

SEDANA MEDICAL ANNOUNCES PDUFA TARGET ACTION DATE FOR ITS NEW DRUG APPLICATION IN THE U.S.

Sedana Medical AB (publ) today announced that the U.S. Food and Drug Administration (FDA) has set April 16, 2027 as the target action date under the Prescription Drug User Fee Act (PDUFA) for its review 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 company had announced FDA acceptance of the NDA filing on August 19.

"We are pleased that FDA has now set a clear timeline for completing their review of our NDA. We look forward to a constructive review period and to continuing our close collaboration with the FDA as we work toward bringing a much-needed treatment alternative to critically ill, mechanically ventilated patients in U.S. intensive care units," said Johannes Doll, CEO of Sedana Medical.

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.

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.

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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 announces PDUFA target action date for its New Drug Application in the U. S.