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Sedana Medical receives IND approval for US trials

Sedana Medical AB (publ) (SEDANA: FN Stockholm) today announces 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.

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Sedana Medical is listed on Nasdaq First North Growth Market in Stockholm.

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About Sedana Medical

Sedana Medical AB (publ) is a pioneer medtech and pharmaceutical company focused on inhaled sedation to improve the patient's life during and beyond sedation. Through the combined strengths of the medical device Sedaconda ACD and the pharmaceutical Sedaconda (isoflurane), Sedana Medical provides inhaled sedation for mechanically ventilated patients in intensive care.

Sedana Medical has direct sales in Benelux, France, Germany, Great Britain, the Nordic, and Spain. In other parts of Europe as well as in Asia, Australia, Canada, and South- and Central America, the company works with external distributors.

Sedana Medical was founded in 2005, is listed on Nasdaq First North Growth Market (SEDANA) and headquartered in Stockholm, Sweden.