PRESS RELEASE
21 February 2023 17:20:00 CET

Modus Therapeutics announces positive topline data from its Phase 1b LPS provocation study evaluating the potential of sevuparin for treatment of sepsis

STOCKHOLM, SWEDEN – 21 February 2023: Modus Therapeutics AB ("Modus"), a company developing innovative treatments for patients with major unmet medical needs, announces positive top-line data from its Phase 1b lipopolysaccharide (LPS) provocation study, a key step in evaluating the potential of its lead asset, sevuparin, as a treatment for sepsis and other conditions with systemic inflammation.

In this study, healthy volunteers received LPS to induce a transient systemic inflammation reaction together with one of three dose levels of sevuparin, or placebo for 6 hours. They were then followed up at 24 hours post treatment. Provocation with LPS is a well-established model used to characterize the early stages of septic inflammation by provoking a range of measurable symptoms.

All three dose levels of sevuparin were found to be safe and well tolerated throughout the study period, confirming a favorable safety profile of the candidate drug under induced inflammatory conditions.

Furthermore, sevuparin treatment induced statistically significant and dose-dependent increases in the levels of certain white blood cell populations as well as a dose-dependent inhibition of the increase in respiratory rate induced by LPS. These findings are indicative of clinically relevant and immunomodulatory effects exerted by sevuparin in a state of systemic inflammation.

The study outcome strengthens the potential for sevuparin as a treatment for systemic inflammation including sepsis and septic shock. This is an area of high unmet medical need as current treatment options fail to address the high disease burden of these critically ill patients.

Sevuparin also demonstrated a favorable safety and tolerability profile when combined with the blood thinning heparin (enoxaparin), which is an important standard of care in severely ill patient populations that need thrombosis prophylaxis.

The positive top-line data from this trial will be used to design the Modus Phase 2a study of sevuparin in patients with sepsis. For example, this data will inform the dose of sevuparin to be assessed, the dosing schedule and the patient population for the planned patient study.

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John Öhd, Chief Executive Officer of Modus Therapeutics commented: "We are delighted by the encouraging results from our LPS-challenge study, a very important milestone in our mission to develop sevuparin as a fundamental change in the treatment for sepsis and other conditions with systemic inflammation. The results enhance our understanding of the immunomodulatory action of sevuparin and reinforce its potential in this area of extremely high unmet need. These data will also allow us to develop an optimized trial protocol for our planned Phase 2a trial in sepsis patients. We would like to thank all our collaborators, who were critical to the success of this initial clinical study, for their continued support, and we look forward to providing more updates in the future."

The Phase 1b study was conducted in collaboration with The Centre for Human Drug Research in Leiden, The Netherlands, an independent Contract Research Organisation (CRO), which specializes in advanced early clinical drug research based on its leading expertise in inflammation models.

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This information is information that Modus Therapeutics Holding AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2023-02-21 17:20 CET.

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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.

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Attachments

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