

**PRESS RELEASE**

**Forendo Pharma commences Phase 1b Proof of Mechanism study with its lead endometriosis program, HSD17B1 inhibitor FOR-6219**

**Turku, Finland, August 20<sup>th</sup> 2019:** [Forendo Pharma](#), a clinical stage drug development company focusing on novel treatments in women's health, today announces initiation of dosing in a Phase 1b clinical study in its lead endometriosis program with the aim to demonstrate Proof of Mechanism. The novel oral compound, FOR-6219, is a HSD17B1 inhibitor aiming to reduce estrogen production locally in the endometriosis lesions. The first women participating in the study have been dosed.

Earlier this year, the first-in-human Phase 1a study of FOR-6219 was successfully completed. Single doses from 2mg up to 175mg and multiple doses up to 150mg twice daily over 10 days were found to be safe and well tolerated in 36 healthy postmenopausal women. The pharmacokinetics of FOR-6219 was dose-proportional and steady state was reached within 3 days. The observed elimination half-life was around 16-18 hours, offering potential for once daily dosing. The pharmacokinetic profile of FOR-6219 was similar in a fasted and fed state indicating that FOR-6219 can be administered with or without food.

In the on-going Phase 1b study FOR-6219 is given to premenopausal women to explore the effect of FOR-6219 on the endometrium by measuring changes in endometrial thickness and endometrial estrogen levels. In addition to these local effects, systemic hormone levels will also be measured. Other endpoints are based on safety and tolerability.

**Risto Lammintausta, CEO of Forendo Pharma, said:** "The commencement of the Phase 1b study marks an important milestone for the company as we aim to demonstrate Proof of Mechanism for this novel concept in premenopausal women for the first time. The selective ability of FOR-6219 to inhibit local estrogen production in the endometrium and endometriotic lesions, without suppressing systemic estrogen levels, is unique and expected to be the key differentiator against competing endometriosis therapies. If we can demonstrate this new mechanism in healthy premenopausal women, we will have a solid basis to study FOR-6219 in endometriosis patients who need better long-term treatment alternatives for this chronic and high burden disease".

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**NOTES TO EDITORS**

**About Forendo Pharma**

Forendo Pharma is a privately held drug development company, with core competences in modulating tissue specific hormone mechanisms. The company was founded in 2013 by leading academic endocrinology experts and Finnish drug development pioneers. Forendo is supported by strong international investors: Novo Seeds, Karolinska Development, Innovestor, Novartis Venture Fund, M

Ventures, Vesalius Biocapital III Partners and Sunstone Life Science Ventures. The company's pipeline includes HSD17B1 inhibitor (phase I) for the treatment of endometriosis; inhibitor of another enzyme from the HSD17B family for the treatment of undisclosed gynecological condition (discovery); and Fispemifene (phase 2), a novel SERM for the treatment of male urological conditions. Further information is available at [www.forendo.com](http://www.forendo.com).

### **About FOR-6219**

FOR-6219 is the first drug that aims for a targeted effect in endometriosis lesions without effecting systemic estrogen. The clinical compound FOR-6219 inhibits the conversion of low potency estrone into highly potent estradiol in endometrial tissues. The most important expected differentiator of FOR-6219 compared to currently available treatments is its selective activity and the ability to act locally in the target tissues, without impacting systemic hormone levels. This selective activity allows a safe and well tolerated, long term treatment opportunity for endometriosis. Positive Phase 1a results were reported in March 2019. [<https://forendo.com/positive-phase-1a-results-of-for-6219/>]

### **About Endometriosis**

Endometriosis is a chronic condition that affects up to 10% of women in reproductive age and causes repeated pain symptoms, infertility and impaired quality of life. Currently available treatments for endometriosis have limitations in efficacy or cause harmful side effects. They often lead to systemic estrogen depletion, with known safety issues on bone mineral density and menopausal symptoms. There is no known cure for the disease. [Download a pdf about endometriosis](#) »