

Karolinska Development's portfolio company Aprea Therapeutics announces that FDA has issued a clinical hold on lymphoid malignancy program

STOCKHOLM, SWEDEN – August 12, 2021. Karolinska Development AB (Nasdaq Stockholm: KDEV) announces today that the US Food and Drug Administration (FDA) has issued a clinical hold for Aprea Therapeutics clinical program evaluating eprenetapopt with acalabrutinib or venetoclax and rituximab in lymphoid malignancies. The issue means there will be a pause in the patient enrollment until the agency reverses the decision. Patients previously enrolled and showing positive clinical responses will continue to receive study treatment.

Aprea Therapeutics was initially notified of a partial hold in the myeloid malignancy clinical program and shortly thereafter received notification from the FDA that a clinical hold had also been issued in the ongoing lymphoid malignancy study. The agency's decision is related to the safety and efficacy data presented in a recent Phase 3 study of eprenetapopt in TP53-mutated myelodysplastic syndrome (MDS).

Aprea Therapeutics intends to work in close dialogue with the FDA to clarify and address the agency's concerns in order to resume activity in the clinical trial program as soon as possible.

Karolinska Development has an interest in Aprea Therapeutics through KDev Investment amounting to a total holding of 8.4% of the outstanding shares in Aprea Therapeutics.

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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.