

Press release January 28, 2020, 08.00 am, CET.

Sedana Medical receives approval for AnaConDa in Mexico

Sedana Medical AB (publ) (SEDANA: FN Stockholm) today announced that the company has obtained market approval for AnaConDa in Mexico. Sedana Medical's Mexican distributor Goba will begin sales work in the next few months and in parallel Sedana will evaluate the possibility of registering the drug IsoConDa. Goba will also work for a registration of AnaConDa in Colombia.

"The fact that we can now start selling on a new continent is gratifying, the approval in Mexico came sooner than both we and our distributor had expected, and we choose to see that as a sign of strength. However, work still remains to be done to get our drug IsoConDa registered. It is a process that can take time, but with the approval of AnaConDa we can seriously take on the Mexican market. It is a significant market with 125 million inhabitants and over 4,000 intensive care units, of which 30 percent are privately owned." said Christer Ahlberg, CEO of Sedana Medical.

The approval means that AnaConDa may be marketed, sold and used for the administration of volatile anaesthetics for mechanically ventilated patients in Mexico. Sedana Medical's Mexican distributor Goba, one of Mexico's leading distributors of medical supplies, will soon begin its sales work. In parallel, Sedana Medical will initiate an evaluation of a registration of the drug IsoConDa. Goba will also work for a registration of AnaConDa in Colombia and expects to receive this in 2020.

The Mexican approval is in line with Sedana Medical's strategy; that inhaled sedation with the help of AnaConDa and IsoConDa should become a global standard method for sedation of mechanically ventilated patients in intensive care.

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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 28, 2020 at 08.00 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.