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Sedana Medical receives market approval in the UK

The Medicines and Healthcare products Regulatory Agency (MHRA) has granted Sedana Medical AB (publ) marketing authorization for the company's pharmaceutical product Sedaconda® (isoflurane) in the United Kingdom.

This market approval will enable Sedana Medical to sell Sedaconda® (isoflurane) in the UK and to promote the clinical and health economic benefits of its therapy for inhaled sedation in intensive care. The medical device Sedaconda ACD has been sold in the UK for several years, and the company submitted the application for marketing authorization for Sedaconda® (isoflurane) in early 2021.

Already in 2022, the UK National Institute for Health and Care Excellence (NICE) recommended the Sedaconda ACD as a cost-saving option for delivering inhaled sedation in intensive care. According to NICE, cost modelling had shown cost savings compared with intravenous (IV) sedation of almost £4,000 per adult patient (30-day time horizon for adult patients needing mechanical ventilation for 24 hours or longer in intensive care).

"I am very pleased to receive the marketing authorization in the UK and would like to thank the MHRA for their trust and confidence.", says Johannes Doll, President and CEO of Sedana Medical. "This approval will allow us to offer the first and only registered therapy for inhaled sedation of mechanically ventilated intensive care patients also in the UK. Together with the positive NICE guidance, we hope that the approval will lead to many ICU patients in the UK benefitting from the clinically proven advantages of inhaled sedation."

Sedana Medical has now received market authorization for Sedaconda® (isoflurane) in all 18 countries where an application for approval has been submitted. In addition to the UK, the pharmaceutical is approved in Austria, Belgium, Croatia, Denmark, Finland, France, Germany, Ireland, Italy, the Netherlands, Norway, Poland, Portugal, Slovenia, Spain, Sweden, and Switzerland.

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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.