Press release January 20, 2021, 16.45 pm CET.

Sedana Medical submits application for marketing approval in Switzerland

Sedana Medical AB (publ) (SEDANA: FN Stockholm) today announced that the company has submitted an application for marketing approval for the drug candidate Sedaconda (isoflurane), formerly known as IsoConDa, for inhaled sedation in intensive care in Switzerland.

“Through this application, we cover another important European market ahead of our upcoming launch. If all goes well, we expect to be able to launch in the second half of 2021 in the first 15 European countries for which we have already submitted an application. In Switzerland, we expect to be able to launch in 2022," said Christer Ahlberg, CEO of Sedana Medical.

The marketing approval application is based on the strong results in Sedana Medical's pivotal phase III study, Sedaconda (SED001). In December 2020, Sedana Medical submitted a marketing approval application for Sedaconda in 15 of the EU member states, including Norway. If all goes well, Sedana Medical expects an approval in the EU during the second half of 2021. After that, an application for a second group of EU countries can be submitted.

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Sedana Medical is listed on Nasdaq First North Growth Market in Stockholm.
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About Sedana Medical

Sedana Medical AB (publ) develops and sells the medical device AnaConDa for the administration of volatile anaesthetics. Through a combination of AnaConDa and the drug candidate Sedaconda (isoflurane), Sedana Medical provides inhaled sedation for mechanically ventilated intensive care patients. The company has applied for marketing approval in Europe for Sedaconda and expects an approval in 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. Globally, seven to eight million patients are estimated to be sedated in intensive care due to mechanical ventilation, evenly distributed between the US, Europe, and Asia. These patients are on average sedated three to four days. Sedana Medical estimates the total market potential to SEK 20-30 billion. Three years after marketing 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 processes to obtain marketing approval in the US in 2024 and also in markets outside the EU.

Sedana Medical has direct sales in Benelux, France, Germany, Great Britain, the Nordics and Spain as well as external distributors in other parts 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.