

Karolinska Development's portfolio company Forendo Pharma advances FOR-6219 to Phase 2 based on positive Phase 1 data

STOCKHOLM, SWEDEN – March 3, 2021. Karolinska Development AB (Nasdaq Stockholm: KDEV) announces today that its portfolio company, Forendo Pharma, has successfully completed a Phase 1 program for FOR-6219 – a candidate drug aimed for the treatment of endometriosis. Based on the positive results generated in this program, Forendo Pharma is now preparing a Phase 2 study in the US.

The randomized, double-blind, placebo-controlled Phase 1 program of FOR-6219 included 66 healthy pre- and postmenopausal women. In the Phase 1a part of the study, single and multiple doses of the candidate drug were found to be safe and well tolerated. All primary endpoints of the study were met, and no serious adverse events were recorded. 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. The premenstrual women under treatment experienced a continued normal ovulatory menstrual cycle. The positive data will be valuable in the design of subsequent clinical studies in endometriosis patients.

“Current therapies for endometriosis are struggling to be widely adopted due to their side effects. Hence, the positive safety profile for Forendo Pharmas candidate drug FOR-6219 that has been documented in the Phase 1 program, together with the favorable pharmacokinetic profile, provides a compelling platform for its continued clinical development,” comments Karolinska Development's CEO, Viktor Drvota.

Endometriosis is an estrogen-dependent disease that affects approximately 10 percent of all fertile women and is caused by cells that normally grow inside the uterus spreading outside the uterus, leading to chronic inflammation in the surrounding tissue. The disease manifests itself in many different ways and often causes very painful menstruation and chronic abdominal pain. Today's drug treatments alleviate the symptoms by inhibiting the body's estrogen synthesis. A clear disadvantage of this type of treatment is that it disturbs the systemic estrogen balance, which gives rise to osteoporosis and other serious side effects that complicate long-term medication. Forendo's novel oral HSD17B1 inhibitor, FOR-6219, aims to reduce estrogen production locally in the endometriosis lesions, a key differentiator from competing endometriosis therapies.

Karolinska Development's ownership in Forendo Pharma amounts to 10%.

For further information, please contact:

Viktor Drvota, CEO, Karolinska Development AB
Phone: +46 73 982 52 02, e-mail: viktor.drvota@karolinskadevelopment.com

Johan Dighed, General Counsel, Karolinska Development AB
Phone: +46 70 207 48 26, e-mail: johan.dighed@karolinskadevelopment.com

TO THE EDITORS

About Karolinska Development AB

Karolinska Development AB (Nasdaq Stockholm: KDEV) is a Nordic life sciences investment company. The company focuses on identifying breakthrough medical innovations in the Nordic region



that are developed by entrepreneurs and leadership teams. The Company invests in the creation and growth of companies that advance these assets into commercial products that are designed to make a difference to patients' lives while providing an attractive return on investment to shareholders.

Karolinska Development has access to world-class medical innovations at the Karolinska Institutet and other leading universities and research institutes in the Nordic region. The Company aims to build companies around scientists who are leaders in their fields, supported by experienced management teams and advisers, and co-funded by specialist international investors, to provide the greatest chance of success.

Karolinska Development has a portfolio of ten companies targeting opportunities in innovative treatment for life-threatening or serious debilitating diseases.

The Company is led by an entrepreneurial team of investment professionals with a proven track record as company builders and with access to a strong global network.

For more information, please visit www.karolinskadevelopment.com