PRESS RELEASE
19 August 2026 07:30:00 CEST

SEDANA MEDICAL ANNOUNCES FDA ACCEPTANCE FOR REVIEW OF ITS NEW DRUG APPLICATION IN THE U.S.

Sedana Medical AB (publ) today announced that the U.S. Food and Drug Administration (FDA) has accepted the filing of the company's New Drug Application (NDA) for isoflurane delivered via the Sedana Medical ACD Delivery System, for sedation of mechanically ventilated adult patients in intensive care units (ICUs). The FDA will assign a target action date under the Prescription Drug User Fee Act (PDUFA) for the review within the next weeks.

The NDA acceptance confirms that the FDA has determined the application is sufficiently complete to permit a substantive review. The submission is supported by Sedana Medical's clinical program in inhaled sedation, including the two pivotal trials INSPIRE ICU-1 and INSPIRE ICU-2, both of which met their primary endpoint, showed statistically significant reduction in opioid use, and had a safety profile in line with previous studies.

“The FDA's acceptance of our NDA filing is a very positive and defining milestone for Sedana Medical, bringing us a step closer to offering critically ill patients in the United States a treatment alternative that does not exist for them today. This submission is the result of many years of dedicated work by our investigators and study sites, our teams, and everyone who has supported us along the way, and we look forward to working closely with the FDA throughout the review process,” said Johannes Doll, CEO of Sedana Medical.

If market authorization is received, isoflurane delivered via the Sedana Medical ACD Delivery System would be the first and only therapy approved in the United States for inhaled sedation of mechanically ventilated ICU patients, offering physicians and patients a new treatment alternative in a setting where options have remained limited to IV sedatives for decades.

For additional information, please contact:

Johannes Doll, CEO, +46 (0)76 303 66 66
Mikael Haag, CFO, +46 (0)79 583 42 59
ir@sedanamedical.com

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 announces FDA acceptance for review of its New Drug Application in the U.S.