

Press release October 16, 2019, 10.00 am, CET.

Sedana Medical is co-funding AnaConDa study on lung protection

Sedana Medical AB (publ) (SEDANA: FN Stockholm) today announced that the company is co-financing the world's largest multicenter study with AnaConDa in France. The primary purpose of the study is to show that inhaled sedation with AnaConDa has lung protective properties, gives shortened ventilator time and higher survival in lung sick intensive care patients.

"If this large study turns out positive, it will dramatically change the view of inhaled sedation in relation to intravenous sedation. If the results of the study support the hypothesis that inhaled sedation via AnaConDa has therapeutic effects, leads to shorter ventilator treatment and a higher survival rate, it is an important breakthrough for ICU patients with severe lung disease worldwide," said Christer Ahlberg, CEO of Sedana Medical.

The randomized and controlled trial includes 700 patients with Acute Respiratory Distress Syndrome (ARDS). Up to 30 percent of mechanically ventilated patients in an intensive care unit suffer from ARDS, a serious condition with 35-45 percent mortality. The study, which will be conducted in 30 different intensive care units in France, will begin in the fall of 2019 and is expected to take three years to complete.

The study compares the current intravenous standard therapy propofol with inhaled sedation with sevoflurane via AnaConDa. A previous smaller study from the same research group showed that inhaled sedation was associated with improved lung function in patients with ARDS¹. The same effects have also been shown in several animal studies.

"There are good reasons to believe that the effects studied in this trial are class effects of inhaled anesthetics. It is of minor importance that the study is conducted with sevoflurane and not isoflurane that IsoConDa contains," said Peter Sackey, CMO of Sedana Medical.

The study is mainly funded through a grant from the French Ministry of Health. Sedana Medical will provide the investigators in this study with AnaConDa and related equipment, but also with education in the therapy before and during the study. Sedana Medical has previously provided support for studies that, in addition to its own pivotal studies, in the long term contribute to a strong scientific support for inhaled sedation with AnaConDa.

For additional information, please contact:

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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 October 16, 2019 at 10.00 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.

¹ Jabaudon M et al, Am J Respir Crit Care Med. 2017 Mar 15;195(6):792-800

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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 inhaled 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.