



Mithra announces grant of two additional U.S. patents for NEXTSTELLIS®

- Patents are FDA Orange Book listed providing broader protection to 17 June 2036

Liège, Belgium, 10 May 2024 – 16:30 CET – Mithra (Euronext Brussels: MITRA), a company dedicated to women's health, announces today that it has been granted two additional patents for NEXTSTELLIS® (3 mg drospirenone and 14.2 mg estetrol (E4) tablets) in the United States. The U.S. patent numbers are 11,957,694 and 11,964,055.

The patents, which are FDA Orange Book¹ listed, provide additional protection to the NEXTSTELLIS® formulation. Both newly listed patents are terminally disclaimed over [the previously announced](#) U.S. Patent No. 11,793,760 (listed in October 2023) and will also expire on 17 June 2036.

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.

Graham Dixon, Chief Scientific Officer of Mithra, stated, "We are excited to have been granted additional patent coverage for ESTELLE® under the trademark NEXTSTELLIS®, an oral contraceptive with a novel estrogen, in the United States. The new patents complement our previous patent (11,793,760) by offering different or additional scopes of claims to enforce our patent rights. We currently have several additional patent applications pending, demonstrating our ongoing commitment to patent-protect our breakthrough innovations."

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

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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