



## Mithra Announces Presentation of Positive Data on Estetrol (E4) Native Estrogen at NAMS 2023

- Independent global leaders in medical research on women's health, Professor Amanda Black and Professor Wulf Utian, to deliver two presentations each on E4
- E4 is a key active pharmaceutical ingredient in Estelle<sup>®</sup> and Donesta<sup>®</sup> products
- Differentiated efficacy and safety in contraception and postmenopausal symptoms from positive Phase 3 trials

**Liege, Belgium, 27 September 2023 – 7:00 CEST** – Mithra (Euronext Brussels: MITRA), a company dedicated to Women's Health, today announces there will be four presentations on Estetrol (E4) native estrogen at the North American Menopause Society (NAMS) 2023 Annual Meeting, being held September 27-30 in Philadelphia, USA. E4 is a key active pharmaceutical ingredient in both Mithra's marketed contraceptive Estelle<sup>®</sup> and its next generation hormone therapy product candidate for postmenopausal symptoms, Donesta<sup>®</sup>.

**Amanda Black MD, MPH, FRCSC, Professor of Obstetrics and Gynecology at The University of Ottawa**, will hold an independent oral presentation on the use of E4 for contraception and menopause. Dr. Black will be discussing the science and safety behind the use of E4 in the menopause at the opening symposium and will present some of the data on the effects of E4 on breast tissue.

**Dr. Wulf Utian<sup>1</sup>, MD, PhD, DSc, Executive Director Emeritus and Honorary Founding President of NAMS**, who is considered to be one of the world's authorities on menopause and women's health, will hold an oral presentation on the Phase 3 results of E4 in postmenopausal symptoms. The data, from two multi-center, double-blind, placebo-controlled trials with 2,550 postmenopausal women aged 40-65, show beneficial effects from 12-week treatment with E4. These include a significant increase in high-density lipoprotein (HDL) – or "good" – cholesterol and a significant decrease in the ratio total of HDL cholesterol to low-density lipoprotein (LDL) "bad" cholesterol and lipoprotein. There was also a significant decrease in fasting plasma glucose and HbA1c average blood glucose (glycemia) level. Also observed were trends for decreases in insulin and Homeostatic Model Assessment for Insulin Resistance (HOMA-IR).

Dr. Black and Dr. Utian will each also hold poster presentations on E4 at NAMS 2023.

**Graham Dixon, Chief Scientific Officer of Mithra**, commented: "The data will demonstrate that E4 treatment has a favorable safety profile, including a low impact on normal and malignant breast tissue, thanks to its unique mode of action which means it has tissue selective activity, unlike all other estrogens. It has also been shown to be effective at decreasing vasomotor symptoms in postmenopausal women. The evidence clearly shows the potential of E4 to offer women differentiated

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<sup>1</sup> Dr. Utian is a member of the Mithra Advisory Board.

options to support their independence during child-bearing years and maintain their health during menopause.”

Mithra has previously reported positive results from Phase 3 trials, showing strong efficacy and a favorable safety profile for contraception, for Estelle<sup>®</sup>, and separately, a statistically significant reduction in vasomotor symptoms, or hot flushes and night sweats, in postmenopausal women, with Donesta<sup>®</sup>.

**Dr. David Horn Solomon, Chief Executive Officer of Mithra**, commented: “We are proud that Dr. Black and Dr. Utian, two globally recognized experts on women’s health, are presenting this clinical research on our exciting E4 developments. Our scientific founder, Professor Jean-Michel Foidart, was amongst the first to characterize and recognize the potential of this native and selective estrogen, which is produced by the human fetus during pregnancy, passing into maternal blood at relatively high levels and offering unique benefits. His research and development efforts allowed Mithra to develop and test E4 as the key innovative active pharmaceutical ingredient in Mithra’s oral contraceptive Estelle<sup>®</sup> and its Donesta<sup>®</sup> next generation hormone therapy drug candidate.

Our marketing partners are currently accelerating the ongoing commercial launches of Estelle<sup>®</sup>, globally; we are finalizing our application for U.S. marketing authorization of Donesta<sup>®</sup>, for submission later this year. These data presented at NAMS 2023 illustrate the significant goals we are pursuing to provide women with a new era in oral contraception and the next generation hormone therapy for menopause. Our mission is for these and other innovative products to improve women’s health and independence from young adulthood through mid-life and beyond.”

Details of the presentations at NAMS 2023 are as follows:

- **Estetrol (E4): A Promising New Treatment for the Spectrum of Menopausal Symptoms**  
Presenter: Amanda Black – Poster
- **The Effect of Estetrol (E4) on Patient-Reported Outcome Measures in Postmenopausal Women – Results From a Phase 3 Trial**  
Presenter: Wulf Utian – Poster
- **Estetrol (E4), a Promising New Treatment for Menopausal Vasomotor Symptoms (VMS): Beneficial Lipid and Carbohydrate Metabolism in a Phase 3 Randomized, Double-blind, Placebo-Controlled Trial**  
Presenter: Wulf Utian – Oral  
Time: 4:30-4:45pm EST, Thursday 28 September  
Location: Concurrent Session 2—Oral Abstract Presentations; Grand Ballroom (A–D)—Fifth Floor
- **Estetrol (E4) for contraception and Menopause: Where is the Science?**  
Presenter: Amanda Black – Invited Oral (Independent)  
Time: 10:10-10:30am EST, Wednesday 27 September  
Location: Opening Symposium—Precision Oncology for Midlife Women; Grand Ballroom (E–L)—Fifth Floor

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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](http://www.mithra.com)

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