

## **Karolinska Development company Modus Therapeutics' ongoing clinical study with sevuparin in sickle cell disease expands to include adolescent patients**

**STOCKHOLM – November 15, 2016. Karolinska Development AB (Nasdaq Stockholm: KDEV) notes the announcement today from its portfolio company Modus Therapeutics AB that, after a planned 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 for sickle cell disease (SCD). In addition, Modus Therapeutics 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.**

Details from the Modus Therapeutics press release follow:

A planned independent Data Safety Monitoring Board (DSMB) review has been conducted in the multi-centre, randomized Phase II clinical study currently recruiting 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 has decided 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, which was made ahead of the DSMB recommendation, will allow 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.

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."

Viktor Drvota, Chief Investment Officer at Karolinska Development, said: "This is a positive development for Modus Therapeutics, that will allow the company to further build on its encouraging findings with sevuparin for treatment of sickle cell disease."

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## TO THE EDITORS

### **About Modus Therapeutics**

Modus Therapeutics is a clinical-stage drug development company developing new pharmaceutical therapies 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 in sickle cell disease (SCD). 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](http://www.modustx.com)

### **About Karolinska Development AB**

Karolinska Development AB is an investment company focused on identifying medical innovation and investing in the creation and growth of companies developing these assets into differentiated products that will make a difference to patients' lives and provide an attractive return on investment.

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 10 companies targeting opportunities in innovative treatment for life-threatening or serious debilitating diseases.

The Company is led by a team including investment professionals with strong venture capital backgrounds, experienced company builders and entrepreneurs, with access to a strong global network.

For more information, please visit [www.karolinskadevelopment.com](http://www.karolinskadevelopment.com)