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Sedana Medical completes patient recruitment for its clinical program in the US

Sedana Medical AB (publ) announces that all 235 randomized patients have been recruited for its INSPiRE-ICU 2 phase III clinical trial in the United States. Earlier this spring, Sedana Medical reported the completion of enrolment to the parallel phase III clinical trial INSPiRE-ICU 1. The company anticipates topline results from both trials in the second half of 2024, with a planned New Drug Application (NDA) submission in the first quarter of 2025.

"The completion of INSPiRE-ICU 2 concludes Sedana Medical´s clinical trials in the United States. Running this study together with esteemed clinical investigators from highly ranked academic centers such as Columbia, the Harvard-affiliated medical center Beth Israel Deaconess Medical Center and many others has been very exciting and rewarding. Many investigators from the participating sites have been excited to be part of our pioneering studies. The bedside experience in the studies has generated a lot of interest in using inhaled sedation in US practice, which we hope will be possible soon", said Peter Sackey, Chief Medical Officer of Sedana Medical.

Peter Sackey further elaborated: "We now enter into an intense phase of final monitoring, data cleaning and transfer to our statistician team for analysis. In parallel, the long-term outcomes at 3 and 6 months are being collected centrally by the Critical Illness, Brain Dysfunction, and Survivorship team at Vanderbilt Medical Center. With this parallel approach, we expect topline results for the 30-day outcomes in both studies a few months´ apart before the end of this year, and a swift regulatory submission in Q1, 2025".

"The inhaled sedative isoflurane, studied in this trial, is a mainstay of general anesthesia during surgery because of its unique and straightforward pharmacokinetic and pharmacodynamic profile, properties that may potentially also benefit ICU patients. We are very excited to complete enrolment in this trial and eagerly await results evaluating its potential use as a sedative for ventilator-dependent adult ICU patients in the US", said Jeremy Beitler, MD, MPH at Columbia University and Senior Lead Investigator for the INSPiRE-ICU 2 study.

Johannes Doll, President and CEO of Sedana Medical, stated: "Completing enrolment of our clinical program marks an important milestone on our journey towards making inhaled sedation accessible to intensive care patients in the United States. I would like to sincerely thank all our clinical trial sites, partners, and the Sedana Medical team for this significant achievement. It makes me very proud that we have been able to convene this exceptional group of intensive care teams from some of the most prominent US hospitals. Their advice and support will be invaluable as we work towards launching our inhaled therapy on the US market."

INSPiRE-ICU 1 and 2 are two identical randomized phase III trials, aiming to confirm the efficacy and safety for sedation with isoflurane delivered via Sedana Medical's unique medical device Sedaconda ACD. The primary endpoint is the proportion of time spent at adequate depth of sedation, compared with intravenous sedation using propofol. In addition, several important secondary endpoints are being studied, including opioid use, time to wake-up, cognitive recovery and spontaneous breathing. The first patient was included in April 2022, and 31 highly reputed clinics in the United States are involved in

the two trials. The design of the US studies is similar to the Sedaconda study (SED001) successfully performed in Europe in 2017–2019, which resulted in market approval in 2021.

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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 Nordics, 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 Stockholm (SEDANA) and headquartered in Stockholm, Sweden.