PRESS RELEASE
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SEDANA MEDICAL ANNOUNCES POSITIVE HIGH-LEVEL RESULTS ALSO FOR ITS SECOND PIVOTAL TRIAL IN THE UNITED STATES

Sedana Medical AB (publ) announces that its second pivotal US trial INSPiRE-ICU 2 has met its primary endpoint, and hence established non-inferiority of inhaled sedation with isoflurane compared with intravenous sedation using propofol. The safety results were in line with expectations. This follows positive high-level results from the first pivotal US trial INSPiRE-ICU 1, communicated on 19 December 2024.

Sedana Medical is aiming for a US combination registration of the medical device Sedaconda ACD and isoflurane for sedation of mechanically ventilated intensive care patients. The primary endpoint measured the percentage of time spent at targeted depth of sedation, comparing patients receiving isoflurane via the company's proprietary Sedaconda ACD medical device with patients receiving intravenous sedation using propofol.

As for the first study, the primary endpoint was met in the main analysis as well as in all supplementary and sensitivity analyses, above the non-inferiority margin agreed with the FDA. The safety profile of isoflurane was in line with expectations from previous studies and long-established clinical use in ICUs in Europe. This means that positive high-level results have now been achieved in both pivotal US trials, INSPiRE-ICU 1 and INSPiRE-ICU 2.

"It is very gratifying that all the hard work by the investigators and their teams across 31 clinical trial sites with our development therapy, which was novel in the US, has led to consistently positive high-level results for both of our US studies. We have now demonstrated non-inferiority of isoflurane in both European trials and in the pivotal US trials, which is reassuring as we enter an intense phase of NDA preparations. We have established great network of US key opinion leaders whose clinical insight and advice will be invaluable as we progress towards our NDA submission." said Peter Sackey, Chief Medical Officer of Sedana Medical.

"Receiving these positive clinical trial results certainly counts among the highlights of our journey so far. Our products have already helped hundreds of thousands of ICU patients worldwide, and the prospect of making inhaled sedation accessible to more than two million mechanically ventilated ICU patients in the U.S. each year is incredibly motivating. This represents a patient population three times the size of our current direct markets and therefore an opportunity to improve lives on a truly global scale." said Johannes Doll, CEO and President of Sedana Medical.

The high-level results are a key element of a comprehensive data set, which will include the full analyses of all end points, as well as the long-term follow-up of both studies. The full results will be communicated once they are published. The FDA will then make their assessment based on the totality of the future submission, including pooled analyses of both US trials and the European Sedaconda trial (SED001).

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This information is information that Sedana Medical AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2025-02-12 17:30 CET.

About INSPiRE-ICU

INSPiRE-ICU 1 and 2 are two identical randomized phase III trials, aiming to confirm the efficacy and safety for sedation with isoflurane delivered via Sedana Medical's unique medical device Sedaconda ACD. The primary endpoint is the proportion of time spent at adequate depth of sedation, compared with intravenous sedation using propofol. In addition, several important secondary endpoints are being studied, including opioid requirements during treatment, time to wake-up, cognitive recovery and proportion of time with spontaneous breathing. The first patient was included in April 2022 and the last patient was enrolled in May 2024. 31 highly reputed clinics in the United States are involved in the two trials. The design of the US studies is similar to the Sedaconda study (SED001) successfully performed in Europe in 2017–2019, which resulted in market approval in Europe 2021.

About Sedana Medical

Sedana Medical AB (publ) is a pioneer medtech and pharmaceutical company focused on inhaled sedation to improve the patient's life during and beyond sedation. Through the combined strengths of the medical device Sedaconda ACD and the pharmaceutical Sedaconda (isoflurane), Sedana Medical provides inhaled sedation for mechanically ventilated patients in intensive care.

Sedana Medical has direct sales in Benelux, France, Germany, Great Britain, the Nordics, and Spain. In other parts of Europe as well as in Asia, Australia, Canada, and South- and Central America, the company works with external distributors.

Sedana Medical was founded in 2005, is listed on Nasdaq Stockholm (SEDANA) and headquartered in Stockholm, Sweden.

Attachments

Sedana Medical announces positive high-level results also for its second pivotal trial in the United States