Press release January 13, 2020, 07.00 am, CET.

Last patient included in Sedana Medical's pivotal IsoConDa study

Sedana Medical AB (publ) (SEDANA: FN Stockholm) today announced that the last patient has now been included in the pivotal IsoConDa study. Thus, all 300 patients have been included and the study is expected to show top-line results during Q2 2020.

“This is a true milestone for Sedana Medical. It is extremely gratifying that we keep the schedule in the world's largest study of inhaled sedation in intensive care. We expect to be able to present top-line results in the second quarter of 2020 and thus be able to submit our application for European market approval in 16 European countries in a first registration round in the third quarter of 2020. If all goes well, we expect an approval in the second half of 2021,” said Christer Ahlberg, CEO of Sedana Medical.

More about the IsoConDa study

The IsoConDa study is a pivotal clinical phase III study aimed at getting the drug candidate IsoConDa (isoflurane) approved for inhaled sedation in intensive care in Europe. IsoConDa is Sedana Medical's trademark for the generic drug substance isoflurane which is currently only approved for use in general anesthesia. The study has been conducted at more than twenty centers in Germany and Slovenia.

The study is a noninferiority study, which means that its primary purpose is to prove that IsoConDa, administered with AnaConDa, is not inferior to propofol in maintaining an adequate sedation level. This is determined by analyzing the proportion of time that adequate sedation depth is maintained with isoflurane compared to propofol. The study includes 300 mechanically ventilated intensive care patients in need of sedation. Patients are assigned to two equal groups, one of whom is treated intravenously with propofol and the other with IsoConDa administered with AnaConDa.

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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 January 13, 2020 at 07.00 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, France, Great Britain and Spain as well as external distributors in the rest of Europe, Australia, Canada, China, India, Japan and South Korea. The company was founded in 2005 and is headquartered in Stockholm, Sweden with R&D operations in Ireland.