ICU
MANAGEMENT & PRACTICE

SEDANA MEDICAL RECEIVES APPROVAL IN GERMANY

Sedana Medical AB (publ) (SEDANA: FN Stockholm) today announced that the company has received market approval for inhaled sedation in Germany.

The approval applies to the drug Sedaconda (isoflurane) for administration via the medical device AnaConDa (undergoing name change to Sedaconda ACD) for inhaled sedation in intensive care in Germany. The application has been approved by the German pharmaceutical authority BfArM and is based on the DCP approval Sedana Medical received in July.

Since the European DCP approval in July 2021, Sedaconda (isoflurane) has now received national approvals in Austria, Belgium, Denmark, Finland, France, Germany, Netherlands, Norway, Portugal and Sweden.

“The approval means that we can launch the entire therapy inhaled sedation in our largest market, Germany. Given that our medical device is already used in over 900 German critical care units, and that we have noticed a great interest in the therapy, we view the launch very positively. Our organization is ready to launch, and we will have products available for sale by year end,” said Jens Lindberg, Acting CEO of Sedana Medical.

The approval is based on the strong results of the Sedaconda study (SED001), Sedana Medical's pivotal phase III study.

“The results of the Sedaconda study - the largest randomized study in inhaled sedation ever - show that Sedaconda in combination with Sedaconda ACD is at least as effective as propofol but with advantages of a higher rate of spontaneous breathing and predictable and faster awakening. As this therapy widens the opportunities for intensive care patients in need of sedation, it is very valuable for patients”, said the study's principal investigator, Professor Thomas Volk, MD, Saarland University Medical Center, Homburg, Germany.

Short on the Sedaconda study

The results from the Sedaconda study demonstrate that Sedaconda (isoflurane) administered via Sedaconda ACD, compared with intravenous propofol, reduces the need of opioids, facilitates spontaneous breathing, which improves the lung function during and after ventilator treatment and enables a faster and more predictable awakening.

The study was conducted at 23 critical care units in Germany and Slovenia and included 301 mechanically ventilated patients in need of sedation. Half of the patients were treated with Sedaconda administered via Sedaconda ACD and half with propofol. The safety profile of Sedaconda was consistent with previously known findings for isoflurane.

Published on : Tue, 28 Sep 2021