

Press release March 30<sup>th</sup>, 2020, 08.00 am, CET.

## Sedana Medical sees increased demand and keeps time schedule

Sedana Medical AB (publ) (SEDANA: FN Stockholm) today announced that the company sees increased demand for AnaConDa as a result of the Covid-19 pandemic and so far, has had no significant supply chain disruptions. Sedana Medical forecasts a sales increase of about 50 percent for the first quarter of 2020 and about 100 percent for the month of March, compared to the same periods last year. Due to the Covid-19 pandemic Sedana Medical sees a slight risk of delay of the compilation of the IsoConDa study until the beginning of the third quarter of 2020. However, this would not necessarily mean that Sedana Medical's application for European market approval for the drug candidate IsoConDa is delayed. Sedana Medical still expects to keep the timetable and submit the application in the third quarter, or early in the fourth quarter of 2020 and an approval during the second half of 2021.

The novel coronavirus mainly affects the lungs and for the most severely affected the consequence is lung failure (ARDS). This condition is very difficult to treat, but studies indicate that inhaled sedation with AnaConDa may be beneficial for these patients. The thesis is that it can reduce inflammation and increase oxygenation in the lungs. This benefit, together with inhaled sedation providing rapid awakening despite deep and long-term sedation, which is often the case for severely ill Covid-19 patients, allows patients to quickly leave intensive care and thus leave room for new patients. This is important as there is a large lack of intensive care sites. These are likely reasons why demand is now increasing, along with the number of patients generally increasing in intensive care at the moment.

"Of course, our thoughts go to those affected and their relatives. We see a significant number of Covid-19 patients being treated with inhaled sedation with AnaConDa, primarily in Germany but also in other countries such as Italy, France, UK and Spain. As the benefits of inhaled sedation become more and more apparent when used in these patients and the intensive care sites in hospitals are filled up, demand increases, and we are trying to meet it responsibly. We divide our deliveries so as not to risk that some hospitals are without products while building up stock elsewhere," said Christer Ahlberg, CEO of Sedana Medical.

Sedana Medical's manufacturing takes place in Malaysia and so far, the company has not had any serious disruptions in the supply chain, although new challenges are constantly emerging.

As previously announced, the last patient was included in Sedana Medical's pivotal IsoConDa study in January 2020. At present, the administrative part of the study is being completed and the company expects to be able to submit an application for European market approval in the third quarter or early in the fourth quarter of 2020.

"It is a relief to be able to say that the clinical part of our pivotal IsoConDa study is not affected by Covid-19. However, there is a slight risk that the compilation of the study is somewhat delayed as the intensive care units that participated in the study are currently occupied with Covid-19. Thus, we might not announce top line results in the second quarter, but instead early in the third quarter. That does however not necessarily mean that our application will be delayed. We still expect to keep the timetable at large and to submit our application for European market approval during the third quarter, or early in the fourth quarter of 2020, and get a market approval for IsoConDa during the second half of 2021," said Christer Ahlberg.

### **For additional information, please contact:**

Christer Ahlberg, CEO, Sedana Medical AB  
Mobile: +46 70 675 33 30  
E-mail: [christer.ahlberg@sedanamedical.com](mailto:christer.ahlberg@sedanamedical.com)

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](mailto:certifiedadviser@penser.se).

*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 person above, on March 30<sup>th</sup>, 2020 at 8:00 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

# SEDANA MEDICAL

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.