Mithra Provides FDA Update on Myring®

Liege, Belgium, 6 October 2021 – 17:45 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 (CRL) from the US Food and Drug Administration (FDA) in relation to the abbreviated new drug application (ANDA) for Myring®, the vaginal contraceptive ring made of ethylene vinyl acetate copolymers (EVA).

In the letter, Mayne Pharma has been requested to provide additional data on compatibility. All other topics, in particular the manufacturing process by the Mithra CDMO, did not raise any supplementary questions. Mayne Pharma is working closely with Mithra and the FDA to address the few remaining questions raised in the CRL before year-end. Following submission of the response to the CRL, Mayne Pharma will then receive a new target action date from the FDA. This delay should not impact the potential of the product nor our business development strategy in the US, where the addressable market stands at nearly USD 670 million[1].

Mithra has licensed Myring® to industry leaders covering around 40 countries and is currently commercialized in 12 countries worldwide. Additional commercial launches in significant markets are expected in the second half of the year.

Mayne Pharma's CEO Scott Richards said: *"We are now one step closer to approval and are confident that we can address the few remaining outstanding questions raised by the FDA in a timely manner. Pleasingly, the FDA had no questions around Mithra's facility, the drug product manufacturing process, drug substance or bioequivalence. The market opportunity continues to be attractive with two independent generics approved and an addressable market of USD 670 million."*

Leon Van Rompay, CEO Mithra Women's Health, commented*: "We are working closely with our partner Mayne Pharma and are confident we can address the additional requirements asked by US regulators as quickly as possible. In the meantime, we continue to expand our commercial activity in Europe and other additional markets, supported by our Mithra CDMO facility which will produce more than 800,000 rings this year. "*

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[1] IQVIA MAT sales, August 2021

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. 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

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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