PRESS RELEASE

UPDATE ON ZORELINE® PROJECTS INCLUDING LAST INTERIM RESULTS FOR THE PHARMACODYNAMICS STUDY OF THE 3-MONTH IMPLANT

- **Last interim results for the pharmacodynamics (PD) study of the 3-month implant form reveal the study has exceeded the limits of 8 non-responsive patients set for the trial.**

- **The detailed results of this study, still ongoing, will remain completely blinded. Final results are expected end H1 2016 and the full report in the following few weeks.**

- **In parallel, the pharmacokinetics (PK) study, is still in progress. On the basis of PD and PK results, expected end H2, Mithra will review the next steps of Zoreline® 3 month implant development.**

- **The pharmacokinetics and pharmacodynamics studies for the 1-month form of Zoreline® which is focused on Women's Health (endometriosis, fibrosis and breast cancer) are expected to begin in summer 2016.**

Liège, Belgium, 31 March 2016 – Regulated Information – The development process of Zoreline® program which started in 2015 is composed of 3 steps. (i) The pharmacodynamics studies which are designed to demonstrate the ability of Zoreline® 3.6 mg and 10.8 mg to respectively induce estradiol levels suppression to menopause level in women patients and serum testosterone levels suppression to castrate level in male patients with prostate cancer. (ii) The pharmacokinetics studies which are designed to demonstrate the safety of Zoreline® 3,6 mg and 10.8 mg. (iii) These trials form the basis for the regulatory dossier by which Mithra hopes to demonstrate that the 3-month and 1-month form of Zoreline® is indeed therapeutically equivalent to the same form of the originator product, Zoladex®. A third complementary study can be performed.

3-month implant Zoreline® – Pharmacodynamics study

The pharmacodynamics study is composed of 2 cycles of treatment of three months each. The interim analysis includes the data from all 142 enrolled patients, of which 129 have finished the first cycle of treatment and 62 have finished the complete study.

The last interim results for the pharmacodynamics study for the 3-month implant targeting prostate cancer reveal that more than 8 patients are non-responsive to the current form of Zoreline® 10.8mg. This value is currently out of specifications but doesn't mean a "no go" for the entire project.

To date, only 8 patients dropped out the study (mainly for personal reasons), which is a 6% drop-out rate instead of the 20% expected rate (28 patients). We can also confirm that no safety issues have been communicated and the product is well accepted by the medical establishment. No drop-outs

requested by doctors for efficacy or safety issues has been registered. In addition, no Suspected Unexpected Serious Adverse Reactions (SUSAR) have been encountered.

The detailed results of this study, still ongoing, are currently not available, as the study will remain completely blinded from Mithra until end H1 2016, and the full report is expected a few weeks later.

3-month implant Zoreline® – Pharmacokinetics study

In parallel, the pharmacokinetics study designed to demonstrate the safety of Zoreline® 10.8mg implant is still ongoing. With this study, the pharmacokinetics profile of Zoreline® is compared to the originator product, Zoladex® in two arms of 24 patients each. This study will provide Mithra with a crucial insight into the way both products are released *in vivo.* Mithra will be able to access, while the study is ongoing, interim read-outs of this data, and expects to receive the first such read-outs by the summer of 2016.

François Fornieri, CEO of Mithra Pharmaceuticals: *"The pharmacodynamics study for the three-months formulation of Zoreline is outside of the specifications demanded by the regulatory authorities. In short, we have exceeded the threshold of 8 non-responders. However, the study is not finished, 16 patients are still in the trial, and the final results are expected by the end of the first half of 2016. This is the first stage in a three-step process. The second stage is the pharmacokinetic study, which will provide us with sufficient data to orient the direction of the development going forward. We could, for example, choose to undertake a comparative trial between Zoreline and Zoladex, or could choose to launch a new pharmacodynamics study. The information received does allow us to confirm that the product candidate Zoreline was well tolerated, we only saw 8 drop outs (with up to 28 being expected) and no patient dropped out of the trial due to a perceived lack of effect or due to harmful effects."*

1-month implant Zoreline®

Mithra is currently preparing the pharmacokinetic and pharmacodynamics studies for the 1-month version of Zoreline® which are expected to begin in the summer of 2016.

The 1 month Zoladex Implant represents 57,3%[1] of the total market in volume.

Moreover, since 2011 several studies[2] published in peer-reviewed magazines (eg: The Lancet) have demonstrated the efficacy of the combination Gosereline-Tamoxifene in the breast cancer indication. These publications clearly show a growth potential for the product.

All of this information permits to Mithra to attract potential international partners.

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[1] IMS 2016 LB2 class

[2] *Neoadjuvant anastrozole versus tamoxifen in patients receiving goserelin for premenopausal breast cancer (STAGE): a double-blind, randomised phase 3 trial.,* Lancet Oncol. 2012 Apr;13(4):345-52. doi: 10.1016/S1470-2045(11)70373-4. Epub 2012 Jan 20.

Goserelin, as an ovarian protector during (neo)adjuvant breast cancer chemotherapy, prevents long term altered bone turnover. J Bone Oncol. 2016 Feb 11;5(1):43-9. doi: 10.1016/j.jbo.2016.02.003. eCollection 2016.

Pictures

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

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

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About Zoreline

Zoreline® is a biodegradable subcutaneous implant product candidate for prostate and breast cancer and benign gynecological indications. Mithra, through its 100% subsidiary Novalon, is developing Zoreline® in two forms: a one-month implant, containing 3.6 mg of Goserelin, and a three-month implant containing 10.8 mg of Goserelin, and, mirroring the two forms in which the originator product, Zoladex® is available.

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 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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