

Modus Therapeutics announces FDA Acceptance of Sevuparin IND for the treatment of sickle cell disease

STOCKHOLM, November 7, 2018. Karolinska Development's portfolio company Modus Therapeutics announces today that the U.S Food & Drug Administration (FDA) has approved the company's Investigational New Drug (IND) application to initiate a Phase I clinical trial with subcutaneous sevuparin for the treatment of sickle cell disease (SCD)

FDA has decided to accept Modus Therapeutics' IND application of sevuparin for the treatment of SCD. Sevuparin is an innovative, proprietary modified polysaccharide drug with anti-adhesive, anti-aggregate and anti-inflammatory effects due to its multimodal mechanism of action. It has the potential to restore blood flow and prevent further microvascular obstructions in children and adults with SCD.

At present, sevuparin is being evaluated as an intravenous infusion in a Phase II study in SCD patients with ongoing painful crises (also called vaso-occlusive crises, VOC). In order to broaden the clinical scope and utility of sevuparin in the treatment of SCD, the expanded clinical program into the U.S. will be performed using a subcutaneous administration route.

"The FDA's decision to accept the IND application for the development of sevuparin in SCD will allow us to start our clinical development program in the U.S. and constitutes an important milestone in our efforts to provide patients with effective and convenient therapies to treat their disease," said Ellen K Donnelly, PhD, CEO of Modus Therapeutics.

Sickle cell disease is an inherited blood disorder that affects between 90,000-100,000 individuals in the US. It is characterized by severely painful VOCs that lead to organ damage due to a lack of oxygen delivery to the organs. Progressive organ damage limits the life expectancy of patients with SCD and lifetime medical care costs can exceed USD 1 million per patient with an estimated USD 1 billion spent annually in the U.S.

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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 established 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.

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