Presentation of Donesta® Phase 3 Topline Efficacy Results at the NAMS World Congress

Liege, Belgium, 17 October 2022 – 7:30 CET – Mithra (Euronext Brussels: MITRA), a company dedicated to Women's Health, today announces its Phase 3 Topline Efficacy results for Donesta® were presented last Friday at the Annual Meeting of the North American Menopause Society (NAMS) held in Atlanta, Georgia.

Selected in the top-scoring abstract presentations, this oral presentation entitled "*Efficacy and Safety of Estetrol (E4), A Promising New Treatment for Menopausal Vasomotor Symptoms: Results of Two Phase 3 Randomized, Double-Blind, Placebo- Controlled Trial*" has been given by Professor Wulf H. Utian, MD, PhD, DSc, FRCOG, FACOG, FICS.

Donesta® is Mithra's next generation orally-administrated estetrol (E4)-based hormone therapy product candidate offering a potential long-term solution for treating different symptoms of menopause. Launched in late 2019, the Phase 3 Clinical Program carried out in 2,300 postmenopausal women (40- 65 years) includes 2 pivotal studies (C301- 302). This Phase 3 Program aims to measure the treatment effects of vasomotor symptoms' frequency and severity at 15 mg and 20 mg doses of E4, especially for hot flushes. The coprimary efficacy endpoints are the average change from baseline in the frequency and severity of moderate to severe VMS at week 4 and week 12 compared to placebo.

Early 2022, Mithra announced the first efficacy data of Donesta® Phase 3 Program, which demonstrated a meaningful reduction in vasomotor symptoms (VMS) from baseline and compared to placebo with all co-primary efficacy endpoints statistically (all $p<0.05$) met in both studies[1].

Professor Wulf H. Utian, MD, PhD, DSc, FRCOG, FACOG, FICS, commented: "*Estetrol is the biggest advance in post-menopausal estrogen development in almost 100 years, particularly because of its efficacy and apparent greater safety.*"

This presentation is available in the Investor section of the company's website.

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[1] Mithra's press release, 14/04/2022

About E4 Comfort Phase 3 Program

Donesta® phase III Clinical Program "E4 Comfort" carried out on 2,300 postmenopausal women (40-65 years) includes 2 pivotal studies: one in America (NCT04090957-C302); and a second spread over 14 countries in Europe, and America (NCT04209543 -C301). Both studies are worldwide randomized, multicenter, doubleblind, placebo-controlled trials. Each studies is composed of an efficacy and a safety part. The efficacy part in each studies is designed to evaluate the frequency and severity of vasomotor symptoms (VMS) in both hysterectomized and nonhysterectomized postmenopausal participants after treatment with two doses of E4 (15 mg or 20 mg) or placebo for 12 consecutive weeks. For endometrial protection, all non-hysterectomized subjects will receive treatment with 200 mg progesterone (P4) once daily for 14 consecutive days, after completion of the E4/placebo treatment. The safety part of the C302 study is designed to evaluate the general safety and secondary endpoints (healthrelated quality of life, treatment satisfaction, hemostasis, lipid and glucose metabolism, breast density and endometrial safety) in hysterectomized and non-hysterectomize women after treatment with E4 20 mg for one year. The safety part of the C301 study is designed to evaluate the endometrial safety of E4 20 mg in combination with continuous administration of 100 mg P4 in non-hysterectomized women for one year

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. 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 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. www.mithra.com

Donesta® is a registered trademark 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.