 1.6 million upon commercial launch in the US. Mithra will manufacture HALOETTE® at its contract development and manufacturing organisation (CDMO) facility in Belgium.

Mayne Pharma's CEO Mr Scott Richards said: "We are very pleased to announce the approval of HALOETTE® in the US and look forward to bringing this drug-device generic to market. Mayne Pharma is proudly committed to providing women with more affordable and accessible contraceptive choices. After the approval of NEXTSTELLIS® oral contraceptive in the US and Australia, this marks the third regulatory product approval we have received with Mithra as our development partner."

Mithra's CEO Mr Leon Van Rompay said: "This important milestone highlights Mithra's world class drug development and manufacturing capabilities to develop a complex drug-device pharmaceutical. We are thrilled to manufacture HALOETTE® ring at our Mithra CDMO and to support the launch of this affordable contraceptive alternative in the US, the world's largest pharmaceutical market."

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For further information contact:

Mayne Pharma
Lisa Pendlebury (VP Investor Relations & Communications)
+61 419 548 434 - lisa.pendlebury@maynepharma.com

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

Authorised for release to the ASX by the Mayne Pharma Chair

[1] Actual market sales are expected to be significantly smaller than IQVIA sales due to off-invoice discounts and rebates

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 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. maynepharma.com

Mayne Pharma Group Limited

ABN 76 115 832 963

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. mithra.com

About HALOETTE® (etonogestrel and ethinyl estradiol) vaginal ring

HALOETTE® contraceptive is indicated for use by females of reproductive age to prevent pregnancy. The flexible birth control ring is inserted in the vagina and is to remain in place for 3 weeks (21 days). It is removed for one week (7 days) and a new vaginal ring is inserted on the same day of the week it was inserted in the previous cycle. Etonogestrel and ethinyl estradiol vaginal ring contains a combination of a progestin and estrogen, 2 kinds of female hormones. Birth control methods that contain both an estrogen and a progestin are called combination hormonal contraceptives (CHCs).