Press release January 4, 2023, 08.00 CET.

Sedana Medical receives FDA Fast Track Designation in the United States

Sedana Medical AB (publ) (SEDANA: FN Stockholm) today announces that the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation (FTD) for the evaluation of isoflurane via the Sedaconda ACD-S device for sedation of mechanically ventilated patients in the intensive care (ICU) setting.

Fast Track is a process designed to facilitate the development, and expedite the review of therapies that treat serious conditions and fill an unmet medical need. The purpose is to get important new therapies to the patient earlier. Clinical programs with Fast Track Designation may benefit from frequent communication with the FDA throughout the development and review process and may be eligible to Accelerated Approval and Priority Review if relevant criteria are met. Another possible benefit may be a Rolling Review, which means that completed sections of the New Drug Application (NDA) can be submitted for review by FDA, rather than waiting until every section of the NDA is completed.

"The FDA's decision to grant Fast Track Designation underscores the potential for our product candidates to address a serious unmet need and bring meaningful benefits to ventilated patients in intensive care. We are fully committed to work even more closely with FDA to bring our therapy to US patients as soon as possible" said Johannes Doll, CEO of Sedana Medical. "This excellent news represents an important step forward in our highest potential market."

Sedana Medical is aiming for a combination registration of the medical device Sedaconda ACD and the pharmaceutical isoflurane for sedation of mechanically ventilated intensive care patients in the United States. Two identical Phase III studies, INSPiRE-ICU 1 and 2, are ongoing with the objective to confirm the efficacy and safety of inhaled sedation with isoflurane delivered via Sedaconda ACD in intensive care.

Sedana Medical will engage in discussions with the FDA on how the development program can benefit from the FTD. At present, the guidance regarding the timeline is unchanged: assuming rapid enrolment of patients and successful trials, Sedana Medical expects the NDA submission in 2024 and a launch in early 2025.

About the studies INSPiRE-ICU 1 and INSPiRE-ICU 2 (SED003 and SED004)

The INSPiRE-ICU (Inhaled Sedation vs Propofol in Respiratory failure) studies are two identical phase III studies aiming to confirm the efficacy and safety of inhaled isoflurane, delivered via the Sedaconda ACD, for the sedation of adult mechanically ventilated ICU patients, in comparison to intravenous infusion of propofol.

The studies will enrol a total of 470 adult patients across 25-30 sites in the US. Patient enrolment is expected to be completed in 2023.

The primary endpoint is the proportion of time spent within the target range of sedation depth in absence of rescue sedation, as assessed according to the Richmond Agitation Sedation Scale (RASS). In addition, the studies will investigate several secondary endpoints, including the use of opioids, the wake-up time, the cognitive recovery after

end of sedation, and the spontaneous breathing effort. The assessments will be performed by blinded assessors to meet the requirements of the FDA.

Further information on the studies is available at www.clinicaltrials.gov (NCT05312385 for SED003 and NCT05327296 for SED004).

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Sedana Medical is listed on Nasdaq First North Growth Market in Stockholm.
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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 Nordic, 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 First North Growth Market (SEDANA) and headquartered in Stockholm, Sweden.