

Press release November 22, 2023, 08.00 CET.

Sedana Medical secures data exclusivity and market protection for Sedaconda® (isoflurane) until 2031

Sedana Medical AB (publ) announces that the European Medicines Agency's Paediatric Committee has issued a positive opinion regarding the compliance with the company's Paediatric Investigation Plan. This confirms data exclusivity and market protection for Sedana Medical's Sedaconda® (isoflurane) until 2031.

In 2021, Sedana Medical's proprietary pharmaceutical Sedaconda (isoflurane) received its first market authorization in Europe for administration via the medical device Sedaconda ACD for inhaled sedation of mechanically ventilated patients in intensive care. As part of the approval, Sedana Medical could obtain eight years of data exclusivity and two additional years of market protection, provided that the company would comply with the agreed Paediatric Investigation Plan.

The Paediatric Committee of the European Medicines Agency has now confirmed that all elements of the Paediatric Investigation Plan, including the clinical trial IsoCOMFORT, were performed in compliance with the agreed plan and all timelines have been respected accordingly.

"We welcome this good news from the Paediatric Committee ahead of the anticipated time", says Johannes Doll, President and CEO of Sedana Medical. "This important milestone means that no other company will be allowed to market isoflurane in intensive care until at least 2031 in the European countries where we hold approvals, which protects our valuable market position as Europe's first and only approved inhaled sedation therapy for the ICU."

For additional information, please contact:

Johannes Doll, CEO, +46 (0)76 303 66 66

Johan Spetz, CFO, +46 (0)730 36 37 89

ir@sedanamedical.com

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.