



## tranScrip is proud to be associated with a unique new oestrogen which has received its first product approvals

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tranScrip is thrilled to be working with [Mithra Pharmaceuticals](#) (Mithra), who has announced that the [Committee for Medicinal Products for Human Use](#) (CHMP) of the [European Medicines Agency](#) (EMA) has adopted a positive opinion for Mithra's novel combined oral contraceptive (COC), containing 15 mg Estetrol (E4), a unique native oestrogen and 3 mg drospirenone (DRSP), to be marketed under the trademark Estelle<sup>®</sup>. This announcement follows the positive response from [Health Canada](#) who last week gave the first in the world regulatory approval of Estelle<sup>®</sup>.

The E4 containing COC approval represents a significant milestone in women's health. E4 is a naturally occurring oestrogen produced in the human body, with a unique mechanism of action that displays oestrogen receptor selective activity. E4 shows agonist activity on the vagina, the uterus and the endometrium, the bones and the brain, and antagonistic activity in breast tissue. It has neutral impact on lipids and its distinct metabolic and haemostatic profile provide further differentiation based on its unique mechanism of action. The first regulatory approval granted worldwide for Estelle<sup>®</sup> is a significant milestone in the E4 development programme and in treatments for women's health.

tranScrip is supporting Mithra's E4 COVID-19 research programme, now in Phase 2. Oestrogen has been proposed as a potential broad-spectrum treatment against respiratory viral disease following pharmacological studies (Mauvais-Jarvis, Klein, and Levin 2020) and epidemiological studies showed reduced COVID-19 mortality in women taking hormone replacement therapy (Seeland et al. 2020; Dambha-Miller et al. 2021). As a unique selective oestrogen, E4 is a potential candidate for managing respiratory viral disease, including COVID-19.

### References

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3. Mauvais-Jarvis, F., S. L. Klein, and E. R. Levin. 2020. 'Estradiol, Progesterone, Immunomodulation, and COVID-19 Outcomes', *Endocrinology*, 161.
4. Seeland, U., F. Coluzzi, M. Simmaco, C. Mura, P. E. Bourne, M. Heiland, R. Preissner, and S. Preissner. 2020. 'Evidence for treatment with estradiol for women with SARS-CoV-2 infection', *BMC Med*, 18: 369.

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### **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 which 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 which 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)