



Mithra announces compelling initial preclinical data in its research collaboration on novel tyrosine kinase inhibitors with BCI Pharma

- **Preclinical studies** confirm the broad potential of innovative and proprietary inhibitors of CSF-1R to treat different pathologies, including endometriosis, cancer and inflammatory disorders.
- Tyrosine kinase inhibitors are **the third fastest growing therapeutic class** in 2021, with a 14% increase in revenues¹ representing USD 45.8 billion
- **First conclusive data reinforce Mithra's intent** to acquire BCI Pharma's IP rights and finalize the acquisition option to develop new tyrosine kinase inhibitors for the treatment of endometriosis, female cancers and other diseases.

Liege, Belgium, 2 March 2023 – 7:30 CET – Mithra (Euronext Brussels: MITRA), a company dedicated to Women's Health, today announces the first conclusive data of the preclinical studies conducted in partnership with BCI Pharma, an innovative bio-pharmaceutical company, on inhibitors of tyrosine kinases, a new development axis notably indicated in the treatment of many pathologies including endometriosis, oncology and inflammatory disorders. BCI Pharma owns a proprietary kinase technology platform and focuses on small molecule drug discovery.

In November 2021², Mithra announced the diversification of its asset-based pipeline through a partnership with BCI Pharma. Mithra has already contributed to fund 450,000 EUR for the preclinical development to launch and confirm the therapeutic potential of innovative inhibitors of CSF-1R kinase. Primary focus is on endometriosis and cancer, while potentially also targeting orphan indications such as triple negative breast cancer (TNBC).

Broad therapeutic potential of tyrosine kinase inhibitors

The first preclinical data have demonstrated promising anti-tumor activity. The lead compound, a potent and selective inhibitor of CSF-1R, was well tolerated. Also, data have shown that it significantly modulated the tumor microenvironment, tumor-associated macrophages populations and significantly decreased tumor growth in the most widely used preclinical model in immuno-oncology. Additional preclinical studies are currently ongoing to demonstrate the potential for combinations with immune checkpoint inhibitors in a range of tumor models.

With regard to endometriosis, the use of a potent inhibitor of CSF-1R in a preclinical model resulted in promising findings as a treatment with the lead compound induced a lower number of endometriotic cysts, reduced pain and improved the overall well-being in animals with endometriosis.

Finally, regarding the treatment of inflammation, additional preclinical data have shown an inhibitory effect on the production of proinflammatory cytokines including IL-1 β and TNF α in a well-established

¹ IQVIA FY 2021

² [Press release published on 29/11/2021](#)

model used as an *in vivo* screening for candidate compounds designed for the treatment of inflammatory conditions and autoimmune diseases, such as neurodegenerative diseases, multiple sclerosis or psoriasis, for example.

Diversification of asset-based portfolio

Through consideration of its advanced asset-based pipeline, which includes the successfully launched Estelle[®], the first Estetrol-based product oral contraceptive and Myring[®], the vaginal contraceptive ring, as well as the recent advances to pave the way for the commercialisation of Donesta[®], a novel product candidate for the treatment of post-menopausal symptoms, Mithra reinforces its interests to further pursue clinical development and accelerate the next acquisition steps of this partnership.

Throughout this collaboration, Mithra intends to strengthen its leadership position in women's health with a new innovative development axis in a fast-growing market led by inhibitors of colony-stimulating factor 1 receptor (CSF-1R) kinase. The innovative class of tyrosine kinases inhibitors represents the third fastest growing therapeutic class in 2021, with a 14% increase in revenues to USD 45.8 billion.

Under the terms of the contract, Mithra has an option to acquire patents covering tyrosine kinases inhibitors series with upfront payment of EUR 2.25 million on execution of option, following the first results conducted by BCI Pharma. Mithra will fund the preclinical and clinical development with a focus on female cancers and endometriosis, while potentially targeting other orphan indications, such as metastatic breast cancer (TNBC).

Dominique Surleraux, CEO at BCI Pharma said: *"Receiving these first conclusive results are great! It's been 10 years since the founding of BCI Pharma and we're glad to kick off 2023 with such promising news. Partnering with Mithra, a major pharmaceutical company with solid experience in women's health, is a significant opportunity for both companies. As of today, this fruitful partnership generated a solid and broad intellectual property. The therapeutic potential showcased by these data reinforce our confidence in an upcoming partnership that should provide answers to therapeutic areas seeking new treatments solutions for cancer, endometriosis and fibrosis."*

Graham Dixon, CSO Mithra Women's Health, commented: *"We're glad to say that these first conclusive data confirm that we are on the right track with BCI Pharma. These preclinical studies were fundamental to assess our interest in acquiring the patents relating to the development programs on innovative inhibitors of tyrosine kinase (CSF-1R). As demonstrated by these results, the therapeutic potential of tyrosine kinase is broad and promising. At this stage, we strongly believe this innovative development is an opportunity to fill therapeutic gaps on the market and be a response to unmet medical needs in the treatment of oncology, inflammatory conditions and endometriosis. We are looking forward to pursuing further clinical development and accelerate the next steps of this partnership that will strengthen our leadership position in women's health and beyond, as the IP acquired for this new innovation axis will consist in a composition of matter patents, which are the securest form of IP."*

Leon Van Rompay, CEO Mithra Women's Health, said: *"We are very much enthused with the progress of this collaboration and the first conclusive data in therapeutic areas of high unmet need which should offer significant future partnering opportunities. Upon execution of the acquisition expected in the second quarter of 2023, Mithra R&D E4 asset-based activity will be complemented and strengthened with a novel, sound, and broad development platform based on tyrosine kinases inhibitors which have great interest within the life sciences industry."*

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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. After having successfully launched the first estetrol-based product in 2021, the contraceptive pill Estelle[®], Mithra is now focusing on its second product Donesta[®], 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, Mithra has an approximate headcount of 300 staff members and is headquartered in Liège, Belgium. www.mithra.com

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About BCI Pharma

BCI Pharma is a biotech company with extensive expertise in medicinal chemistry, with a special focus on an innovative chemical library. The company designs and validates innovative kinase inhibitor libraries (Bikin 1-3). Its kinase platform is based on a new chemotype with excellent physical and chemical properties which enable BCI to run research projects on inflammation, neuroinflammation, pain, cancer and metabolic diseases. BCI also provides screening technology in the discovery of selective, potent kinase inhibitors. BCI identify a preclinical candidate BCI-1446 as a new way to treat peripheral neuropathic pain and psoriasis. Right now BCI has 3 running projects and has advanced partnerships discussions with giant pharma and biotech. So far, the company has received around €2 million public/private investment and research grants from the Walloon Region to support its research projects. BCI is based at two sites: Liège (Belgium, biology) and Montpellier (France, medicinal chemistry). It has ten employees.

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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