Forendo Pharma Successfully Completes Phase 1 Studies of FOR-6219 in Endometriosis, Aiming to Advance Program into Phase 2 Clinical Studies

Turku, Finland, March 3rd, 2021 - Forendo Pharma, a clinical-stage drug development company focusing on novel treatments in women's health, today announced the completion of Phase 1 studies in healthy volunteers for its lead development program in endometriosis, FOR-6219, and provided a development outlook. The successfully concluded Phase 1 program demonstrated that FOR-6219, a HSD17B1 enzyme-targeting small-molecule, was safe and well-tolerated and delivered additional results supporting Forendo's therapeutic concept. The company is now planning the Phase 2 program including endometriosis patients in the US.

"The now completed Phase 1 program delivered an initial body of tolerability, safety and pharmacokinetic data. For chronic endometriosis treatment, tolerability and a lack of systemic estrogen deficiency-related side effects are of the utmost importance as we see current therapies struggling to be widely adopted due to their side effect profiles. A local effect on the target tissue with our intracrinology mechanism provides an opportunity for superior management of endometriosis," commented Risto Lammintausta, CEO of Forendo. "We are now looking forward to expanding our clinical development program into the US and potentially into complementary women's health indications, in addition to endometriosis. The upcoming Phase 2 program will transition the clinical evaluation of FOR-6219 into symptomatic patients and deepen our understanding of the drug's impact on the disease biology and endometriotic tissue."

Eliminating estradiol systemically, using current endometriosis treatment options such as GnRH receptor antagonists, is associated with troubling side effects such as gradual bone loss. Forendo's novel oral HSD17B1 inhibitor, FOR-6219, aims to reduce estrogen production locally in the endometriosis lesions, a concept known as intracrinology, as a key differentiator from competing endometriosis therapies.

The randomized, double-blind, placebo-controlled first-in-human Phase 1 study of FOR-6219 included 66 healthy pre- and postmenopausal women. In the Phase 1a part of the study, single doses from 2 mg up to 175 mg and multiple doses up to 150 mg twice daily were found to be without a safety signal and well tolerated. All primary endpoints of the study were met with no serious adverse events (SAEs) and only grade 1 adverse

events (AEs), which resolved, were reported. The pharmacokinetics of FOR-6219 were dose-proportional and a steady state was reached within 3 days, with the observed half-life of 16-18 hours offering the potential for once-daily dosing.

In the Phase 1b part of the study, FOR-6219 was given to 36 premenopausal healthy women for 14 days during the proliferative phase of the menstrual cycle to expand the safety data and explore secondary outcome measures, which will inform Forendo in designing its subsequent clinical studies in endometriosis patients. Importantly, the premenopausal women under treatment experienced continued normal ovulatory menstrual cycles.

About Forendo:
At Forendo, we are pioneering the translation of intracrinology science into first-in-class therapeutic solutions. Intracrinology enables us to address diseases on an unprecedented tissue-specific level. Our lead clinical compound in endometriosis is positioned to address a significant unmet need through its local effect on endometriotic lesions. Our second program is targeting polycystic ovarian syndrome (PCOS) which currently has no approved therapies.

In addition to women's health programs, Forendo has a strategic collaboration with Novartis leveraging our unique HSD17B platform in chronic liver diseases.

Forendo is based in Finland and backed by Novo Seeds, Karolinska Development, Innovestor, Novartis Venture Fund, M Ventures, Vesalius Biocapital III Partners and Sunstone Life Science Ventures.

For more information, please visit: www.forendo.com. Stay in touch by following us on our social channels: LinkedIn and Twitter.

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