

## **SEDANA MEDICAL RECEIVES A POSITIVE DECISION TO INCLUDE CHILDREN (3-17 YEARS) INTO THE SEDACONDA® (ISOFLURANE) INDICATION**

**Sedana Medical AB (publ) announces that the company has received a positive decision from the authorities in all involved countries that the pediatric indication of Sedaconda (isoflurane) is approvable in Europe. This marks the final step before 14 European countries can grant national marketing authorizations.**

The submission was based on the results of the IsoCOMFORT trial, a randomized active-controlled assessor-blinded study comparing the efficacy and safety of sedation with inhaled isoflurane, administered via the company's medical device Sedaconda ACD-S, with intravenous midazolam in mechanically ventilated patients 3-17 years old.

Now, the Type II variation to extend the indication to include pediatric patients of 3-17 years has received a positive decision at the End of Procedure (EOP) from the Reference Member State (RMS) Germany and 13 Concerned Member States (CMS) in Europe. In the next step, national approval processes of approximately 1-2 months will follow.

“This is a great day for mechanically ventilated children in intensive care – a vulnerable patient group for whom it is often challenging to provide comfort and safety. There has been an unmet medical need for alternative sedation methods, due to the limitations of currently available therapies. Based on the IsoCOMFORT results, we are able to offer these patients the benefits we saw in the study, such as lower opioid requirements and shorter time to extubation compared to midazolam, the only other approved therapy for ICU sedation of children” says Peter Sackey, Chief Medical Officer (CMO) of Sedana Medical.

The main results of the IsoCOMFORT trial are available on the Clinical Trials Registry EudraCT.

For more information, see:

**<https://www.clinicaltrialsregister.eu/ctr-search/trial/2020-000578-31/results>**

**For additional information, please contact:**

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## **About Sedana Medical**

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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**

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**Sedana Medical receives a positive decision to include children (3-17 years) into the Sedaconda® (isoflurane) indication**