

First Patient Dosed in Part 2 of Modus Therapeutics' Phase IIa Study in Chronic Kidney Disease with Anemia

Stockholm, Sweden – December 10, 2025 – Modus Therapeutics Holding AB (“Modus”) today announces that the first patient has been dosed in Part 2 of the company’s ongoing Phase IIa clinical study evaluating sevuparin for the treatment of Chronic Kidney Disease (CKD) with anemia. Part 2 represents the proof-of-concept phase and follows the completion of Part 1 in Q2 2025. The start of Part 2 was preceded by submission of a planned protocol amendment during the summer of 2025 to implement the final dose selection based on Part 1 data. In line with the company’s communicated plans, the first patient in Part 2 was dosed approximately one month after regulatory approval of the amendment.

This study is a key component of Modus’ clinical development program for **sevuparin**, an investigational heparinoid intended to address unmet medical needs in **CKD with anemia** and potentially other chronic inflammatory conditions.

Study Design and Objectives

The Phase IIa study comprises two parts:

- **Part 1 (completed):** Single-dose administration to assess safety and support future dose selection across varying degrees of renal impairment.
- **Part 2 (ongoing):** Repeated-dose evaluation focusing on safety and clinically relevant outcomes including **hemoglobin**, and **hepcidin levels**, as well as other kidney and blood related biomarkers in patients with advanced CKD and anemia.

Across Parts 1–2, the study is expected to enrol **50–60 patients**.

Rationale and Background

Anemia in CKD is common, worsens with disease severity, and impacts quality of life and prognosis. Inflammation-driven increases in **hepcidin** may restrict iron availability and contribute to anemia and treatment hyporesponsiveness. Preclinical and translational clinical data suggest **sevuparin** can reduce hepcidin, providing a mechanistic rationale to improve erythropoiesis alongside renal outcomes.

Comment from CEO John Öhd

“Advancing into Part 2 with **first patient dosed** is a major milestone for Modus and potentially for patients in the future. Building on the safety and pharmacokinetic data from Part 1, we can now evaluate sevuparin’s impact on hemoglobin, hepcidin-and kidney related biology in patients with advanced CKD and anemia,” said **John Öhd**, CEO of Modus Therapeutics.

Collaborators and Study Centers

The trial is being conducted at two leading nephrology centers in Italy – **Centro Ricerche Cliniche di Verona / Policlinico G.B. Rossi (Verona)** and the **Nephrology & Dialysis Unit at Istituti Clinici Scientifici Maugeri (Pavia)** – in collaboration with the **CRO Latis S.r.l.**

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About Modus Therapeutics and sevuparin

Modus is a Swedish biotech company developing its patented polysaccharide, sevuparin, as a treatment option for several major unmet medical needs, including anemia in kidney disease and other chronic inflammatory conditions, severe malaria, sepsis, and other disorders involving severe systemic inflammation. 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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