PRESS RELEASE
09 December 2024 09:55:00 CET

Modus Therapeutics Initiates Phase II Study with Sevuparin for the Treatment of Chronic Kidney Disease with Anemia

Stockholm, December 9, 2024 - Modus Therapeutics Holding AB ("Modus") today announced that the first dose has been administered in the company's Phase II clinical study evaluating the drug candidate sevuparin for the treatment of chronic kidney disease (CKD) with associated anemia. The study is being conducted at the Centro Ricerche Cliniche di Verona, Italy.

This milestone builds in part upon promising preclinical and clinical data recently published in the scientific journal *HemaSphere*. The article highlights sevuparin's ability to significantly reduce hepcidin levels—a key regulator of iron metabolism and a crucial contributor to the development of CKD-related anemia—further reinforcing the scientific foundation for the study.

Study Design and Objectives
The Phase IIa study consists of two parts:

• **Part 1**: Evaluates the safety and determines dose levels of sevuparin through single-dose administration in patients with varying degrees of kidney impairment, alongside a small reference group of healthy volunteers.

• **Part 2**: Focuses on the effects of repeated dosing and clinical outcomes, including hemoglobin levels, kidney function, hepcidin levels, and other biomarkers in patients with advanced CKD and anemia.

The study is expected to enroll a total of 50–60 patients, with the completion of Part 1 planned for the first half of 2025.

Scientific Background
Research has demonstrated that elevated hepcidin levels contribute to iron dysregulation in CKD and chronic inflammation, exacerbating the anemia that occurs in these conditions. In the *HemaSphere* article, sevuparin was shown to significantly reduce hepcidin levels in both preclinical models and healthy volunteers, achieving reductions of up to 72% at the highest dose. Furthermore, in a preclinical disease model for CKD with anemia presented by Modus at the conference ASH 2023, sevuparin was found to lower hepcidin, treat anemia symptoms and ameliorate the kidney status in mice with CKD. These results, combined with its favorable safety profile, support sevuparin's potential as an innovative treatment option for patients with limited alternatives today.

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Comment from CEO Johan Öhd
“The initiation of this Phase II study marks an important milestone for Modus Therapeutics and our development of sevuparin as a potential new treatment for patients with CKD-related anemia. We are excited by the scientific progress supporting our clinical strategy and look forward to sharing new data as the study progresses.”

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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 2024-12-09 09:55 CET.

Certified Adviser
Svensk Kapitalmarknadsgranskning AB
Website: **www.skmg.se**

About Modus Therapeutics and sevuparin
Modus is a Swedish biotechnology company that is developing its proprietary polysaccharide sevuparin as a potential treatment for several major healthcare needs including sepsis, endotoxemia, severe malaria and other disorders with severe systemic inflammation as well as states of anemia, related to chronic inflammation such as kidney disease. There is a great need for new treatments that can effectively treat these conditions. Modus’ ambition is to create a paradigm shift in the care of these diseases, where sevuparin could provide therapeutic benefits. 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 immunomodulating, 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.

Attachments
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