PRESS RELEASE
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BOTH OF SEDANA MEDICAL´S PIVOTAL US STUDIES MEET FIRST KEY SECONDARY ENDPOINT

Sedana Medical AB (publ) announces that both of the company's pivotal US studies, INSPiRE-ICU 1 and INSPiRE-ICU 2, have shown a greater reduction of opioid doses compared to the control group and have therefore met their first key secondary endpoint. This news follows positive high-level results from both US trials earlier this year. An investor webcast will be held tomorrow 11 June at 13:00 CET to discuss the results (link).

The main study results from Sedana Medical´s two pivotal US trials, INSPiRE-ICU 1 and 2, have been made publicly available on the clinical trials portal ClinicalTrials.gov (NCT05312385 and NCT05327296). This non-peer reviewed reporting, in line with standard requirements of ClinicalTrials.gov, will be followed with more granular data reporting in peer-reviewed publications, expected later this year.

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. As previously communicated, non-inferiority for the primary efficacy endpoint - percentage of time at target sedation level - was demonstrated in both studies.

For the most important key secondary endpoint – opioid dosing – a significant and clinically relevant opioid dose reduction compared to baseline opioid dose was found in the isoflurane group. In both studies, the dose reduction was significantly greater in the isoflurane group than in the propofol group.

Wake-up times after end of treatment were short overall. More than 75% of patients in the isoflurane group woke up within one hour from ending sedation. While no statistically significant differences between groups were found in the studies, the wake-up data for isoflurane are otherwise consistent with the results from the pivotal European adult and pediatric studies, Sedaconda and IsoCOMFORT. Cognitive recovery one hour after end of treatment, was not significantly in favour of any of the treatments. The proportion of time with spontaneous breathing was significantly higher in the isoflurane group for INSPiRE-ICU 2, and did not differ between groups in INSPiRE-ICU 1.

The safety data, in terms of adverse events and 30-day outcomes, showed an overall similar proportion of patients with serious adverse events in the two study groups and did not reveal any new safety signals for isoflurane. A clinically relevant, but not statistically significant difference in mortality was found in favor of isoflurane, with an absolute mortality difference of 5 percentage points at 30 days in both studies. There was a non-statistically significant difference in ICU-free days, favoring isoflurane in both studies.

Long-term follow-up in the studies did not reveal any clinically important or statistically significant differences between study groups.

“Based on the available data from our clinical studies and available documentation for isoflurane, we have an optimistic outlook on the US NDA submission and look forward to the next steps, namely pooling of data and completing the clinical documents for NDA submission” said Peter Sackey, CMO of Sedana Medical. “

“I am pleased that our therapy once again showed a clinically meaningful reduction of opioid doses. The US continues to be plagued by a devastating opioid epidemic, with millions of patients and their families battling the terrible effects of addiction. Making inhaled sedation available as an alternative for ICU sedation could help ICU teams, not only with an efficacious sedative, but also to reduce opioid exposure in this vulnerable patient group.” said Johannes Doll, CEO of Sedana Medical.

The clinical results will represent a key element for the FDA’s assessment of a potential US marketing authorization. In line with FDA discussions, the submission will also include pooled analyses of both US trials and the European Sedaconda trial (SED001).

For additional information, please contact:

Johannes Doll, CEO, +46 (0)76 303 66 66
Johan Spetz, CFO, +46 (0)730 36 37 89
ir@sedanamedical.com

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

Both of Sedana Medical´s pivotal US studies meet first key secondary endpoint