Sedana Medical informs about adjusted US submission plan following FDA interaction

Sedana Medical AB (publ) today informs that the US Food and Drug Administration (FDA) has requested the company to include long-term outcomes data in the Clinical Study Report (CSR) of the INSPIRE-ICU trials before the New Drug Application (NDA) can be submitted. This is expected to move the filing date by approximately one year to Q1 2025, but is not expected to materially impact the overall cost for the clinical program.

INSPIRE-ICU 1&2 are two identical phase III studies to confirm the efficacy and safety of inhaled isoflurane delivered via Sedaconda ACD, compared to IV propofol, for sedation of adult mechanically ventilated ICU patients. Besides the main study part to support the primary and secondary endpoints, the study plan also includes long-term follow up after approximately 3 and 6 months to perform cognitive, psychological and quality of life assessments.
Sedana Medical had planned to submit the long-term outcome data during the NDA review period, since most of the end points are exploratory in nature. The FDA has now clarified that the long-term follow-up data is considered a critical component of the evaluation of Sedaconda. This means that the NDA can only be submitted once the long-term follow-up is completed, evaluated and integrated into the Clinical Study Report. Sedana Medical estimates that this will shift the submission to Q1 2025 and – assuming a standard review time – the approval to late 2025 or early 2026.

The timeline currently assumes no positive effects from the Fast Track Designation granted earlier in the year. Sedana Medical will however have the opportunity to discuss possible measures to accelerate the timeline, such as accelerated approval, priority review and rolling review, in a pre-NDA meeting closer to submission.

"Our aim is to bring the clinical and health-economic benefits of inhaled sedation to US patients and intensive care teams as soon as possible. Of course, we will respect the FDA's feedback and continue our constructive dialogue. We are looking forward to discussing possible benefits of the Fast Track Designation in a pre-NDA meeting.", said Johannes Doll, CEO of Sedana Medical.

The adjusted submission plan is not expected to materially impact the overall cost for the clinical program.

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This information is such that Sedana Medical AB (publ) is obliged to disclose pursuant to the EU Market Abuse Regulation. The information was released for public disclosure, through the agency of the contact persons above, on July 12, 2023 at 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, 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.