PRESS RELEASE
03 November 2025 13:00:00 CET

Modus Therapeutics receives regulatory approval for Part 2 of the Phase IIa study in CKD-with anemia

Stockholm, Sweden – November 3, 2025— Modus Therapeutics Holding AB (publ) ("Modus" or the "Company") announces that the competent authorities in Italy have approved the Company's dose selection for its ongoing Phase IIa study evaluating sevuparin in patients with anemia associated with chronic kidney disease (CKD). This approval enables initiation of Part 2 (repeat-dose; proof-of-concept) in Q4 2025, in line with previously communicated plans.

What the approved amendment covers

Final dose selection: Three sevuparin doses are specified for Part 2, based on single-dose data from Part 1. The Part 2 dose levels pertain to patients with CKD stages 3–5. Data from Part 1 also indicate that no sevuparin dose adjustment is required for patients with CKD stages 1–2 (mild CKD).

Safety data: In Part 1, sevuparin was well tolerated regardless of kidney function, with no treatment discontinuations or clinically meaningful safety signals.

Timeline: With this approval, Part 2 remains on track to start in Q4 2025 as planned.

CEO comment

"The protocol approval is an important milestone for our CKD program. We can now proceed to repeat dosing in patients and evaluate sevuparin's clinical potential in **CKD with anemia**. This keeps us on our planned timeline to start Part 2 in Q4 2025."
— **John Öhd, CEO**

About the study

The ongoing Phase IIa study is conducted at two leading nephrology centers in Italy (Verona and Pavia) together with the CRO partner Latis S.r.l. Part 1 (single dose) provided the basis for dose selection and design ahead of Part 2.

Medical need and rationale

Preclinical and translational findings show that sevuparin can lower hepcidin, improve hematologic parameters, and modulate markers of kidney injury/fibrosis—supporting development in **CKD with anemia**, where novel hepcidin-targeted therapies are needed.

Next steps

Site activation and patient screening for Part 2 (repeat dosing, PoC) are intended to start in Q4 2025. Business development activities continue in parallel with study execution.

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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
Modus Therapeutics receives regulatory approval for Part 2 of the Phase IIa study in CKD-with anemia