PRESS RELEASE
13 March 2026 08:00:00 CET

SEDANA MEDICAL REPORTS FIRST PATIENT TREATED IN EARLY ACCESS PROGRAM IN THE U.S.

Sedana Medical AB (publ) today reports that the first patient has been treated in the company's Early Access Program (EAP) in the U.S. The program is approved by the U. S. Food and Drug Administration (FDA) and provides eligible patients access to the Sedana Medical's inhaled sedation treatment prior to market authorization. New Drug Application (NDA) submission to the FDA remains planned for mid-year 2026.

The EAP was approved by the FDA in April 2025 and the first patient has now been treated at Vanderbilt University Medical Center in Nashville, Tennessee.

"This is an important milestone in our journey and it is very rewarding that we have come to this point. The patients that are treated within the EAP are at high risk for complications related to being 'difficult to sedate' or experiencing adverse effects of available sedative options. There is a true medical need for alternatives for this vulnerable patient group and we are happy that our therapy can be offered to patients in the US, in waiting for FDA´s review of our upcoming NDA submission." said Peter Sackey, CMO of Sedana Medical.

Christopher Hughes, Professor of Anesthesiology at Vanderbilt University Medical Center, added: "Sedation is one of the most common and important medical treatments that we provide our patients in the ICU. Unfortunately, our current approved sedative options have limitations and risks that leave many patients unable to be adequately sedated in a safe manner. The ability to now utilize isoflurane for these 'difficult to sedate' patients through the expanded access program is an important step in patient care and in providing suitable sedation for all patients in the ICU."

The EAP pathway, also known as Expanded Access Program, 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.

Sedana Medical's EAP is approved for "difficult-to-sedate" patients, i.e. those who are unable to achieve and maintain target sedation levels with 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.

In line with standard practice for EAPs, Sedana Medical will provide its investigational products free of charge to participating hospitals. 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, 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 reports first patient treated in Early Access Program in the U.S.