

Modus Therapeutics: SEVUSMART study of sevuparin in children with severe malaria published in Nature Communications

Stockholm, October 21, 2026 — Modus Therapeutics Holding AB (publ) (Nasdaq First North Growth Market: MODTX) announces that the manuscript based on the Phase Ib study SEVUSMART in severe malaria, lead-authored by Professor Kathryn Maitland of Imperial College London with co-authors from the SMAART consortium including members such as University College London and the University of Oxford, has been published today in the peer-reviewed journal Nature Communications, following independent peer review. The manuscript was submitted in June 2026 and made available ahead of peer review as a preprint via Research Square.

SEVUSMART is a Phase Ib study evaluating sevuparin as an adjunctive treatment for severe malaria in children. The study is conducted as an investigator-led study with Imperial College London as sponsor and Professor Maitland as principal investigator, supported by the SMAART consortium that focuses on severe malaria and gathers world-leading institutions in the area of tropical diseases, and with funding from a Wellcome research grant (209265/Z/17/Z). Modus Therapeutics contributed sevuparin as well as scientific and regulatory expertise and holds the commercial rights to the drug candidate.

The study enrolled 23 children with severe malaria in Kenya and Zambia and, using a continual reassessment method, identified a maximum tolerated dose of 3 mg/kg per infusion, consistent with the dose level previously established in adult studies. The dose-limiting toxicities observed were laboratory-defined modest elevations (>2.5 times the upper limit of normal) in APTT, a coagulation marker, with no clinical bleeding complications. The 28-day mortality in the study was 4.3 percent (1 of 23 children), compared with an expected mortality risk of at least 10 percent based on the children's disease severity, and with historical comparator data of 21–34 percent from the SMAART observational study in the same patient populations presenting with coma (cerebral malaria). The study was an uncontrolled Phase I study without a comparator arm; the results should therefore be interpreted with caution and require confirmation in a controlled trial.

“The publication of the SEVUSMART study in Nature Communications, following independent peer review, is a strong external validation of sevuparin's clinical profile in severe malaria. The study clearly defined the dose for the next study and confirmed sevuparin's favorable safety and tolerability profile in a very vulnerable patient population,” says John Öhd, CEO of Modus Therapeutics. “We look forward to working with Professor Maitland and her team on the next steps in the program, including the planning of a Phase II study.”

“We are pleased that our findings on sevuparin in children with severe malaria have now been published in Nature Communications, having gone through rigorous peer review. The results give us a clear dose to move forward with and provide an encouraging safety profile in a patient group where treatment options remain limited. We look forward to building on this work in a larger, controlled study,” says Professor Kathryn Maitland, Imperial College London, principal investigator of SEVUSMART.

The article, “Sevuparin in children with severe malaria: A phase I safety and dose finding trial”, is available at <https://www.nature.com/articles/s41467-026-78536-3>

About SEVUSMART

SEVUSMART (ISRCTN number: ISRCTN32271864) is a Phase Ib study evaluating the dosing and tolerability/safety of sevuparin in combination with standard of care for severe malaria in children aged 3 months to 12 years; the study enrolled 23 children. The study was conducted at research centers in Kenya and Zambia and completed patient recruitment in March 2025. Imperial College London is the sponsor; the study was funded by Wellcome.

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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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