PRESS RELEASE
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SEDANA MEDICAL'S PAEDIATRIC STUDY PUBLISHED IN THE LANCET

Sedana Medical AB (publ) announces that the results of the company's paediatric study IsoCOMFORT (SED002) have been published in The Lancet Respiratory Medicine.

"The publication in The Lancet Respiratory Medicine is a recognition for the investigators and for Sedana Medical's paediatric clinical trial. Randomized controlled trials are rare in paediatric critical care and this study is a great achievement, especially as it was performed in the middle of the Covid-19 pandemic. This is the largest paediatric study of inhaled isoflurane sedation via the Sedaconda ACD and demonstrates its efficacy and safety in children aged 3-17 years. The results were presented by the first author Dr. Jordi Miatello at the annual meeting of the European Society of Paediatric and Neonatal Intensive Care (ESPNIC) in Alicante June 26th, 2025. Besides non-inferior sedation efficacy versus midazolam, the study demonstrated lower opioid requirements and shorter and more predictable wake-up time compared with the control group – key features of inhaled isoflurane sedation", said Peter Sackey, Chief Medical Officer of Sedana Medical.

"Our successful IsoCOMFORT study has led to paediatric approval in 13 European countries, three additional years of data exclusivity and market protection until 2032, and now a publication in a highly ranked journal. Publishing the results in a high-impact journal targeting a broad audience is good for the dissemination of the results in the paediatric as well as the adult critical care community. Overall, an excellent outcome that we are very proud of", said Johannes Doll, CEO of Sedana Medical.

Link to the publication: **https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(25)00203-6/fulltext**

Short on the IsoCOMFORT study
The IsoCOMFORT multicenter randomized controlled trial included 94 mechanically ventilated paediatric patients in need of sedation at 19 intensive care units in Spain, France, Germany and the UK. Patients were randomized in a 2:1 ratio to isoflurane or midazolam. The safety profile of Sedaconda (isoflurane) was consistent with previously known findings for isoflurane. The study provided necessary data for the paediatric approval of Sedaconda (isoflurane) for children aged 3-17 in 13 European countries. The results of the study also led to a one-year additional extension of the market exclusivity for Sedaconda (isoflurane), rendering a total additional three year extension of the marketing exclusivity thanks to the conclusion of the paediatric study, with a concluding statement from the Co-ordination Group for Mutual Recognition and Decentralized Procedures – Human): "The new (expanded) indication represents a significant clinical benefit over existing therapies".

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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's paediatric study published in The Lancet