Press release May 17, 2023, 08.00 CET.

Sedana Medical reports topline results from phase 3 paediatric IsoCOMFORT study

Sedana Medical AB (publ) today announces that the primary endpoint of its Phase 3 IsoCOMFORT study was met in the full analysis set, but was not met in the per-protocol analysis. The completion of the trial extends the company's data exclusivity of the adult indication to 2031. The approval of the paediatric indication will be subject to regulatory review.

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. Sedana Medical´s objective for the IsoCOMFORT study was two-fold: to secure extended data exclusivity for Sedaconda (isoflurane)'s main indication in adult patients and to obtain an approval for sedation of mechanically ventilated children in intensive care.

With the completion of the paediatric trial and assuming a positive compliance check by EMA, Sedana Medical expects to secure extended data exclusivity for sedation of mechanically ventilated adult ICU patients. In the countries where Sedaconda (isoflurane) has received market authorization, other companies would be prohibited from promoting inhaled sedation in intensive care until 2031, unless a full clinical trial is run. The extended data exclusivity is independent of the study results.

A potential approval of the paediatric indication will be determined by the Reference Member State and the Concerned Member States. In the full analysis dataset, i.e. when including all 92 eligible patients, non-inferiority was met. However, when excluding 7 patients for the per-protocol analysis, non-inferiority was not met. This divergence in the results warrants careful interpretation. Sedana Medical will further analyse the underlying data and is planning to submit the dossier to the authorities in the 2nd half of the year.

"We are happy to be one step closer to the completion of our paediatric submission. We are cautiously optimistic and look forward to compiling our regulatory dossier and entering into discussions with the competent authorities", stated Peter Sackey, Chief Medical Officer of Sedana Medical.

"The completion of our IsoCOMFORT study is an important milestone for us as it will secure data exclusivity for our adult indication until 2031, allowing us to benefit from being the only approved therapy for inhaled sedation in intensive care units.", says Johannes Doll, President and CEO of Sedana Medical. "In addition, we are hoping to receive an approval of a new treatment alternative for a vulnerable and difficult-to-treat patient population."

After thorough review of all efficacy and safety results, Sedana Medical will apply for an extension of the indication for inhaled sedation to comprise the paediatric population in Europe. In accordance with standard regulatory timelines the review process would be completed by H1 2024. Assuming a positive decision, the national authorities would then decide on local market authorizations in the respective countries.

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 May 17, 2023 at 08:00 am (CET).

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.