

## Development Milestone: Mithra announces patient recruitment completion of their COVID-19 Study

23 June 2021

tranScrip is pleased to announce that [Mithra](#) together with [tranScrip](#) have completed the recruitment of a randomised, double-blind, placebo-controlled trial to determine the safety and efficacy of estetrol (e4) for the treatment of hospitalised patients with confirmed SARS-CoV-2 infection. The study included both male and female patients suffering from COVID-19 infection in the Coronesta™ Program, which is evaluating the potential protective role of estetrol (E4) in COVID-19 viral infection.

An international panel of experts brought together by Mithra confirmed the strong scientific basis for estrogens as potential treatment of COVID-19 and other viral diseases, justifying the evaluation in randomised controlled clinical trials in the Coronesta™ programme.



Epidemiological evidence of the impact of COVID-19 indicates that men are almost twice as likely to develop severe disease and die than women, which is consistent with data seen in other infectious diseases caused by human coronaviruses, such as Severe Acute Respiratory Syndrome (SARS). If clinical trial data are supportive in COVID-19, the panel suggested that starting estrogen therapy early, in men as well as women, may offer a potentially valuable treatment option.

Following the safety assessment from the Drug Safety Monitoring Board, the adaptive placebo-controlled trial and Coronesta™ programme will continue, with top-line data expected during summer 2021.

For further reading, please visit [Mithra Press Release](#)

**END**

### Notes for Editors

#### **Coronesta™ Phase II Design**

The international Phase II Coronesta™ study aims to explore the potential 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 and allow patients to recover more quickly. This adaptive clinical trial is expected to be the first prospective clinical trial of an estrogen to report results for the treatment of COVID-19.



The Study is a multicentre, randomised, double-blind, placebo-controlled study evaluating the efficacy, safety and tolerability of estetrol 15 mg tablet relative to placebo in hospitalised patients (male/female) with moderate COVID-19 (i.e., not on high flow oxygen or mechanical ventilation). This study so far 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 clinical trial is to assess the ability of estetrol to improve the percentage of patients who recover after 28 days compared to placebo.

### **About tranScrip**

tranScrip is a global leader in the Specialist Service Sector, supporting pharma & biotech companies and investors from Europe, North America and Asia. tranScrip's senior in-house multi-disciplinary teams are unique, with high-level expertise and deep functional competencies that deliver both strategic leadership and operational support to clients, covering strategic development, medical, regulatory, drug safety and commercial services across a multitude of therapy areas from pre-clinical through to commercialisation. tranScrip forms long-standing and successful partnerships with clients, a beneficial approach that maximises opportunities, reduces risk, creates value and accomplishes strategic goals.

### **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).

### **Reference**

[Mithra Press Release](#)