



Sedana Medical Receives IND Approval for US Trials



Sedana Medical AB (publ) has announced that the company has received Investigational New Drug (IND) clearance from the US Food and Drug Administration (FDA) to initiate phase III pivotal clinical trials with its Sedaconda products in the United States.

Sedana Medical is aiming for a combination registration of the medical device Sedaconda ACD and the pharmaceutical Sedaconda (isoflurane) for sedation of mechanically ventilated intensive care patients. As previously announced, the company is planning to commence patient recruitment at the turn of Q1/Q2 2022, with the objective to obtain US approval in 2024.

"We are concluding the year with another important milestone towards the registration of our Sedaconda products in the United States. With the IND approval, we can keep our ambitious timelines for initiating our pivotal clinical trials. The US market represents our largest commercial opportunity, and we are looking forward to bringing our products to intensive care patients in the US," said Johannes Doll, CEO of Sedana Medical.

About the studies

Sedana Medical aims to conduct two multicenter randomized, assessor-blinded controlled trials to confirm efficacy and safety. The number of patients for both trials together will be around 500. The study design is similar to the successful Sedaconda trial (SED001) that was conducted in Europe and formed the basis for the European approval earlier this year. The primary endpoint in each study will be to show that Sedaconda (isoflurane), administered via Sedaconda ACD, is effective and non-inferior to propofol for sedation of mechanically ventilated intensive care patients. The secondary endpoints relate to opioid needs, spontaneous breathing, wake-up time and cognitive recovery.

Source: [Sedana Medical](#)

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