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Sedana Medical completes patient recruitment for pediatric IsoCOMFORT study

Sedana Medical AB (publ) (SEDANA: FN Stockholm) announces that the last patient has been recruited for its pediatric phase III clinical study in Europe (IsoCOMFORT). Assuming positive study results, the company expects approval of the pediatric indication in Q4 2023 or Q1 2024 within Europe, enabling data exclusivity/market protection for the adult indication until 2031.

The IsoCOMFORT study compares the efficacy and safety of Sedana Medical's pharmaceutical Sedaconda (isoflurane), administered via the company's medical device Sedaconda ACD, with intravenous midazolam for sedation of mechanically ventilated ICU patients in the age group of 3–17 years. Sedana Medical will now conclude the study and apply for an extension of the indication for inhaled sedation to comprise the pediatric population in Europe.

"I would like to thank the study teams at our clinical trial sites in Spain, France, Germany and the UK that have helped us reach this important milestone", says Johannes Doll, President and CEO of Sedana Medical. "The pediatric indication is important for us in two ways. It would provide pediatric ICUs with a new treatment alternative for a vulnerable and difficult-to-treat patient group. And it will also secure data exclusivity/market protection for both the adult and pediatric indication until 2031 and thus protect our valuable market position as the first and only approved inhaled sedation therapy for the ICU."

The 10-year data exclusivity/market protection enabled by completing the pediatric study based on the Pediatric Investigation Plan (PIP) means that only Sedana Medical can market Sedaconda (isoflurane) for inhaled sedation in intensive care based on the results of the company's clinical studies, including the Sedaconda study which led to the European registration in 2021.

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Sedana Medical is listed on Nasdaq First North Growth Market in Stockholm. The company's Certified Adviser is Erik Penser Bank, +46 8 463 83 00, certifiedadviser@penser.se.

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.