

Press release December 4th, 2019, 08.00 am, CET.

Sedana Medical supports isoflurane sedation study for reduction of delirium

Sedana Medical AB (publ) (SEDANA: FN Stockholm) today announced that the company is funding a large French multicenter study with isoflurane – the substance in the company's drug candidate IsoConDa – delivered by the company's medical device AnaConDa. The aim is mainly to show a reduced incidence of delirium in mechanically ventilated intensive care patients compared to intravenous sedation with propofol. A positive result would significantly strengthen the company's clinical base for regulatory and commercial expansion.

"If this study turns out positive, it is clear evidence of the advantages with our therapy in the case of delirium, which is one of the major medical challenges when sedating ICU patients. Positive results from such a large study could also be used regulatorily and would significantly promote the commercial uptake of our therapy," said Christer Ahlberg, CEO of Sedana Medical.

The randomized, controlled trial will include 250 patients who are expected to be mechanically ventilated in intensive care for more than 24 hours. The study will be conducted in nine different intensive care units and will be led by principal investigators Dr Pierre Bailly and professor Erwan L'Her at Centre Hospitalier Regionale Universitaire Brest, France. The study will begin early 2020 and is expected to be finalized in early 2023 after 24 months of inclusion and a twelve-month cognitive follow up.

The primary endpoint of the study is the incidence of delirium after sedation with isoflurane via the AnaConDa, compared with the current intravenous standard therapy propofol. Isoflurane is the drug substance in Sedana Medical's candidate drug IsoConDa. Secondary endpoints include delirium-free days after sedation, ventilator-free days, ICU-free days, 28-day mortality, three- and twelve months cognitive outcomes, hemodynamic effects of sedation, organ safety assessment, quality of life and a health-economical evaluation.

Sedana Medical will provide the investigators in this study with AnaConDa, related equipment, local training in the participating ICUs before and during the study, as well as with financial support. Sedana Medical has previously provided support for studies that, in addition to its own pivotal studies, in the long term will contribute to a strong scientific platform for inhaled sedation with AnaConDa and IsoConDa.

"We have high hopes that the study will confirm the results from previous, smaller studies, and clinical experiences, where inhaled sedation with AnaConDa has been associated with improved cognitive recovery and function. Delirium in ICU patients is associated with significantly higher mortality, longer ICU and hospital stays, increased costs and long-term cognitive impairment. An ICU sedative that reduces the incidence, duration and consequences of delirium without negative consequences would be a game-changer in ICU sedation", said Peter Sackey, CMO of Sedana Medical.

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Sedana Medical is listed on Nasdaq First North Growth Market in Stockholm.

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The information was released for public disclosure, through the agency of the contact person above, on December 4th, 2019 at 08:00 a.m. (CET).

About Sedana Medical's market

Sedana Medical's market consists primarily of sedation of mechanically ventilated intensive care patients. The market for sedation of mechanically ventilated intensive care patients today consists of established drugs that are

administered intravenously. There are several challenges for both patients and care givers with today's intravenous treatment that are solved by inhaled sedation. Today, it is estimated that between seven and eight million patients are sedated due to mechanical ventilation in intensive care globally, evenly distributed between the US, Europe and Asia. These patients are sedated on average three to four days. Sedana Medical estimates the total market potential to SEK 20-30 billion.

Sedana Medical AB (publ) has developed and sells the medical device AnaConDa, for the administration of volatile anaesthetics to mechanically ventilated patients. A major clinical registration study is currently ongoing to obtain market approval in Europe for inhalation sedation in intensive care units with the pharmaceutical IsoConDa® (isoflurane).

Sedana Medical has direct sales in the Nordic countries, Germany, France, Great Britain and Spain as well as external distributors in the rest of Europe, Canada, Australia, Japan and South Korea. The company headquarters are based in Stockholm, Sweden with R&D operations in Ireland.