

Modus Therapeutics announces first patient enrolled in the Phase I SEVUSMART clinical trial evaluating sevuparin in paediatric patients with severe malaria

STOCKHOLM, SWEDEN – 1 September 2022: Modus Therapeutics Holding AB (“Modus”), a company developing innovative treatments for patients with high unmet medical needs, announces the inclusion of the first patient and the start of SEVUSMART, an Imperial College London/Wellcome sponsored phase I clinical trial evaluating the Company’s proprietary drug sevuparin in paediatric patients with severe malaria.

The SEVUSMART phase I trial will evaluate the safety and tolerability of escalating doses of sevuparin in up to 20 paediatric patients aged 3 months to 12 years presenting with severe malaria at the Kilifi County Hospital, Kilifi, Kenya. The study is designed to identify the appropriate dose of sevuparin together with standard of care in severe malaria to be taken forward in future clinical studies.

Sevuparin has already shown promising effects on the malaria parasite in patients with uncomplicated malaria and in human samples (Leitgeb et al 2017, Saiwaew et al 2017).

The trial is the result of a collaboration between Modus and a team led by Professor Kathryn Maitland from Imperial College London, UK. The project is funded by a collaborator grant in science from Wellcome (209265/Z/17/Z) to Professor Maitland’s research group at KEMRI-Wellcome Trust Programme, Kilifi Kenya and to the international consortium “Severe Malaria Africa – a consortium for Research and Trials” (SMAART), the goal of which is to identify and research new treatments for severe malaria.

Modus is currently developing sevuparin in sepsis/septic shock, and other conditions with systemic inflammation, of which severe malaria constitutes an example.

Severe malaria remains an unaddressed medical problem in the parts of the world with endemic malaria. The condition primarily affects young children infected with the parasites. In severe malaria, the parasitic infection causes a systemic inflammation syndrome that shares similarities with sepsis and other severe conditions which uncontrolled may then progress into shock and multi-organ failure.

Professor Kathryn Maitland of Imperial College London commented: *“We’re excited to be starting this trial, which was designed by a team of global experts in the field. We believe that sevuparin has the potential to support the treatment of severe malaria in children. Through our work we hope to grow our understanding of how to improve patient outcomes in what remains a very challenging disease area.”*

Mats Wahlgren, Professor of Infectious Disease Control at Karolinska Institutet and scientific adviser to Modus, said: *“Sevuparin has already demonstrated promising effects on the malaria parasite and these data, combined with Professor Maitland’s world-leading expertise and the backing of Imperial College London and Wellcome, make this study a key milestone in tackling one of*

the world's most notorious diseases. The devastating impact of severe malaria cannot be overstated, and the need for transformative treatments is as great as it has ever been."

John Öhd, CEO of Modus Therapeutics, said: *"We're delighted to be moving forward with this important collaboration researching sevuparin in severe malaria. We are rapidly expanding our understanding of the drug's impact on systemic inflammation mechanisms due to different causes, and collaborations like this remain a key part of our strategy to maximize the development potential of sevuparin."*

This information is such information that Modus Therapeutics Holding AB is obliged to publish in accordance with the EU Market Abuse Regulation. The information was submitted, through the care of the contact person below, for publication on September 1st, 2022.

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About Modus Therapeutics and sevuparin

Modus Therapeutics is a Swedish biotechnology company headquartered in Stockholm that develops sevuparin with a focus on diseases with a high unmet medical need. The company's focus in the near future is to develop sevuparin for patients with sepsis / septic shock, which is a serious and often fatal condition. Modus Therapeutics is listed on the Nasdaq First North Growth market ("MODTX"). More information is available at www.modustx.com

Sevuparin is a clinical stage, innovative proprietary polysaccharide drug with a multimodal mechanism of action, including anti-inflammatory, anti-adhesive and anti-aggregate effects. Sevuparin is a heparinoid with markedly attenuated anti-coagulation features that allows severalfold higher doses to be given, compared to regular heparinoids, without the associated risk for bleeding side-effects. Two routes of administration of sevuparin are currently being tested – an IV formulation for in-patient administration and a subcutaneous formulation that allows ambulatory and home care administration.

About severe malaria and sevuparin

One key event in severe malaria is when red blood cells that are infected with malaria parasites stick to the very deep parts of the blood vessels. This occurs throughout the body causing poor blood flow to the tissues which leads to a build-up of body acids (called lactate) and inflammation. Currently, there are no treatments available to prevent, reverse or stop cells from sticking to the blood vessels when infected with malaria parasites.

In addition to counteracting harmful mediators from white blood cells (Rasmuson *et al* 2019), sevuparin acts by preventing malaria parasites getting into red cells (necessary for parasite survival). Furthermore, sevuparin prevents red cells infected with malaria parasites from sticking to the blood vessels and is also able to 'detach' cells infected with malaria parasites already stuck to the blood vessel with a potential for positive effects on blood flow (Leitgeb *et al* 2017, Saiwaew *et al* 2017).