Press release May 12, 2020, 09.00 a.m. CET.

Sedana Medical supports multinational study of inhaled sedation in Covid-19 ARDS

Sedana Medical AB (publ) (SEDANA: FN Stockholm) today announced that the company will give financial support to a multinational, observational study comparing outcomes for patients sedated with inhaled anaesthetics with patients receiving intravenous sedation.

The study, Inhaled Sedation in Covid-19-related Acute Respiratory Distress Syndrome, (ISCA), is planned to enroll a minimum of 400 patients and will be conducted in approximately 30 ICUs in France, Germany, Spain and Switzerland. The primary endpoint is ventilator-free days up to day 28.

“This study is highly relevant in this day and time when patients are receiving high doses of multiple intravenous sedatives in order to facilitate mechanical ventilation. Their use is deemed necessary but also associated with complications such as delirium and prolonged ventilator times. Inhaled sedation holds promise in this context, due to postulated anti-inflammatory effects and favorable pharmacokinetics in patients with ARDS and multiple organ failure. In an article published in the British Medical Journal a few weeks ago, studies evaluating inhaled sedation in Covid-19 were called for[1]. We are happy to be able to support such an initiative,” said Peter Sackey, CMO of Sedana Medical.

The study will be led by associate professor Matthieu Jabaudon from Clermont-Ferrand, France. The national coordinators are professor Jean-Michel Constantin, Paris (France), associate professor Tobias Becher, Kiel (Germany), professor Rafael Badenes, Valencia (Spain), associate professor Martin Schläpfer and professor Beatrice Beck-Schimmer, Zürcich (Switzerland).

For additional information, please contact:
Christer Ahlberg, CEO, Sedana Medical AB
Mobile: +46 70 675 33 30
E-mail: christer.ahlberg@sedanamedical.com

Peter Sackey, CMO, Sedana Medical AB
Mobile: +46 70 771 03 64
E-mail: peter.sackey@sedanamedical.com

1) Sevoflurane, a sigh of relief in COVID-19? Nieuwenhuijs-Moeke GJ et al. British Journal of Anesthesia 1 May 2020. https://doi.org/10.1016/j.bja.2020.04.076

Sedana Medical is listed on Nasdaq First North Growth Market in Stockholm.
The company's Certified Adviser is Erik Penser Bank, +46 8 463 83 00, certifiedadviser@penser.se.

The information was released for public disclosure, through the agency of the contact person above, on May 12, 2020 at 09:00 a.m. (CET).

About Sedana Medical

Sedana Medical AB (publ) has developed and sells the medical device AnaConDa, for the administration of volatile anaesthetics to mechanically ventilated patients. A major pivotal study is currently ongoing to obtain market approval in Europe for inhaled sedation in intensive care units with the pharmaceutical IsoConDa® (isoflurane). The company expects the registration of IsoConDa in Europe to take place during the second half of 2021. Three years thereafter Sedana Medical expects sales of SEK 500 million in Europe and an EBITDA margin of about 40 percent.

The market for Sedana Medical’s sedation therapy of AnaConDa and IsoConDa consists primarily of sedation of mechanically ventilated intensive care patients. Today, these patients are sedated intravenously which leads to several challenges for both patients and care givers. Challenges that are solved by inhaled sedation. Based on an estimate of seven to eight million patients being sedated in intensive care due to mechanical ventilation globally, on average three to four days, Sedana Medical estimates the total market potential to SEK 20-30 billion, evenly distributed between the US, Europe and Asia. The company has initiated a process to obtain market approval in the US in 2024. Registration activities are also initiated in other markets outside the EU.

Sedana Medical has direct sales in the Nordic countries, Germany, Benelux, France, Great Britain and Spain as well as external distributors in parts of the rest 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.