



## Mithra Completes Recruitment of Covid-19 Phase II Study

- International expert panel confirms strong scientific basis for estrogens as potential treatment of Covid-19 and other viral diseases
- Completion of the recruitment of male and female patients suffering from Covid-19 infection for the Phase II Coronesta Program
- First prospective clinical trial of an estrogen expected to report results in Covid-19.
- Positive DSMB<sup>1</sup> assessment from a safety perspective, allowing the trial to proceed: top-line data expected Summer 2021

**Liege, Belgium, 17 June 2021 – 7:30 CEST** – Mithra (Euronext Brussels: MITRA), a company dedicated to Women's Health today announces that it has completed recruitment of the Coronesta Phase II, aiming to assess the protective role of Estetrol in Covid-19 infection. Estetrol is a naturally occurring estrogen produced by the human fetus during pregnancy.

### Estrogen's protective effect

Since early in the Covid-19 pandemic, it has been recognized that men are almost twice as likely to progress to severe Covid-19 disease and die than women. This male predominance of deaths is consistent with that seen in other infectious diseases caused by human coronaviruses, such as Severe Acute Respiratory Syndrome (SARS).

Estrogens are known to modulate the immune system and there is increasing evidence that estrogens may be playing an important role in improving the outcomes of Covid-19 infection. Estrogen acts on a protein known as Angiotensin Converting Enzyme 2 (ACE2) and enables its expression to be reduced. This ACE2 protein specifically serves as a gateway for certain coronaviruses to enter human cells. Recent international studies, such as the one conducted at King's College London<sup>2</sup>, also support a protective effect of an estrogen present at high levels in the body of women infected by Covid-19.

### International Panel of Experts

Mithra brought together an international panel of experts<sup>3</sup> in endocrinology, women's health, infectious disease, and intensive care medicine, to present and discuss the different types of estrogens and how they are currently being studied as treatment for Covid-19 and other viral diseases. This Panel

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<sup>1</sup> Independent Data Safety Monitoring Board

<sup>2</sup> [Costeira et al, 2020, Estrogen and COVID-19 symptoms: associations in women from the COVID Symptom Study](#)

<sup>3</sup> Expert Panel "Estrogens: Harnessing the power of nature against COVID-19 and emerging viral infections", 28 May 2021. Summary available on Mithra's Investor website (Section Presentation).

confirmed the strong scientific basis for estrogens as potential treatment of COVID-19 and other respiratory viral diseases, pending results of randomized controlled clinical trials.

*“We have not been able to develop many effective medications for Covid-19, and so we need something more effective,”* said Prof. Jean-Louis Vincent, Professor of Intensive Care Medicine, Université Libre de Bruxelles, and Dept. of Intensive Care, Erasme University Hospital, Brussels, Belgium. *“Estetrol seems to have the advantages of transdermal estradiol in an oral form and could be an interesting option for both male and female patients”.*

*“There’s very low risk to using estrogens and there’s really good evidence for the way they work as immune modulators,”* said Dr. Louise Newson, General Practitioner and Menopause Specialist, Newson Health, Stratford-upon-Avon, UK. *“If clinical trial data are supportive in Covid-19, we should considering starting estrogen therapy early, in men as well as women. Men would likely only need to be given estrogens for a short period of time for Covid-19.”*

### Coronesta Phase II design

The international Phase II Coronesta study aims to explore the action of Estetrol on the immune, inflammatory and vascular response of patients infected with Covid-19 and to establish whether Estetrol could reduce the risk of progression to more severe disease. This clinical trial is expected to be the first prospective clinical trial of an estrogen to report results in Covid-19.

The Phase II Study<sup>4</sup> is a multicenter, randomized, double-blind, placebo controlled Phase 2 study evaluating the efficacy, safety and tolerability of Estetrol 15 mg tablet relative to placebo in 175 hospitalized patients (male/female) with moderate Covid-19 (i.e., not on high flow oxygen or mechanical ventilation). This Clinical Program includes centres in Belgium, Russia and Poland, with subjects receiving an active dose or placebo for a treatment period of 21 days. The primary objective of this Phase II clinical trial is to assess the ability of Estetrol to improve the percentage of patients who recover after 28 days compared to placebo.

Graham Dixon, CSO Mithra Women’s Health, commented: *“ We are pleased to confirm the completion of patient recruitment and to have received a positive safety assessment from the independent board of experts on the DSMB, allowing us to continue our clinical trial without any modification. In the current context of the fight against Covid-19, all possible therapies against this virus and its variants are a priority. Estrogens, and especially Estetrol, could offer promising therapeutic potential to address respiratory diseases, in particular Covid-19. We are looking forward to get the top-line results during this summer.”*

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### For more information, please contact:

**Benoît Mathieu (IRO)** : +32 473 35 80 18 - [investorrelations@mithra.com](mailto:investorrelations@mithra.com)

**Maud Vanderthommen (Press)** : +32 473 58 61 04 – [press@mithra.com](mailto:press@mithra.com)

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<sup>4</sup> More information about Coronesta Study available [here](#)

## 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 (Covid-19, neuroprotection...). 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](http://www.mithra.com)*

## 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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