Mithra participates to the pharmaceuticals environmental challenges conference held at the European Parliament, Brussels

- **Panel discussion between European institutions, Academia and Industry on current and future challenges to improve the management of pharmaceuticals residues in the environment and limit Industry footprint on wildlife and ecosystems**
- **High need to improve the overall monitoring of pharmaceuticals in Europe and to increase support for the development of environmentally friendly medicines such as Mithra's core asset Estetrol (E4)**
- **Revision of the EU pharmaceuticals legislation ongoing with a regulation for all Member States anticipated by the end of 2023**

Liege, Belgium, 8 November 2022 – 17:45 CET – Mithra (Euronext Brussels: MITRA), a company dedicated to Women's Health, today took part in the panel discussion "*The direct effects of pharmaceuticals on wildlife, knowledge and policy gaps & solutions to support research and innovation to achieve the Zero Pollution Ambition*" held at the European Parliament in Brussels. The minutes and conclusions of this conference will be available on the company's website in the upcoming days.

Emerging concern

With over 100,000 tons of pharmaceutical products consumed globally every year (24% in Europe) and despite current wastewater filtration systems, pharmaceutical residues are found in the environment, in particular in water and soil, with a negative impact on wildlife, such as fish, birds, frogs and insects, and knock-on effects on wider ecosystems. Various recent studies[1] have shown that some pharmaceuticals such as antibiotics, painkillers or cancer treatments, even at very low concentrations, have direct effects on wildlife. For example, fish exposed to low concentrations of certain antidepressants have been found to change their behaviour in ways that could affect their survival. Oral contraceptives based on natural or synthetic estrogens cause feminisation of fish and amphibians, and residues of psychiatric drugs alter fish behaviour.

As described in the last OCDE report[2] on this emerging concern, unless adequate measures are taken to manage the risks, pharmaceutical residues will increasingly be released into the environment as ageing populations, advances in healthcare, and intensification of meat and fish production spur the demand for pharmaceuticals worldwide.

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[1] Wojnorowski et al. 2021; Czarny et al. 2017. [1] Dzieweczynski, TL et al. 2016. J Exp Biol. 219: 797-804. "Pharmaceuticals pollution of the world's rivers », February 2022.

[2] OECD Report "Pharmaceutical Residues in Freshwater", November 2019

Strengthening of global data and support to accelerate the development of sustainable medicines

It is not feasible, neither technically nor financially, to entirely treat the sewage waters. The main challenge for a better management of the pharmaceutical residues is therefore to work upstream and strengthen the monitoring of pharmaceuticals, bring together existing data sets and develop research to fill the key data gaps in this field. e.g. on the cocktail effects of pharmaceuticals.

In addition to this data consolidation, experts also stressed the importance of supporting R&D projects for environmentally sustainable medicines, for example by providing specific funding for academia / industrial research or through incentivization like rewarding a medicine showing a favorable environmental profile with an accelerated registration process conducted by the European Medicines Agency (EMA).or with a differentiated pricing and reimbursement scheme.

"Considering the urgency of the environmental challenge for society, an attractive incentivization scheme needs to be envisaged by EU and national policy makers to support and accelerate the route to market for innovative medicines offering greater societal and patient environmental sustainability, starting from the development stages all the way to market access and pricing", **explained Jean-Manuel Fontaine, Chief Commercial and External Affairs Officer at Mithra.** *"We are currently developing a portfolio of innovative products based on E4, a novel kind of estrogen which displays a significantly more environmentally-friendly profile compared to alternatives currently on the market. We are working with Academia to further characterize, beyond agency requests, the environmental profile of E4. Policies that provide incentives in terms of funding to strengthen the collaboration with Academia and generate the missing data is critical".*

Prof. Patrick Kestemont, President of Research Institute of Life, Earth & Environment at the University of Namur (Belgium), commented:" *At the moment the monitoring is only done by the academia and we still need a lot of information and research to be able to develop new techniques and to assess environmental impact of each compound, as well as the mixture (cocktail effects) of different compounds. There is a need for a public regulation and the EU needs to encourage the Member States to adopt ad hoc legislations to support pharmaceutical companies which are developing environmentally friendly drugs."*

New EU pharmaceuticals legislation for 2023

In 2019, the European Commission defined a series of actions to address the issue of pharmaceuticals in the environment and has set out a European Green Deal to tackle environmental-related challenges. In 2020, the Commission integrated the issue in the larger "Pharmaceutical Strategy for Europe".

As **Hans Stielstra, Deputy Head of Unit Sustainable Freshwater Management in the European Commission** explained, two relevant proposals – one for a revision of the List of groundwater and surface water pollutants and one for a revision of the urban wastewater treatment Directive – were published recently. On top of this, in a few months, the Commission will publish a proposal for the revision of the general pharmaceuticals legislation which aims to improve the current legislation in terms of environmental risk assessment provisions. The text will then be discussed in the European Parliament and the Council for a publication as regulation for all Member States by the end of 2023.

In the European Parliament, **MEP Cristian Silviu Buşoi**, who was co-rapporteur of the Resolution on a strategic approach to pharmaceuticals in the environment in 2020, announced he will "*stand for strong measures to reduce the discharge of pharmaceuticals in the environment and reducing waste*". In the same vein, **MEP Sirpa Pietikäinen** called on the Commission to "*look at the cost of non-action, because quite often we see that when you need to do something new, it's going to cost money for the industry and the consumers, but then if you don't do anything, the price you pay is 10 times the initial investment*".

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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 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

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