Modus Therapeutics - Independent DSMB endorses inclusion of adolescents in ongoing clinical study with sevuparin in Sickle Cell Disease

STOCKHOLM – November 15, 2016. Modus Therapeutics AB today announced that after a safety review by an independent Data Safety Monitoring Board, adolescents between the age of 12 and 18 will now be enrolled into its ongoing clinical study with sevuparin in Sickle Cell Disease (SCD). In addition, the Company has decided to increase the sample size of the current Phase II study to around 150 patients in total, so that this study can play a more important role in the overall clinical program needed to register sevuparin.

A planned independent Data Safety Monitoring Board (DSMB) review has been conducted in the multi-centre, randomized Phase II clinical study currently recruiting SCD patients in Europe and Middle East. In accordance with the study protocol, the first 25 SCD patients that were treated were adults in order to establish sevuparin's safety. The independent DSMB has now reviewed all safety and pharmacokinetic data for these first 25 adult patients. The recommendation from the DSMB is to continue the study as planned and to extend the inclusion criteria to allow the recruitment of adolescents between the ages of 12 and 18 years.

The ongoing Phase II study is designed to demonstrate a reduced time to resolution of Vaso-Occlusive Crises (VOC) in hospitalized SCD patients treated with sevuparin in comparison to those treated with placebo. The study is targeting a potential 30% reduction in the time to resolution of the VOC, which would make a significant difference to the SCD patients as well as for healthcare providers. This anticipated reduction is based on an analysis of the clinical data with Low-Molecular-Weight heparin that is available in the literature.

Modus Therapeutics decided prior to the DSMB review to remove the sample size re-calculation originally planned after 45 randomized patients (a. k. a. the interim analysis) and instead aim for a total of 120 evaluable VOC resolutions. This would require the study to enrol about 150 patients. This amendment will allow the Company to fully explore the clinical potential of sevuparin to support a pivotal Phase III study. The top-line phase II data is now expected in H1 2018.

Commenting on today's announcement, Christina Herder, CEO of Modus Therapeutics, said: "This positive recommendation by the DSMB is an important milestone for our clinical Phase II study as it will allow us to include adolescents with SCD. As with adults, they are also in need of new treatments which are effective in resolving the severe and devastating VOCs, which cause them extreme pain and increase their risk of long-term complications including organ damage and premature death."

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About Modus Therapeutics

Modus Therapeutics is a clinical-stage drug development company developing new pharmaceutical therapies designed to restore impaired blood flow and oxygen transport in rare diseases with large unmet medical need. The Company's most advanced candidate, sevuparin, is currently being evaluated in a Phase II clinical trial for management of acute VOC in subjects with in sickle cell disease (SCD), for more details please visit NCT02515838. Repeated painful crises in SCD, so called vaso-occlusive crises ("VOC"), leads to loss of vital organ function and often significantly reduced life span.

Modus Therapeutics is based in Stockholm. The Company's major shareholders are KDev Investments AB (an investment fund jointly owned by Karolinska Development AB and Rosetta Capital), Östersjöstiftelsen (The Foundation for Baltic and East European Studies), and Praktikerinvest PE AB.

For more information, please visit www.modustx.com

About sevuparin

Sevuparin is an innovative, disease-modifying proprietary polysaccharide drug, which has the potential to restore blood flow and prevent further microvascular obstructions in SCD patients via a multimodal, anti-adhesive mechanism. The microvascular obstructions cause the severe pain during VOCs and the high morbidity through organ damage as well the risk of premature death.

Modus Therapeutics has received Orphan Drug Designation for sevuparin for use in SCD in the US and EU.

About Sickle Cell Disease

Sickle cell disease (SCD) is a painful, inherited blood disorder affecting millions of people around the globe and the most common inherited blood disorder in the US affecting between 90,000-100,000 subjects, with medical care costs amounting to more than $1 billion. In Europe it is estimated that there are 35,000-40,000 SCD patients, and this number is higher in the Middle East and North Africa regions, with over 850,000 SCD patients.

There is currently no pharmaceutical product available that targets the underlying cause of VOCs that affect SCD patients. Current therapies are predominantly strong intravenous pain medications and SCD patients often have to be hospitalized in order to be treated.