

## **Karolinska Development's portfolio company Aprea Therapeutics receives FDA Fast Track designation for eprenetapopt in AML**

STOCKHOLM, SWEDEN – November 30, 2020. Karolinska Development AB (Nasdaq Stockholm: KDEV) announces today that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for eprenetapopt in the treatment of patients with *TP53* mutant acute myeloid leukemia (AML). The company previously received Breakthrough Therapy, Orphan Drug and Fast Track designations for eprenetapopt in the treatment of patients with *TP53* mutant myelodysplastic syndromes (MDS).

The FDA's Fast Track designation is intended to facilitate the development and review of drug candidates that treat serious conditions and address an unmet medical need. A drug candidate that receives Fast Track designation may be eligible for more frequent interaction with the FDA to discuss the drug candidate's development plan as well as eligibility for accelerated approval and priority review.

Eprenetapopt (APR-246) is a small molecule that has demonstrated reactivation of mutant and inactivated p53 protein by restoring wild-type p53 conformation and function – thereby inducing programmed cell death in human cancer cells. Pre-clinical anti-tumor activity has been observed with eprenetapopt in a wide variety of solid and hematological cancers, including myelodysplastic syndromes (MDS), acute myeloid leukemia (AML), and ovarian cancer. A Phase 1/2 clinical program with eprenetapopt has been completed, demonstrating a favorable safety profile and both biological and confirmed clinical responses in hematological malignancies and solid tumors with mutations in the *TP53* gene. A pivotal Phase 3 clinical study of eprenetapopt and azacitidine for frontline treatment of *TP53* mutant MDS is ongoing.

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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 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](http://www.karolinskadevelopment.com)