

## **Karolinska Development's portfolio company Aprea Therapeutics receives FDA Breakthrough Therapy Designation**

STOCKHOLM, SWEDEN – January 30, 2020. Karolinska Development (Nasdaq Stockholm: KDEV) announces today that its portfolio company Aprea Therapeutics has been granted Breakthrough Therapy Designation for APR-246 in combination with azacitidine for the treatment of myelodysplastic syndrome (MDS) with a TP53 mutation. A Breakthrough Therapy Designation facilitates expedited development and regulatory review of a drug candidate.

APR-246 is a small molecular drug candidate that binds, refolds and stabilizes mutant p53, occurring in approximately 50% of all human tumors. A pivotal Phase 3 clinical trial of APR-246 and azacitidine for frontline treatment of TP53 mutant MDS is ongoing. APR-246 has previously received Orphan Drug and Fast Track designations from the FDA for MDS, and Orphan Drug designation from the EMA for MDS, acute myeloid leukemia (AML) and ovarian cancer.

“This is yet another success for Aprea Therapeutics, and we look forward to following the continued development of its potentially ground-breaking cancer therapy”, says Viktor Drvota, CEO, Karolinska Development AB, in response to the announcement.

MDS represents a spectrum of hematopoietic stem cell malignancies in which bone marrow fails to produce sufficient numbers of healthy blood cells. Approximately 30-40% of MDS patients progress to acute myeloid leukemia (AML) and mutation of the p53 tumor suppressor protein is thought to directly contribute to disease progression and a poor overall prognosis.

The FDA's Breakthrough Therapy Designation is intended to expedite the development and review of a drug candidate that is planned to treat a serious or life-threatening disease or condition when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapies on one or more clinically significant endpoints.

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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](http://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 13:30 CET on 30 January 2020.*