PRESS RELEASE
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Modus Therapeutics Receives Approval to Initiate a Phase IIa Clinical Trial for Chronic Kidney Disease (CKD)

STOCKHOLM, SWEDEN – November 18, 2024: Modus Therapeutics Holding AB ("Modus") announces that it has received approval from the relevant authorities in Italy for its planned Phase IIa clinical trial with sevuparin.

As previously communicated, the planned Phase IIa study will be conducted in two parts. Part 1 aims to establish dosage levels and safety of sevuparin through single doses in 25-30 patients with varying degrees of kidney failure. Part 1 will also include a small reference group of healthy volunteers and may also provide an opportunity to assess early effects on hepcidin in a relevant patient population.

Part 2, the so-called "proof of concept" segment, will evaluate the effects of repeated dosing of sevuparin based on the dose levels established in Part I, focusing on endpoints related to anemia, hepcidin, kidney status, and relevant biomarkers in patients with more severe chronic kidney disease and anemia. It is expected to recruit 25-30 patients, bringing the total study enrollment to 50-60 patients. The approval is in line with Modus' target to execute Part I of the study during the first half of 2025.

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About Modus Therapeutics and sevuparin
Modus is a Swedish biotechnology company that is developing its proprietary polysaccharide sevuparin as a potential treatment for several major healthcare needs including sepsis, endotoxemia, severe malaria and other disorders with severe systemic inflammation as well as states of anemia, related to chronic inflammation such as kidney disease. 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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