

Karolinska Development's portfolio company OssDsign receives expanded FDA market clearance for OssDsign Cranial PSI

STOCKHOLM, SWEDEN, 4 October 2021 Karolinska Development AB (Nasdaq Stockholm: KDEV) today announces that its portfolio company OssDsign AB has received an expanded marketing authorization from the U.S. Food and Drug Administration (FDA) for the company's patient-specific cranial implant product OssDsign Cranial PSI. The approval underlines that OssDsign's patented calcium phosphate composition has osteoconductive properties inducing resorption and formation of new bone tissue.

The new 510(k) clearance is based on the previous market clearance from 2017 and means that the FDA has now cleared the osteoconductive component of the ceramic material in OssDsign Cranial PSI that is resorbed and replaced with bone tissue during the healing process.

OssDsign's titanium-reinforced calcium phosphate implant is designed for the reconstruction of cranial bone defects, an area of treatment where post-operative infections are considered one of the most common complications. Both published data and clinical documentation show that the OssDsign Cranial PSI is associated with a low risk of infection in the early postoperative stage, which may otherwise lead to the need for implant removal.

"The expanded approval from the FDA highlights the important ability of OssDsign Cranial PSI to induce bone healing. The announcement strengthens our portfolio company's commercial position on the market and its possibility to provide patients suffering from complex bone defects with a high-quality treatment option," said Viktor Drvota, CEO, Karolinska Development.

Karolinska Development's shareholding in OssDsign AB, including an indirect ownership via KCIF Co-Investment Fund, amounts to 10.4 per cent.

For further information, please contact:

Viktor Drvota, CEO, Karolinska Development AB
Phone: +46 73 982 52 02, e-mail: viktor.dravota@karolinskadevelopment.com

Johan Dighed, General Counsel and Deputy CEO, Karolinska Development AB
Phone: +46 70 207 48 26, e-mail: johan.dighed@karolinskadevelopment.com

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.