Development Milestone: Mithra announces top-line results for COVID-19 estrogen study

24 September 2021

tranScrip is pleased to announce that Mithra together with tranScrip have completed the top-line analysis of the data from a randomized, double-blind, placebo-controlled trial of estetrol (E4) for the treatment of hospitalized patients with confirmed SARS-CoV-2 infection. E4 is a native occurring estrogen produced by the human fetus during pregnancy.

This is the first prospective clinical trial of an estrogen to report results in COVID-19.

The CORONESTA® Phase II study included 175 male and female patients who were hospitalized with moderate COVID-19 and aimed to assess the safety and efficacy of E4 in this population.

The top-line results showed the following:

- Estetrol (E4) did not differ from placebo on the primary study endpoint, but no firm conclusion can be made due to confounding factors
- E4 was well-tolerated with no apparent safety signals in hospitalized men or post-menopausal women suffering from moderate COVID-19
- No adverse effect observed on clotting markers or COVID-19 related embolic events
- These first data in comorbid patients, both male and female, further support the unique safety profile of estetrol

Data from the study were presented on 23rd September 2021 at the North American Menopause Society's Annual Conference (link).

Mithra together with tranScrip will continue to explore the complexity of the data, especially the possible impact on the study outcome of the patients' multiple other medical conditions and treatments, as well as further analysing laboratory markers including viral load.

For further reading, please visit Mithra Press Release.

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Notes for Editors

Phase II Design

The Phase II study was an international, multicenter study that evaluated the safety and efficacy of estetrol (E4) 15 mg tablet, relative to placebo, in 175 patients (male/female) hospitalized with moderate COVID-19 (i.e., not on high flow oxygen or mechanical ventilation). Patients were randomly assigned to receive either E4 or identical placebo for 21 days. All patients received anticoagulant therapy as part of standard-of-care for COVID-19 for 21 days. The clinical program included centers in Belgium, Russia, and Poland.

The primary assessment of the study was the ability of E4 to increase the percentage of patients hospitalized with moderate COVID-19 that recover within 28 days compared with placebo. The secondary assessments included evaluation of safety (including markers of potential blood clotting), and measurements of disease worsening, time to recovery and viral load. Exploratory biochemical markers of inflammation and other measures of disease progress were also collected.

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 maximizes opportunities, reduces risk, creates value and accomplishes strategic goals. www.transcrip-partners.com

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's health and beyond. 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

Reference

Mithra Press Release