Modus Therapeutics receives Orphan Drug Designation in the U.S. for sevuparin in Sickle-Cell Disease

STOCKHOLM, SWEDEN - March 20, 2015. Modus Therapeutics AB today announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation for sevuparin (DF02) for the treatment of patients with sickle-cell disease (SCD). The company is currently in the final stage of study preparation for a Phase II study in SCD with sevuparin and aim to start recruitment of patients during the first half of 2015.

Sevuparin is an innovative, proprietary polysaccharide drug, which has the potential to restore blood flow and prevent further microvascular obstructions, caused by abnormal blood cells in SCD patients. With its anti-adhesive properties, sevuparin could thereby offer treatment of the underlying cause of vaso-occlusive crisis (VOC) in SCD patients, with earlier pain relief, shorter hospital stay, reduced need of opioids and improved quality of life. Modus Therapeutics is currently in the final stage of preparation for a Phase II study and aim to start recruitment of patients during the first half of 2015.

"An Orphan Drug Designation in the US is an important step in our efforts to bring an important new, valuable and needed treatment to SCD patients. The designation gives advantages in FDA assistance, user-fee benefits and, after orphan drug registration, seven years of market exclusivity. Continued interactions with FDA and regional expert clinicians will enable future clinical development of sevuparin in the U.S.," said Christina Herder, CEO of Modus Therapeutics.

SCD is a disabling and potentially fatal disease with a large unmet medical need in both the developed and developing world. In the US, it estimated that close to 100,000 patients are diagnosed with this hereditary disease. SCD patients undergo on average one VOC per year. This acute complication is caused by sickle blood cells obstructing the blood flow to organs leading to ischemia and often severe pain. Long-term, SCD patients are at risk of organ damage and premature death.

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TO THE EDITORS

About Modus Therapeutics AB
Modus Therapeutics is a Swedish drug development company developing sevuparin, an innovative, proprietary polysaccharide drug, which has potential to restore blood flow and prevent further microvascular obstruction in both sickle cell disease and malaria patients.

Sevuparin originates from research at the Karolinska Institute and Uppsala University. The drug development has involved world leading experts in the field of heparin from the Swedish pharmaceutical industry.

The main owner of Modus Therapeutics is KDev Investments AB, part of Karolinska Development AB (STO: KDEV) and Rosetta Capital. Other larger owners are The Foundation for Baltic and European Studies (Östersjöstiftelsen) and Praktikerinvest AB. For more information, please visit www.modustx.com