

Modus Therapeutics temporarily pauses enrollment in Phase IIa study of sevuparin in CKD with anemia

Modus Therapeutics Holding AB (publ) (“Modus” or the “Company”) today announced that it has voluntarily decided, as a precautionary measure, to temporarily pause enrollment in Part 2 of the ongoing Phase IIa study of sevuparin within the Company’s program in CKD with anemia. The decision was made after a serious adverse event in a patient treated with sevuparin was reported to the relevant regulatory authorities as a suspected unexpected serious adverse reaction (an event also denoted as a SUSAR), and following a review with the study’s safety committee. The pause is not the result of a regulatory decision. The Company’s preliminary assessment is that the pause will shift the proof-of-concept readout from around the turn of the year 2026/2027, as previously communicated, to the first quarter of 2027.

The classification as a SUSAR means that a causal relationship to the study drug cannot be excluded, but not that a causal relationship has been established. At the time of the decision, no other patient in the study was receiving treatment, and the pause has therefore not required any ongoing treatment to be discontinued. Together with the study investigators and safety committee, Modus is now evaluating the available data to determine next steps, including the assessment of causality. The Company intends to provide more definitive information on the expected impact on the timeline as soon as the ongoing assessment has been completed. The Company’s cash and cash equivalents, including the proceeds from the directed share issue in September 2026, are expected, based on the current cash flow forecast, to fund operations into the second quarter of 2027. Any effects of the pause on costs and timeline will be reflected in the updated assessment of the Company’s financing that Modus intends to present in its interim report for the third quarter, to be published on November 24, 2026.

“Patient safety is our highest priority. We have therefore chosen to temporarily pause enrollment while the event is evaluated. We are in close dialogue with the investigators, the study’s safety committee and the relevant authorities, and will provide an update as soon as we have more information,” said John Öhd, CEO of Modus Therapeutics.

About the study

The study is part of the Company’s program in CKD with anemia and is an open-label Phase IIa study evaluating sevuparin in patients with CKD stages 3–5, with endpoints including hemoglobin, hepcidin and kidney-related biomarkers. The study is being conducted at two nephrology centers in Italy. In the ongoing Part 2, sevuparin is administered subcutaneously once daily for up to 28 days at three dose levels, one per CKD stage. Part 1, with single doses, was completed in 2025 with no discontinuations due to adverse events.

For more information on Modus Therapeutics, please contact:

John Öhd, CEO, Modus Therapeutics
Phone: +46 (0) 70 766 80 97
Email: john.ohd@modustx.com

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 2026-10-14 20:30 CEST.

Certified Adviser

Bergs Securities AB
Hemsida: www.bergssecurities.se

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 temporarily pauses enrollment in Phase IIa study of sevuparin in CKD with anemia