

Karolinska Development's portfolio company PharmNovo receives positive FDA feedback prior to IND application for Phase 2a trial

STOCKHOLM, SWEDEN – March 12, 2025. Karolinska Development AB (Nasdaq Stockholm: KDEV) today announces that portfolio company PharmNovo received positive feedback regarding its most advanced drug candidate, PN6047, in a pre-IND meeting with the U.S. Food and Drug Administration (FDA). The meeting aimed to provide guidance on the design of the company's planned Phase 2a clinical trial for the treatment of peripheral neuropathy and allodynia.

PharmNovo conducted a regulatory pre-IND Type B meeting with the FDA in January 2025. Such meetings are typically held before submitting an Investigational New Drug (IND) application, which is required to conduct clinical studies in the U.S. During the meeting, PharmNovo presented preclinical data, sought advice on its Chemistry, Manufacturing, and Controls (CMC) activities, and received guidance on the design of its planned Phase 2a study for PN6047. FDA did not direct any negative remarks neither concerning the CMC information nor the preclinical data and provided useful guidance for the continued clinical development

Based on the feedback, PharmNovo plans to apply for IND approval from FDA before the end of 2025. Furthermore, the company aims to apply for approval to initiate a clinical Phase 2a trial in Europe in the third quarter of 2025. PharmNovo's most advanced drug candidate, PN6047, is a selective delta-opioid receptor agonist (DORA) being developed as a new treatment for complex pain conditions.

"Pain management is an area of significant commercial interest. We are therefore very pleased with the outcome of PharmNovo's pre-IND meeting with the FDA and look forward to following the company's continued efforts to launch its planned Phase 2a clinical study," said Viktor Drvota, CEO of Karolinska Development.

Karolinska Development's ownership in PharmNovo amounts to 20%.

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 and Deputy CEO, 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 eleven 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.