Karolinska Development's portfolio company Aprea Therapeutics presents positive results from a Phase 1b/2 study of APR-246 and azacitidine in MDS and AML

STOCKHOLM SWEDEN – June 12, 2020. Karolinska Development AB (Nasdaq Stockholm: KDEV) announces today that its portfolio company Aprea Therapeutics has released results from a Phase 1b/2 clinical trial evaluating APR-246 (eprenetapopt) with azacitidine for the treatment of TP53 mutant myelodysplastic syndromes (MDS) and acute myeloid leukemia (AML). The overall response rate (ORR) of 28 evaluable MDS patients reached 75%, with a 57% complete remission (CR) rate. With a median duration of follow-up of 9.7 months, the median overall survival (OS) for all enrolled patients, as well as for the MDS patients, was 12.1 months.

All enrolled patients in the Phase 1b/2 study were to receive APR-246 as a 4,500 mg fixed dose IV daily for 4 days and azacitidine over 7 days in 28-day cycles. The primary endpoint of the trial is CR rate. The clinical trial is sponsored by the Groupe Francophone des Myélodysplasies (GFM).

As of the April 1, 2020 data cutoff, the overall response rate (ORR) in 28 evaluable MDS patients was 75%, with a 57% complete remission (CR) rate, by International Working Group (IWG) criteria. With a median duration of follow-up of 9.7 months, the median overall survival (OS) for all enrolled patients (n=52) was 12.1 months and in MDS patients (n=34) was 12.1 months. For patients who remained on treatment for 3 or more cycles of treatment the median OS was higher at 13.7 months versus 2.8 months for patients who were on treatment for fewer than 3 cycles. Relative to baseline, mutant *TP53* variant allele frequency (VAF) was decreased in responding patients by 3 cycles of treatment, including 20 (51%) patients who achieved mutant *TP53* negativity by next-generation sequencing (NGS).

"The clinical trial results presented today is very encouraging. The ORR and CR rates in MDS and AML patients are substantially higher than what can be expected with azacitidine monotherapy. Furthermore, we note the highly encouraging overall survival that appears to be better than azacitidine alone or in combination with other agents in this very high-risk group of patients with a TP53 mutation", comments Viktor Drvota, CEO at Karolinska Development.

The study results were presented at the 25th European Hematology Association Annual Meeting (EHA).

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TO THE EDITORS

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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.

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