

Press release November 16, 2023, 08.00 CET.

## Key results of Sedana Medical's paediatric study IsoCOMFORT published

**Sedana Medical AB (publ) today announces that the main results from the paediatric IsoCOMFORT study have been published in the Clinical Trials Registry EudraCT.**

IsoCOMFORT was a randomised active-controlled assessor-blinded study comparing the efficacy and safety of sedation with inhaled isoflurane, administered via the company's medical device Sedaconda ACD-S, with intravenous midazolam in mechanically ventilated paediatric patients 3 to 17 years old. The primary endpoint was to compare the time that the targeted sedation depth was maintained. Key secondary endpoints included opioid requirements during sedation, time to extubation and adverse events.

As previously communicated, the primary endpoint, proportion of time at target sedation level, was met in the main analysis (full analysis data set) with least square means (LSM) (95% confidence interval[CI]) of 68.94 (52.83 to 85.05)% for isoflurane vs 62.37 (44.70 to 80.04)% for midazolam, but not in the per protocol analysis set (LSM [95% CI] of 70.91 [50.75 to 91.07]% for isoflurane vs 65.57 [44.03 to 87.11]% for midazolam).

Opioid requirements were significantly lower during sedation with isoflurane than with midazolam, with LSM [95% CI] of 2.1 [1.3 to 2.9] fentanyl equivalents/hour for isoflurane vs. 4.6 [3.5 to 5.6] for midazolam. There was no indication of tolerance development during the treatment period. Time to extubation after end of treatment was significantly shorter in the isoflurane group with median (interquartile range) time to extubation of 0.75 (0.25 to 1.5) hours for the isoflurane group vs 1.09 (0.49 to 5.50) hours for the midazolam group. There was no statistical difference in the proportion of time with spontaneous breathing. Adverse events were reported for more isoflurane-treated patients than midazolam-treated patients (83,6% vs 63,6%). The majority of the adverse events were unrelated to treatment and mild and those related to treatment were in line with the known safety profile of isoflurane.

"After having seen the results for our key secondary endpoints, we remain cautiously optimistic regarding the chances to obtain an extended regulatory approval to include also mechanically ventilated paediatric patients (3 to 17 years) in intensive care. The work with the dossier submission is expected to be completed in the next few months, after which the competent authorities will perform an overall benefit and safety evaluation and decide about the approval of the paediatric indication, which we expect approximately mid-2024.", says Peter Sackey, Chief Medical Officer at Sedana Medical.

"Paediatric ICU patients are a vulnerable and difficult-to-treat patient population, with a clear need for alternative sedation methods. Based on our IsoCOMFORT results, we are hoping to receive an approval, so that patients between 3 and 17 years can benefit from the advantages we saw in the study, such as lower opioid requirements and faster time to extubation.", says Johannes Doll, President and CEO of Sedana Medical. "In addition, the IsoCOMFORT study is an important milestone for us as we expect it will secure data exclusivity/market protection for our adult indication until at least 2031, allowing us to benefit from offering the only approved pharmaceutical for inhaled sedation in intensive care units in Europe."

For more information, see:

<https://www.clinicaltrialsregister.eu/ctr-search/trial/2020-000578-31/results>



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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.