PRESS RELEASE
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SEDANA MEDICAL RECEIVES FDA APPROVAL FOR EARLY ACCESS PROGRAM IN THE U.S.

Sedana Medical AB (publ) today announced that the U.S. Food and Drug Administration (FDA) has approved the company's application to initiate an Early Access Program for its investigational inhaled sedation therapy, providing eligible patients access to the treatment prior to market authorization.

The FDA's pathway, also known as Expanded Access Program (EAP), is designed to allow patients with serious or life-threatening conditions to receive an investigational medical product for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available and where the potential patient benefits outweigh the potential risks.

The EAP is approved for "difficult-to-sedate" patients, i.e. those who are unable to achieve and maintain target sedation levels with intravenous (IV) sedatives. Clinical indicators may include repeated episodes of agitation or self-harm, escalating sedative or opioid requirements, or physician concerns over continued IV sedation use.

"It is very encouraging that the FDA has enabled the use of inhaled isoflurane under the route of an EAP. This EAP approval will enable mechanically ventilated intensive care patients in participating U.S. hospitals to gain access to the therapy when conventional IV sedatives fail, which we believe will help patients and caregivers", said Peter Sackey, CMO of Sedana Medical.

"This is fantastic news and we are grateful to the FDA for the constructive dialogue regarding our EAP", said Johannes Doll, CEO of Sedana Medical. "With this approval, we can now meet the demand to use our inhaled sedation therapy for difficult-to-sedate patients well ahead of a possible marketing authorization. Having hospitals fully trained and using our investigational products in the U.S. will provide us with valuable learnings for a future commercial launch."

In line with standard practice for EAPs, Sedana Medical will provide its investigational products free of charge to participating hospitals. The first patients are expected to be treated in the second half of 2025. For more information, please see our Early Access Policy on our corporate website.

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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 Nordics, 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 Receives FDA Approval for Early Access Program in the U.S.