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First patient included in pediatric study IsoCOMFORT

Sedana Medical AB (publ) (SEDANA: FN Stockholm) today announced that the first patient has been included in the company's pediatric study IsoCOMFORT (SED002) which is conducted to investigate if inhaled sedation of Sedaconda (isoflurane) via AnaConDa is a safe and more effective sedation method than intravenously administered midazolam for children under 18 years. The study is expected to be completed during the second half of 2022 and is aimed at leading to an approved pediatric indication for inhaled sedation.

"AnaConDa was approved for use in children in 2019 in Europe and this study is another important step as it ensures a complete market application for Sedaconda and thus ten years of market exclusivity in the EU. As propofol, due to safety concerns, is contraindicated in children for ICU sedation, midazolam is the only sedative option for children in the ICUs and therefore the medical need is great. A positive outcome in the study will lay the foundation for an approved pediatric indication for inhaled sedation," said Christer Ahlberg, CEO of Sedana Medical.

The study compares efficacy and safety of Sedaconda delivered via AnaConDa with intravenous midazolam for sedation of mechanically ventilated patients younger than 18 years (3–17 years). The primary endpoint of the study is the proportion of time with adequate sedation depth (according to the COMFORT-B scale). The study, which includes 160 children, will be conducted in 23 intensive care units in Spain, Germany, France and Sweden. Sedation will last for 12-48 hours. Patient recruitment is estimated to last 18 months and the study is expected to be completed during the second half of 2022.

"The recruitment of the first patient in the study is an important milestone for us, as well as for the study investigators, and we are very happy that the study has been initiated. The study has raised great interest and enthusiasm in the pediatric intensive care community, especially since sedation of children can be very challenging. Previous case reports of inhaled sedation in children indicate that isoflurane works well, and we have high hopes that this prospective study can substantiate these effects," said Peter Sackey, CMO at Sedana Medical.

As Sedana Medical's market application for Sedaconda (submitted in November 2020) contained a pediatric plan (the study plan for the IsoCOMFORT study), an approval would mean that Sedana Medical receives ten years of market exclusivity in Europe for the use of isoflurane in sedation in intensive care. The results from the IsoCOMFORT study are not a requirement for approval for use in adults. Therefore, the timetable for the approval of Sedaconda is not affected by the IsoCOMFORT study. Further information on the study is available at www.clinicaltrials.gov (NCT04684238).

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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) develops and sells the medical device AnaConDa for the administration of volatile anaesthetics. Through a combination of AnaConDa and the drug candidate Sedaconda (isoflurane), Sedana Medical provides inhaled sedation for mechanically ventilated intensive care patients. The company has applied for market approval in Europe for Sedaconda and expects an approval in the second half of 2021.

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Today, mechanically ventilated intensive care patients are sedated intravenously which leads to several challenges for both patients and care givers. Challenges that are solved by inhaled sedation. Globally, seven to eight million patients are estimated to be sedated in intensive care due to mechanical ventilation, evenly distributed between the US, Europe, and Asia. These patients are on average sedated three to four days. Sedana Medical estimates the total market potential to SEK 20-30 billion. Three years after marketing approval in Europe, Sedana Medical expects sales of SEK 500 million in Europe and an EBITDA margin of about 40 percent. The company has initiated processes to obtain market approval in the US in 2024 and in markets outside the EU.

Sedana Medical has direct sales in Benelux, France, Germany, Great Britain, the Nordics and Spain as well as external distributors in other parts of Europe, Australia, Canada, China, India, Israel, Japan, Mexico and South Korea. The company was founded in 2005 and is headquartered in Stockholm, Sweden, with medical device development in Ireland.