Mithra Announces FDA update

- **Mithra's US partner Mayne Pharma receives complete response letter from FDA for Myring™ requesting additional data that is not normally requested for generic products**
- **Based on the information available to date, Mithra expects to have the necessary data in hand to respond to FDA before year-end**
- **No questions or comments have been raised by FDA with regard to Mithra CDMO, which provides comfort regarding robustness of manufacturing process**
- **Mid-cycle review with FDA regarding the New Drug Application (NDA) for Estelle (Nextstellis) raised no substantive issues**
- **Solid cash position and funding facilities to cover working capital needs**

Liege, Belgium, 6 October 2020 – 07:30 CEST – Mithra (Euronext Brussels: MITRA), a company dedicated to Women's Health, today announces that its US commercial partner Mayne Pharma (ASX: MYX) has received a Complete Response Letter from the US Food & Drug Administration (FDA) related to the abbreviated new drug application (ANDA) for Myring™, the vaginal ring made of ethylene vinyl acetate copolymers (EVA).

In the letter, Mayne has been requested to provide additional data to support the application. This additional data is not normally requested for generic products. Mithra is not concerned by the additional queries and expect to have the necessary data to be able to answer the FDA before year-end.

As a consequence, there is expected to be a delay in US, which will be clarified once the responses to the additional queries have been submitted to the FDA. The overall 10 year business plan is not expected to be impacted as the competitive landscape has evolved reflecting the complexity of the ring development. There is currently only one independent generic NuvaRing® competitor in the US. NuvaRing remains the largest contraceptive sold in the US with sales of more than US$920m[1] .

Mithra, together with Mayne, has also recently participated in a mid-cycle review meeting with the FDA regarding the New Drug Application (NDA) for Estelle (NEXTSTELLIS™) to prevent pregnancy. The FDA did not raise any substantive issues at the meeting and indicated that no major safety concerns have been noted at this point in their review.

Outside of the FDA update, Myring™ is ready for regulatory submission in Canada, and a bioequivalence study has just been launched in China. These additional filing dossiers provide for the production of Myring™ at the Mithra CDMO.

Mithra continues to have a solid cash position and funding facilities to cover working capital needs.

[1] IQVIA MAT sales, August 2020

François Fornieri, Chief Executive Officer of Mithra Women's Health, commented: *"We are very surprised by this unexpected setback, especially considering that we are already commercialized in the largest European countries, and soon expect to be commercialized also in the rest of Europe. Marketing Authorization processes are also pending for Latam, Australia and N. Africa. Together with Mayne Pharma, our commercial partner, we expect to have the necessary data to be able to answer the FDA before year-end in order to bring Myring™ to the American market, a market that has increased 25% over the last four years[2].*

Mithra has also licensed Myring™ to industry leaders in ten international markets, including the United States, Austria, Czech Republic, Russia, Denmark, Chile, Australia/New Zealand, the MENA territories , the Argentinean/Uruguay/Dominican Republic zone and Germany.

All these contracts provide for the production of Myring™ at the Mithra CDMO, which has tripled its production capacity to meet the expected market increase. The commercial manufacturing process has been successfully launched in early 2019 and will continue in the second half of the year for the commercial batches for the European market. No questions or comments have been raised by FDA with regard to Mithra CDMO, which provides comfort regarding robustness of manufacturing process.

At the same time, I am pleased that Mayne considers that the mid-cycle review by the FDA for Estelle (Nextstellis) went smoothly and that no major concerns were raised, and that the timing should be respected."

Mayne Pharma's CEO Scott Richards said, *"We are confident we can address the issues raised in the letter in a timely manner. Pleasingly, the FDA has indicated that Mayne Pharma and its development partner Mithra have an acceptable manufacturing process for generic NUVARING. Furthermore, the market opportunity continues to be highly attractive with only one independent generic approved and an addressable market of US$920m[1]."*

The NEXTSTELLIS mid-cycle review meeting with the FDA provided us with some insights into the review process so far, and we are pleased that no significant issues and no major safety concerns were raised. This meeting marks the halfway point of the NEXTSTELLIS NDA review process, and with approximately six months until the PDUFA date, we continue to advance our US commercial strategy and infrastructure to support the potential launch of this novel contraceptive in the first half of calendar 2021."

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About Myring™

Myring™ (etonogestrel/ethinyl estradiol vaginal ring) is a non-biodegradable, flexible, transparent, combination contraceptive vaginal ring, with an outer diameter of 54 mm and a cross-sectional diameter of 4 mm. It is made of ethylene vinylacetate copolymers, and contains 11.7 mg etonogestrel and 2.7 mg ethinyl estradiol. When placed in the vagina, each ring releases, in line with the originator (Nuvaring®), on average 0.120 mg/day of etonogestrel and 0.015 mg/day of ethinyl estradiol over a three-week period of use. The

[2] USD 740M (IQVIA MAT Sales, December 2016) to USD 920M (IQVIA MAT Sales August 2020)

ring is to remain in place continuously for three weeks. It is removed for a one-week break, during which a withdrawal bleed usually occurs. A new ring is inserted one week after the last ring was removed.

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. Its three lead development candidates are built on Mithra's unique native estrogen platform, Estetrol (E4): Estelle®, a new era in oral contraception, PeriNesta®, the first complete oral treatment targeting perimenopause and 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 250 staff members and is headquartered in Liège, Belgium. www.mithra.com

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.