ICU
MANAGEMENT & PRACTICE

# Sedana Medical Announces Positive FDA Interaction

SEDANAMEDICAL
Pioneering volatile anaesthetic delivery

**Sedana Medical AB (publ) today announced that the company has completed a successful End of phase II meeting with the US Food and Drug Administration (FDA). The FDA accepted Sedana Medical's proposals for phase III program, including study design and primary endpoints for the studies. This positive outcome means that the company can enter phase III in line with the communicated schedule.**

Sedana Medical is working to submit an IND during the fall and expects to receive an approval to conduct two randomized, controlled trials involving approximately 250 patients each, to confirm and ensure safety and efficacy. As previously announced, Sedana Medical aims to include the first patients in the studies at the turn of the quarter Q1/Q2 2022 and to receive market approval before the end of 2024.

"The interactions with the FDA have been very constructive and we have also received good support from the principal investigators in our upcoming phase III program. The interest in participating in the studies has been noticeable from a large number of leading US centers. We aim to include about 30 US centers and look forward to starting the inclusion of patients," said Jens Lindberg, Acting CEO of Sedana Medical.

The purpose of an End of phase II meeting is to discuss the documentation prior to phase III and to agree on the plan and design of the studies in phase III.

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