Mithra's NEXTSTELLIS® granted additional patent in the United States

- **New patent extends protection for NEXTSTELLIS® (ESTELLE®) until 2036**
- **Mayne Pharma has a 20-year exclusive license and supply agreement in the US and Australia for NEXTSTELLIS®**

Liege, Belgium, 07 November 2023 – 07:00 CET – Mithra (Euronext Brussels: MITRA), a company dedicated to Women's Health, announces today that it has been granted an additional patent for NEXTSTELLIS® (3 mg drospirenone and 14.2 mg estetrol (E4) tablets) in the United States.

Granted by the United States Patent and Trademark Office, the new patent will provide NEXTSTELLIS® with oral-dosage-unit protection in the US market until 2036. The patent is a continuation of U.S. Patent No. 11,147,771, covers the composition of NEXTSTELLIS® and was listed in the Orange Book[1] on Friday, 3 November 2023.

NEXTSTELLIS® is the first and only contraceptive pill featuring the new estrogen E4, in combination with the well-established progestin drospirenone. E4 is a native and tissue-selective estrogen with distinct effects on breast tissues and the liver. Notably, E4 is naturally produced by the human fetus during pregnancy. The E4 in NEXTSTELLIS® is produced from a plant source.

Mithra's commercialization partner, Mayne Pharma Group Limited (ASX: MYX), holds the license and supply agreement for NEXTSTELLIS®/ESTELLE® in the United States since 2021.

David Horn Solomon, CEO of Mithra: "*We are excited to have been granted this additional patent coverage for ESTELLE® under the trademark NEXTSTELLIS®, an oral contraceptive with a novel estrogen, in the United States. The patent will allow us to further realize its potential in the US market over the coming years and to make a significant difference to the lives of millions of women. Furthermore, the extension of the patent protection could help us achieve an additional 7 years of peak sales opportunities in the US. E4 was the first new estrogen to be introduced in the United States in over 50 years, and we believe it will continue to contribute to redefining women's health there.*"

[1] Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations List (fda.gov)

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About Mithra

Mithra Pharmaceuticals SA (Euronext: MITRA) is a Belgian biopharmaceutical 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. After having successfully launched the first estetrol-based product in 2021, the contraceptive pill ESTELLE®, Mithra is now focusing on its second product DONESTA®, the next-generation hormone therapy. Mithra also offers partners a complete spectrum of solutions from early drug development, clinical batches and commercial manufacturing of complex polymeric products (vaginal ring, implants) and complex liquid injectables and biologicals (vials, pre-filled syringes or cartridges) at its technological platform Mithra CDMO. Active in more than 100 countries around the world, is headquartered in Liège, Belgium. www.mithra.com

ESTELLE®, DONESTA® and NEXTSTELLIS® are registered trademarks of Mithra Pharmaceuticals or one of its affiliates.

About NEXTSTELLIS®

Developed by Mithra, NEXTSTELLIS® (ESTELLE®) 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® tablets. 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.

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.

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