Press release July 10, 2020, 7.00 am, CET.

Sedana Medical announces positive top line result in pivotal IsoConDa study

Sedana Medical AB (publ) (SEDANA: FN Stockholm) today announced a positive top line result for the company's pivotal phase III study, IsoConDa. The study reached its primary endpoint; to show that IsoConDa (isoflurane), administered with AnaConDa, is an effective sedation method, for ventilator-intensive care patients, which is non-inferior to propofol. Secondary endpoints are under analysis and will be published together with the primary endpoint in a scientific journal after peer-review. The results indicate that IsoConDa is an effective and safe sedation method and will form the basis for the company's application for European market approval later this autumn.

" We are proud to have conducted the world's largest study of inhaled sedation in intensive care. This is the most significant milestone in inhaled sedation since the development of the AnaConDa. The study confirms the clinical experience of IsoConDa administered with AnaConDa as an effective and safe sedation method. With the results from the study, we are in a good position for the future, both with the continued global clinical development of inhaled sedation and the work with the application for market approval in Europe," said Peter Sackey, Chief Medical Officer of Sedana Medical.

“The study results are in line with the long-standing clinical experience of many doctors all over the world. Isoflurane is safe and efficacious as a sedative for invasively ventilated critically ill patients. We hope that more patients will benefit from the advantages of inhaled sedation in the future” said Coordinating Investigator Germany of the IsoConDa study Assoc. Prof. Andreas Meiser Saarland University Medical Center, Homburg, Germany.

The study, which aims to support the approval of the candidate drug IsoConDa (isoflurane) for inhaled sedation in intensive care in Europe, has been conducted at 21 centers in Germany and three in Slovenia. The study is a noninferiority study, which means that its primary purpose is to show that IsoConDa, administered with AnaConDa, is non-inferior to propofol in maintaining an adequate sedation level. This is determined by comparing the proportion of time that adequate sedation depth is maintained with isoflurane compared to propofol. The study included 301 mechanically ventilated intensive care patients in need of sedation and is a so-called randomized, controlled and open-label study to confirm efficacy and safety. The patients were divided into two equal groups, where patients in one group were treated intravenously with propofol and the other with IsoConDa administered with AnaConDa.

“The goal we had when we initiated the work with the IsoConDa study several years ago was to be able to register inhaled sedation with IsoConDa administered with AnaConDa and thus approach our vision to make inhaled sedation a new standard method in intensive care units around the world. With these strong results as a base, we have come a giant leap closer to our vision. We will submit our application for European market approval in 16 European countries in a first registration round as soon as possible in the fourth quarter 2020. If all goes well, we expect an approval during the second half of 2021," said Christer Ahlberg, CEO of Sedana Medical.

Conference call and online presentation

Sedana Medical will host a conference call and an online presentation today, Friday 10 July, at 1.00 pm CET. The call will be hosted by Christer Ahlberg, CEO and Peter Sackey, CMO who will present the results and answer questions. The presentation will be held in English.

The dial-in numbers for the conference call are:

SE: +46 856642651 Pin code: 34271979#
UK: +44 3333000804
US: +1 6319131422

The presentation will be webcasted and can be followed here:
https://tv.streamfabriken.com/sedana-medical-top-line-result-2020

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

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.

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 July 10, 2020 at 7:00 a.m. (CET).

About Sedana Medical

Sedana Medical AB (publ) has developed and sells the medical device AnaConDa for the administration of volatile anaesthetics. Through a combination of AnaConDa and the candidate drug IsoConDa (isoflurane), Sedana Medical provides inhaled sedation for mechanically ventilated intensive care patients. The company is working to obtain market approval in Europe for inhaled sedation in intensive care with the pharmaceutical IsoConDa® (isoflurane) during the second half of 2021.

Today, mechanically ventilated intensive care 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. Three years after market approval in Europe Sedana Medical expects sales of SEK 500 million in Europe and an EBITDA margin of about 40 percent. The company has initiated a process to obtain market approval in the US in 2024. Registration activities have also been 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.