Press release July 20, 2021, 18.00 CET.

Sedana Medical receives approval for European dossier

Sedana Medical AB (publ) (SEDANA: FN Stockholm) today announced that the company has received a positive outcome for its European registration application for the drug Sedaconda (isoflurane) for inhaled sedation. Sedaconda is indicated for sedation of mechanically ventilated adult patients during intensive care and should only be administered via the medical device AnaConDa. From October 1st, AnaConDa will change name to Sedaconda ACD.

The application was approved through a decentralized European procedure (DCP) by the German Medicines Agency BfArM (acting as reference country) in consultation with 14 other European Medicines Agencies.

“This is the first important step towards market approval for Sedaconda. The DCP procedure has gone faster than expected thanks to the quality of our application and that the agency seems to have prioritized a fast process. The outcome means that we can apply for national approvals to launch the therapy inhaled sedation in Europe during the second half of this year, in line with our communicated time plan. The national processes take about 1-3 months. This is a crucial milestone in making inhaled sedation a global standard therapy," said Jens Lindberg, acting CEO of Sedana Medical.

Sedana Medical is now working to get national market approvals as soon as possible in the countries where the DCP approval applies and plans to submit applications for additional EU countries in the coming six months.

“In connection with the launch, we are changing the name of AnaConDa to Sedaconda ACD, where ACD stands for Anaesthetic Conserving Device. The name strengthens the connection to Sedana Medical and the unique application sedation. Sedaconda is approved only to be used in combination with Sedaconda ACD and together they constitute the therapy inhaled sedation", said Jens Lindberg.

The countries included in the DCP approval are Austria, Belgium, Croatia, Denmark, Finland, France, Germany, Ireland, Netherlands, Norway, Poland, Portugal, Slovenia, Spain, and Sweden.

Short on the Sedaconda study (SED001)

The application for market approval is based on the strong results in Sedana Medical's pivotal phase III study, SED001. The topline results, announced in July 2020, showed that the study reached its primary goal; to show that Sedaconda administered via AnaConDa is an effective sedation method for ventilated ICU patients, comparable to propofol.

Secondary objectives in the study show that Sedaconda administered via AnaConDa, compared with propofol, enables a faster and more predictable awakening, reduced need of opioids and a higher proportion of spontaneous breathing, which improves the conditions for maintained lung function during and after ventilator treatment. The safety profile of Sedaconda was consistent with previously known findings for isoflurane.

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Sedana Medical is listed on Nasdaq First North Growth Market 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 person above, on July 20, 2021 at 18.00 (CET).

About Sedana Medical

Sedana Medical AB (publ) is a pioneer medtech and pharmaceutical company focused on inhaled sedation to improve the patient's life during and beyond sedation. Through the combined strengths of the medical device AnaConDa and the pharmaceutical Sedaconda (isoflurane), Sedana Medical provides inhaled sedation for mechanically ventilated patients in intensive care.

Sedana Medical has direct sales in Benelux, France, Germany, Great Britain, the Nordic, and Spain. In other parts of Europe as well as in Asia, Australia, Canada, and South- and Central America, the company works with external distributors.

Sedana Medical was founded in 2005, is listed on Nasdaq First North Growth Market (SEDANA) and headquartered in Stockholm, Sweden.