PRESS RELEASE
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SEDANA MEDICAL REPORTS POSITIVE PRE-NDA MEETING WITH FDA

Sedana Medical AB (publ) announces that the company has completed its pre-NDA meeting with FDA and reached broad alignment with the Agency on the contents of the New Drug Application (NDA). FDA confirmed that safety and efficacy data from the clinical trials appear adequate to permit submission and review of the NDA. With some additional requested analyses of the run-in training patients, the NDA submission is expected to be around mid-year 2026.

The purpose of the pre-NDA meeting is to seek FDA´s confirmation on different strategic topics in preparation for the NDA submission. The main objective was to confirm that available safety and efficacy data are sufficient for submission and review. FDA agreed that the safety and efficacy data from our clinical studies SED003 and SED004, supported by the European study SED001 and published literature, appear adequate to permit submission and review of the NDA for the proposed indication of sedation of adult patients requiring mechanical ventilation. The Agency was also in agreement with most of the company's proposals regarding structure and contents of the file.

FDA requested an additional description and analysis of the run-in training patients from both US studies. As run-in patients served for the initial training of clinical trial sites and were thus not randomized, these analyses were not part of the initial proposed plan and will therefore require some additional work for side-by-side comparisons of the study populations in the clinical part of the submission. The NDA submission is now expected to be around mid-year 2026.

"We are very pleased with the very productive and collaborative pre-NDA meeting with the FDA. Based on the Agency's feedback, we are confident about our upcoming NDA submission. The additional work is manageable, and our team is fully focused on completing it as quickly as possible. With two successful US clinical trials, Fast Track designation, the Early Access Program, and now a positive pre-NDA meeting, we are well on our way towards bringing inhaled sedation to our highest-potential market", said Johannes Doll, CEO of Sedana Medical.

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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 2025-11-24 08:00 CET.

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, 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 reports positive pre-NDA meeting with FDA