Press release April 10, 2019, 07:30 CET.

The road to registration in the US clarified

Sedana Medical AB (publ) (SEDANA: FN Stockholm) today announced that the US Food and Drug Administration (FDA) during a pre-IND meeting is positive about the combination registration of IsoConDa and AnaConDa in the US. Sedana Medical now has a clear view of measures that have to be taken in order to reach marketing authorization approval of both IsoConDa and AnaConDa in the US. The meeting also confirmed Sedana Medical's estimate of the time and cost of a US approval that is expected to occur in 2024.

"The FDA has set clear requirements that are in line with the expectations we had, and they are also possible for us to live up to. Our image of what needs to be done is thus very good," said Christer Ahlberg, CEO of Sedana Medical.

Since the drug substance isoflurane has been around for decades, the FDA has accepted that Sedana Medical is taking a path to registration[1] which, somewhat simplified, allows the use of previously collected data. Since the registration requirements have been tightened over the years since isoflurane was first registered, Sedana Medical needs to fill some gaps in current documentation and add more data to be approved by the FDA; including toxicological animal studies and a human factors validation. Sedana Medical will also need to do two clinical, randomized and double-blind studies[2] confirming and ensuring efficacy and safety. The number of patients needed for both studies together is the same as Sedana Medical initially had as a requirement in the European study, i.e. 300-550 patients. These patients will also be included in a safety database of 500 isoflurane patients who are required by the FDA.

“The requirements are in line with what we thought. If you set the requirements in relation to the market potential of SEK 6 - 15 billion, it feels really good. Although we thought we had a good idea of what the FDA would require, it has been extremely satisfying to have that confirmed. We can now work fast, according to the established plan, both for Europe and the USA. We intend to set up a company in the USA to be able to carry out the work on studies, registration and market access ourselves. Around 2022, we will decide whether we to launch ourselves or together with a local partner,” continues Ahlberg.

Sedana Medical’s market in brief
Sedana Medical's market consists primarily 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. The target group the company is focusing on are those patients who are ventilated for more than 24 hours, a target group that globally amounts to between two and four million patients per year. In total, the company consider this to be a market of SEK 10-20 billion per year, of which Europe accounts for about SEK 6 billion and US 6-15 billion.

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Sedana Medical is listed on Nasdaq First North in Stockholm.
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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 persons above, on April 10, 2019 at 07:30 a.m. (CET).

[1] Path 505 (b) (2), which is usually less demanding than 505 (b) (1) that entirely new drug substances must take.
[2] Since the ongoing European registration study is not blinded, it will not be one of the two clinical studies required by the FDA, but it can still be supportive of the NDA application and used in the safety database.

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 inhalation 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.