

Karolinska Development's portfolio company BOOST Pharma successfully completes pre-IND meeting with FDA and receives second tranche of investment

STOCKHOLM, SWEDEN, November 5 2024. Karolinska Development AB (Nasdaq Stockholm: KDEV) today announces that its portfolio company BOOST Pharma has successfully completed a pre-IND meeting with the U.S. Food and Drug Administration, FDA, for its cell therapy aiming to treat children with the rare bone disease Osteogenesis Imperfecta (OI). The positive outcome from the meeting will trigger the second tranche of Karolinska Development's investment in BOOST Pharma.

BOOST Pharma has completed a pre-IND meeting with the FDA where the company received positive response of the proposed clinical development plan for its allogeneic cell therapy as a treatment of the rare bone disease Osteogenesis Imperfecta (OI). The primary objective of the meeting was to present results from the phase 1/2 clinical trial BOOSTB4 and to seek concurrence on the development plan and the design of a phase 3 clinical trial to be qualified as a registration trial. BOOST Pharma received positive and constructive feedback from the FDA and will now start preparations for the phase 3 clinical program to be executed in U.S. and Europe, which includes submission of an IND containing the full phase 3 trial protocol to the FDA.

The positive outcome from the pre-IND meeting will trigger the second tranche of Karolinska Development's investment in BOOST Pharma according to the agreement concluded earlier this year.

"The successful pre-IND meeting marks an important milestone for our portfolio company BOOST Pharma in the ongoing development of a potentially groundbreaking treatment for an agonizing disease. Following this important advancement, Karolinska Development is delighted to increase its ownership in this exciting and mature project, which is rapidly approaching phase 3." says Viktor Drvota, CEO of Karolinska Development.

BOOST Pharma is developing a first-in-class and potentially groundbreaking cell-based treatment for the congenital disease osteogenesis imperfecta (OI), a condition characterized by fragile bones, constant fractures and deformities of bones. The treatment is based on novel cell therapy, using human stem cells, with especially high bone-forming capabilities. The company is the first to develop a treatment to be administered directly upon diagnosis, either before or right after birth, providing a possible treatment advantage in the early years of life, when most fractures occur.

BOOST Pharma's cell therapy has received Rare Pediatric Disease designation in the U.S. and Orphan Drug Designation in the U.S. and EU.

Karolinska Development's ownership in BOOST Pharma will amount to 10% following this second tranche.

For further information, please contact:

Viktor Drvota, CEO, Karolinska Development AB
Phone: +46 73 982 52 02, e-mail: viktor.drvota@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 BOOST Pharma ApS

BOOST Pharma ApS is a Danish company founded based on research from Karolinska Institutet, focusing on novel cell therapy treatments for osteogenesis imperfecta, OI. The company's treatment has a unique position on the market since it targets the underlying condition causing fractures and bone deformities, unlike any other product under development.

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 eleven 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