Karolinska Development´s portfolio company Aprea Therapeutics presents data from two Phase Ib/II studies of APR-246 at the American Society of Hematology meeting

STOCKHOLM, SWEDEN – December 9, 2019. Karolinska Development (Nasdaq Stockholm: KDEV) announces today that its portfolio company Aprea Therapeutics presented results from two Phase Ib/II clinical trials at the 2019 American Society of Hematology (ASH) Annual Meeting in Orlando. Both trials evaluated the safety and efficacy of APR-246 in combination with azacitidine for the treatment of TP53 mutated Myelodysplastic Syndrome (MDS) and Acute Myeloid Leukemia (AML).

Aprea Therapeutics is a biopharmaceutical company focused on developing novel cancer therapeutics that reactivate mutant tumor suppressor protein p53. Mutations of the p53 gene occur in around 50% of all human tumors and are often associated with resistance to anticancer drugs and poor overall survival. APR-246 is a small molecule that has demonstrated reactivation of mutant and inactivated p53 protein. Today Aprea Therapeutics presented results at the 2019 ASH Annual Meeting from two Phase Ib/II studies of APR-246 in combination with azacitidine for the treatment of TP53 mutated MDS and AML.

In one of the presented studies, as of the data cutoff, the overall response rate (ORR) in 33 evaluable MDS patients was 88%, with a 61% complete remission (CR) rate, by International Working Group criteria. The median duration of response was 8.4 months, with 7.3 months median duration of CR in evaluable MDS patients. Seventeen (52%) evaluable MDS patients discontinued therapy to pursue stem cell transplant. Median overall survival (OS) for all enrolled patients (n=55) was 10.8 months. Median OS in responding patients versus non-responders was 13.7 vs. 3.9 months.

In the other study, as of the data cutoff, ORR in 24 evaluable MDS patients was 74%, with a 66% complete remission rate, based on International Working Group criteria. With a median duration of follow-up of 6.4 months, the median OS for all enrolled patients (n=53) had not been reached. In addition, all responding patients were alive at data cutoff. Relative to baseline, mutant TP53 variant allele frequency (VAF) was significantly decreased in responding patients and undetectable in all patients who achieved a CR.

A pivotal Phase 3 clinical trial of APR-246 and azacitidine for frontline treatment of TP53 mutant MDS is ongoing. APR-246 has received Orphan Drug and Fast Track designations from the FDA for MDS, and Orphan Drug designation from the EMA for MDS, AML and ovarian cancer.

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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 nine 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

This information is information that Karolinska Development AB (publ) (Nasdaq Stockholm: KDEV) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of Viktor Drvota, at 17:00 CET on December 9, 2019.