ICU MANAGEMENT & PRACTICE

Sedana Medical Submits IND for US Clinical Trials

Sedana Medical AB (publ) has announces that the company has submitted an Investigational New Drug (IND) application to the US Food and Drug Administration (FDA), with the aim to commence its phase III pivotal clinical trials with its Sedaconda products in the United States.

Sedana Medical is aiming for a combination registration of the medical device Sedaconda ACD and the pharmaceutical Sedaconda (isoflurane) for inhaled sedation of mechanically ventilated patients in intensive care. Provided that the IND is approved, the company is planning to commence patient recruitment at the turn of Q1/Q2 2022, with the objective to obtain US approval in 2024.

“We are happy to announce that we have now submitted the IND to the FDA and the preparations for our clinical program in the United States are progressing according to plan. The US market represents the largest commercial opportunity for Sedana Medical and we are looking forward to bringing our Sedaconda products to intensive care patients in the US. We have recruited many of the most reputable centers for our US clinical trials and are eager to commence patient enrollment” said Johannes Doll, CEO of Sedana Medical.

Sedana Medical aims to conduct two multicenter, randomized controlled, assessor-blinded clinical trials to confirm efficacy and safety. The number of patients in both trials combined will be around 500. The study design is similar to the SED-001 trial that was successfully completed in Europe and formed the basis for the European approval earlier this year. The primary endpoint in each study will be to show that Sedaconda (isoflurane), administered via Sedaconda ACD, is effective and non-inferior to propofol for sedation of mechanically ventilated patients in the intensive care unit. The secondary endpoints relate to opioid requirements, spontaneous breathing, wake-up time and cognitive recovery.

Source: Sedana Medical

Published on : Wed, 24 Nov 2021