

Press release December 23, 2022, 08.00 CET.

Sedana Medical receives positive opinion from EMA's Pediatric Committee on reduced pediatric study design

Sedana Medical AB (publ) (SEDANA: FN Stockholm) reports a positive outcome from its interaction with the European Medicines Agency's Pediatric Committee (PDCO), aimed at modifying the agreed Pediatric Investigation Plan (PIP) for the company's ongoing pediatric phase III clinical study in Europe (IsoCOMFORT). The change will enable faster study completion, earlier approval of the pediatric indication and reduced investments.

Completion of the study according to the PIP is a requirement for obtaining a pediatric indication for the Sedaconda therapy in Europe and for securing 10-year data exclusivity in Europe for the Sedaconda therapy for adults (and planned to be expanded to children based on IsoCOMFORT). As a result of the changes, Sedana Medical expects to conclude the study based on approximately 90 patients, instead of 160 patients previously. As of today, 88 evaluable patients have been recruited for the study.

The company now expects European approval of the pediatric indication in a decentralized procedure in Q4 2023 or Q1 2024. Data exclusivity for the adult indication would be secured until 2031.

"We are glad that the PDCO has viewed our proposal favorably. Assuming positive study results, the change will accelerate the extension of our label to include ICU sedation of children above 3 years of age. This would provide an important treatment option for sedation in a vulnerable and challenging patient population. At the same time, the new study design allows for a more cost-efficient way for us to complete the PIP to ensure 10-year data exclusivity in Europe. This is an important milestone as it will protect our valuable market position as the first and only approved inhaled sedation therapy for the ICU.", says Johannes Doll, President and CEO of Sedana Medical.

The IsoCOMFORT study compares 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. The previous study design was statistically powered to show superiority versus midazolam and required 160 patients. Under the new design, the study is powered for non-inferiority, which means that 90 evaluable patients are sufficient. Once the 90 patients are reached, Sedana Medical plans to conclude the IsoCOMFORT study and submit a type II variation to extend the indication for inhaled sedation to comprise the pediatric population in Europe. The 10-year data exclusivity 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.

For additional information, please contact:

Johannes Doll, CEO, +46 (0)76 303 66 66

Johan Spetz, CFO, +46 (0)730 36 37 89

ir@sedanamedical.com



This information is such that Sedana Medical AB (publ) is obliged to disclose pursuant to the EU Market Abuse Regulation. The information was released for public disclosure, through the agency of the contact persons above, on December 23, 2022, at 08:00 am (CET).

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.