

SEDANA MEDICAL SUBMITS NEW DRUG APPLICATION TO THE U.S. FDA FOR INHALED SEDATION IN THE ICU

Sedana Medical AB (publ) today announces that it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for the drug-device combination product isoflurane delivered via the Sedana Medical ACD Delivery System for the sedation of mechanically ventilated adult patients in intensive care units (ICUs).

"This is a defining milestone for Sedana Medical, bringing us a step closer to offering a new treatment alternative to critically ill patients in the United States. The submission is the result of several years of dedicated work, and I want to thank our employees, the investigators and study sites behind our clinical program, and everyone who has supported us along the way," said Johannes Doll, CEO of Sedana Medical.

"The application reflects a comprehensive body of clinical, non-clinical, device and manufacturing data generated over the course of our US development program. We appreciate the constructive interactions with the FDA throughout the development and look forward to working closely with the Agency during the review process", said Jessica Westfal, VP Regulatory Affairs & Quality Assurance.

The submission follows the completion of dossier preparations and marks the start of the FDA's review process. The application now enters the FDA's filing review (validation) period, during which the FDA assesses whether the submission is sufficiently complete for substantive review. The company expects notification regarding acceptance of the application for filing in approximately two months. If the NDA is accepted, the FDA will assign a target action date under the Prescription Drug User Fee Act (PDUFA) by which it aims to complete its review.

The NDA is supported by Sedana Medical's clinical program in inhaled sedation, including the two pivotal trials INSPIRE ICU-1 and INSPIRE ICU-2. Both studies met their primary endpoint. A key secondary endpoint, opioid use, was also statistically significant in favor of isoflurane, and the safety profile was in line with previous studies. If approved, isoflurane delivered via the Sedana Medical ACD Delivery System would be the first and only inhaled sedation therapy approved for use in intensive care in USA.

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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, 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 submits New Drug Application to the U.S. FDA for inhaled sedation in the ICU