



FORMULATION DEVELOPMENT OF THE PRODUCT CANDIDATE MYRING IS COMPLETE, PRODUCTION OF CLINICAL BATCHES FOR THE FINAL BIOEQUIVALENCE STUDY CAN START

- Formulation development of Mithra's vaginal ring product candidate is complete
- The completion of a such complex process shows Mithra's deep know-how in long acting complex therapeutical entities .
- Production of clinical batches for the final bioequivalence study can start
- The final objective is to transfer the technology to the CDMO in Flemalle

Liège, Belgium 30 March 2016 – Mithra announces the completion of formulation development of its vaginal ring product candidate, Myring. This significant milestone was reached in line with objectives and schedule and paves the way to the next phase of development, the production of clinical batches for the bioequivalence study.

Valérie Gordenne, Chief Scientific Officer of Mithra Pharmaceuticals : *“The pilot scale phase of development is now finalized. This achievement means that the team has now completely defined the critical product and process parameters and is now ready for production of clinical batches. This is also an important step because this means the product formulation as it will be used for all following batches is now fixed, and this stage of development has now been successfully closed.”*

To achieve this milestone, Mithra has relied on expertise of the technological platform team and also invested in specific equipment (both existing and newly developed by Mithra) that will contribute to improving the technological capabilities and expertise of Mithra's technological platform, as this equipment will also be fully exploited for other R&D projects within Mithra CDMO.

François Fornieri, Chief Executive Officer of Mithra Pharmaceuticals: *“The formulation development of a polymeric form is a complex process that Mithra achieved thanks to its deep know-how regarding long-acting complex therapeutical entities such as IUD's, implants or in this case, biocompatible rings. We are pleased to announce that, as the formulation development was expected to be finished by H1 2016, we are in line with objectives and schedule for this project”.*

In order to avoid delaying the project while GMP¹ agreements of its CDMO are put in place in order to start the final bioequivalence study, Mithra plans an intermediate technology transfer to an external CMO for the production of clinical batches that will be used for the bioequivalence study. This intermediate transfer concerns a number of Mithra employees working on the CMO's site (thus applying and protecting Mithra's proprietary knowledge, technologies, manufacturing methods) using

¹ Good Manufacturing Practices are practices required to ensure that products are consistently produced and controlled according to quality standards. These are designed to minimize risks involved in all pharmaceuticals production.

Mithra's equipment related to the product candidate Myring. These will be installed on the premises of this CMO temporarily, for production of the clinical batches.

Once GMP approval (currently expected Q4 2016) is received, all equipment and technology developed by Mithra will be finally transferred to its own CDMO in Flemalle for validation and commercial production.

Pictures

For pictures of François Fornieri, please click here on the following link:

<http://www.mithra.com/logo-et-charte-graphique/>

For more information, please contact:

Press

Julie Dessart

Chief Communication Officer

+32 4 349 28 22

+32 475 86 41 75

press@mithra.com

Investor Relations

François Fornieri, CEO

+32 4 349 28 22

investorrelations@mithra.com

About Mithra

Mithra Pharmaceuticals SA, founded in 1999 as a spin-off of the University of Liège by Mr. François Fornieri and Prof. dr. Jean-Michel Foidart, is a pharmaceutical company focused on Women's Health. Mithra's mission is to support and assist women at every stage of their life, thereby improving their overall quality of life. As such the Company aims to become a worldwide leader in women's health by developing, manufacturing and commercialising proprietary, innovative and differentiated drugs and complex therapeutical entities in four therapeutic fields of women's health, fertility and contraception, menopause and osteoporosis, vaginal infections and cancers.

Mithra has a total headcount of approximately 85 staff members and is headquartered in Liège, Belgium. Further information can be found at: 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

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