



## Mithra Announces New Positive Preclinical Data from CSF-1R Inhibitor Program

- CSF-1R inhibitors show promising anti-tumor activity
- Lead compound shows synergy with PD1 cancer immune checkpoint inhibitor
- Preclinical development conducted in partnership with BCI Pharma

**Liege, Belgium, 15 June 2023 – 7:30 CEST** – Mithra (Euronext Brussels: MITRA), a company dedicated to Women's Health, today announces new positive data from preclinical studies on inhibitors of CSF-1R in development, in collaboration with BCI Pharma, for treatment of endometriosis, oncology and inflammatory disorders.

Colony-stimulating factor 1 receptor (CSF-1R) is a cell-surface tyrosine kinase receptor and a key regulator of macrophage biology and homeostasis. Tumor-associated macrophages are key components of the tumor microenvironment and have emerged as a promising avenue for discovery of novel cancer immunotherapies. CSF-1R kinase inhibition is therefore a promising therapeutic strategy for cancer treatment.

**Graham Dixon, Chief Scientific Officer of Mithra**, commented: "We are encouraged that the lead CSF-1R inhibitor demonstrated efficacy as a single agent in 3 different preclinical cancer models and that the data suggest it may be synergistic when used in combination with PD-1 inhibitors. This provides a strong rationale supporting further development of CSF-1R inhibitors in combination with immune checkpoint inhibitors. We look forward to further evaluating and advancing these promising small molecule therapeutic candidates."

A first study, conducted in a widely used preclinical immune-oncology model, demonstrated that the lead compound, as well as several backups, showed anti-tumor activity as a single agent. The well tolerated compounds demonstrated pronounced and consistent modulation of the tumor microenvironment, including an increase of T cells, which mediate anti-tumor immune responses, and infiltration of natural killer (NK) cells, containing enzymes that can kill tumor cells, into the tumors. Data showed a decrease in tumor-infiltrating macrophages, a type of white blood cell that plays an important role in the human immune system, and repolarization of the tumor-supportive M2 macrophage to the tumor-suppressive M1 macrophage. These results are consistent with anti-tumor activity, and tumor growth inhibition of up to 59%.

The efficacy of the lead compound was further assessed as a single agent or in combination with anti PD1 therapeutic antibody in additional preclinical studies using three different cancer models: MC38 (colorectal), 4T1 (orthotopic triple negative breast) and EMT6 (triple negative breast).

The significant anti-tumor activity of the lead compound used as a single agent was confirmed and was further enhanced with twice daily administration, compared to once daily. Additivity or synergy on tumor growth inhibition was observed when the lead compound was used in combination with anti-PD1 therapy; the triple negative breast cancer model showed that 50% of the animals achieved a complete tumor regression after the combination treatment. Further data will be presented in a peer-reviewed setting.

The research was conducted under a partnership with BCI Pharma, first announced in November 2021. Mithra's primary focus is on endometriosis and cancers affecting women, including orphan indications such as triple negative breast cancer (TNBC). Under the terms of the agreement, Mithra has an option to acquire from BCI all rights, title and interest in the series of CSF-1R inhibitors, and part of the BCI rights, title and interest in and to the results of the research and related intellectual property.

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### About Mithra

Mithra Pharmaceuticals SA (Euronext: MITRA) is a Belgian biopharmaceutical 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<sup>®</sup>, Mithra is now focusing on its second product Donesta<sup>®</sup>, the next-generation hormone therapy. Mithra also offers partners a complete spectrum of solutions from early drug development, clinical batches and commercial manufacturing of complex polymeric products (vaginal ring, implants) and complex liquid injectables and biologicals (vials, pre-filled syringes or cartridges) at its technological platform Mithra CDMO. Active in more than 100 countries around the world, is headquartered in Liège, Belgium. [www.mithra.com](http://www.mithra.com)

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