Mithra Announces FDA Filing Acceptance of New Drug Application for Estelle® in the US

Liege, Belgium, 24 June 2020 – 7:30 CEST – Mithra (Euronext Brussels: MITRA), a company dedicated to Women's Health, today announces the New Drug Application (NDA) for Estelle® has been accepted for review by the US Food and Drug Administration (FDA). The FDA is expected to complete its review in the first half of calendar 2021.

Developed by Mithra, the product candidate is composed of 15 mg Estetrol (E4) and 3 mg drospirenone (DRSP). E4 is a naturally occurring estrogen that is produced by the human foetal liver during pregnancy. Following many years of research and development, Mithra can synthesise E4 at scale through a complex plant-based production process.

The NDA submission includes results from two phase III clinical studies conducted on 3,725 women. Estelle® showed positive top-line results against primary efficacy and safety endpoints and achieved positive secondary endpoints including good bleeding profile, cycle control, and tolerability.

If approved, Estelle® would be the first contraceptive product containing E4 and the first new estrogen introduced in the US for contraceptive use in approximately 50 years. US sales of combined hormonal contraceptives are more than US$ 4 billion per annum, with 10 million US women using combination (estrogen + progestin) oral pills, patches or vaginal rings[1]. Mithra recently extended its strategic relationship with Mayne Pharma to also commercialize Estelle® in the Australian market[2].

Mayne Pharma's CEO Scott Richards said, "*This is another important milestone for E4/DRSP and brings us one step closer to providing women in the US with a new contraceptive that we believe will be effective, safe and well-tolerated. We look forward to working with the FDA and Mithra during the ongoing review of our application. In parallel, we continue to advance our US commercial strategy and infrastructure to ensure we are well positioned to support the potential launch of E4/DRSP in the first half of calendar 2021.*"

François Fornieri, CEO Mithra Women's Health, commented :"*We are very pleased to have received filing acceptance in the US, the world's largest pharmaceutical market. We continue to believe that our product has the potential to revolutionize the contraceptive landscape, offering an optimal benefit/ risk profile to women around the world and where predicted environmental exposure to Estetrol due to human use is unlikely to have negative effects on aquatic environments.*"

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[1] IQVIA, MAT Sales and NSP Units Feb 2020

[2] Press release Mithra, 28/05/2020

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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. Its three lead development candidates are built on Mithra's unique native estrogen platform, Estetrol (E4): Estelle®, a new era in oral contraception, PeriNesta®, the first complete oral treatment targeting perimenopause and Donesta®, the next-generation hormone therapy. 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 250 staff members and is headquartered in Liège, Belgium. www.mithra.com

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 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.

Important information

The contents of this announcement include statements that are, or may be deemed to be, "forward-looking statements". These forward-looking statements can be identified by the use of forward-looking terminology, including the words "believes", "estimates," "anticipates", "expects", "intends", "may", "will", "plans", "continue", "ongoing", "potential", "predict", "project", "target", "seek" or "should", and include statements the Company makes concerning the intended results of its strategy. By their nature, forward-looking statements involve risks and uncertainties and readers are cautioned that any such forward-looking statements are not guarantees of future performance. The Company's actual results may differ materially from those predicted by the forward-looking statements. The Company undertakes no obligation to publicly update or revise forward-looking statements, except as may be required by law.