ICU
MANAGEMENT & PRACTICE

Last Patient Included In Sedana Medical's Pivotal Isoconda Study

Sedana Medical AB today announced that the last patient has now been included in the pivotal IsoConDa study. Thus, all 300 patients have been included and the study is expected to show top-line results during Q2 2020.

“This is a true milestone for Sedana Medical. It is extremely gratifying that we keep the schedule in the world's largest study of inhaled sedation in intensive care. We expect to be able to present top-line results in the second quarter of 2020 and thus be able to submit our application for European market approval in 16 European countries in a first registration round in the third quarter of 2020. If all goes well, we expect an approval in the second half of 2021,” said Christer Ahlberg, CEO of Sedana Medical.

More about the IsoConDa study
The IsoConDa study is a pivotal clinical phase III study aimed at getting the drug candidate IsoConDa (isoflurane) approved for inhaled sedation in intensive care in Europe. IsoConDa is Sedana Medical's trademark for the generic drug substance isoflurane which is currently only approved for use in general anesthesia. The study has been conducted at more than twenty centers in Germany and Slovenia.

The study is a noninferiority study, which means that its primary purpose is to prove that IsoConDa, administered with AnaConDa, is not inferior to propofol in maintaining an adequate sedation level. This is determined by analyzing the proportion of time that adequate sedation depth is maintained with isoflurane compared to propofol. The study includes 300 mechanically ventilated intensive care patients in need of sedation. Patients are assigned to two equal groups, one of whom is treated intravenously with propofol and the other with IsoConDa administered with AnaConDa.

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