

Modus Therapeutics on track to initiate Part 2 of Phase IIa sevuparin study in CKD-related anemia

Stockholm, Sweden – 1 August 2025 – Modus Therapeutics Holding AB (publ) ("Modus") today announces that dose levels for Part 2 of its ongoing Phase IIa clinical study of sevuparin in patients with chronic kidney disease (CKD) and anemia have been selected. The selection is based on data from Part 1 of the study, and a corresponding protocol amendment has been submitted to the relevant regulatory authorities, in line with the planned timeline.

Part 1 of the study, conducted at leading nephrology centers in Italy, enrolled healthy volunteers and patients across the full spectrum of kidney function—from mild (CKD stages 1–2) to terminal disease (CKD stage 5). Single doses of sevuparin were administered, followed by comprehensive assessments of pharmacokinetics (PK), safety, and tolerability.

The data confirm that sevuparin was well tolerated at all dose levels, with no discontinuations due to adverse events, and no observed clinically significant safety trends. Based on these results, three sevuparin dose levels have been selected for use in Part 2, involving repeated dosing in patients with moderate to severe CKD (stages 3–5). No dose adjustment will be necessary for patients with mild CKD.

"With the submission of dose selection data for Part 2 of our Phase IIa study in CKD-associated anemia, Modus continues to execute its clinical development strategy with precision," said John Öhd, CEO of Modus Therapeutics. "We remain on track to initiate Part 2 in Q4 2025 and look forward to advancing our efforts to establish sevuparin as a potential new therapeutic option for patients with limited treatment alternatives."

The Phase IIa study is being conducted in collaboration with CRO partner Latis S.r.l., alongside the Centro Ricerche Cliniche di Verona/Policlinico G.B. Rossi in Verona, and the Nephrology & Dialysis Unit at Istituti Clinici Scientifici Maugeri in Pavia.

For more information on Modus Therapeutics, please contact:

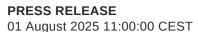
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About Modus Therapeutics and sevuparin

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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