Press release July 26, 2018 at 16.45 CET.

Sedana Medical AB (publ) resumes pivotal phase 3-study IsoConDa with full patient recruitment rate.

Sedana Medical AB (publ) (Sedana Medical or the Company) announces today that the Company has received approval from the central ethical committee for its pivotal phase 3-study in Germany, IsoConDa, to continue to use the original study protocol after certain clarifications. This means that the study will resume in full after it was restricted in April this year.

The central ethical committee for the pivotal phase 3-study IsoConDa, in Saarbrûcken, Germany, has today given its final approval to the changes in the study protocol suggested by Sedana Medical following remarks made in connection with an inspection and was communicated by the Company in a press release April the 10th this year. These changes are mainly clarifications concerning the patients and the methods for obtaining their consent to participate. The adjusted protocol was also approved by the above-mentioned inspectors as well as by the German medical authority BfArM. The Company can now resume the study with full patient inclusion as soon as the participating medical centers have been educated on the updated study protocol.

Sedana Medical expects to be able to communicate the result of the forthcoming interim analysis before year end 2018. The interim analysis will determine how many patients will be ultimately needed in order to show the result required to apply for an IsoConDa marketing approval in Europe.

”It is a success that we are now able to resume inclusion of all types of mechanically ventilated patients in accordance with the study protocol, and that the interruption became so limited. We can now focus on obtaining registration for inhalation sedation with AnaConDa and IsoConDa both in Europe and in the USA” says Christer Ahlberg, CEO of Sedana Medical.

The market in brief

Sedana Medical's market consists primarily of mechanically ventilated intensive care patients. The market for sedation of mechanically ventilated intensive care patients today consists of established drugs that are administered intravenously. The target group the Company is focusing on are those patients who are ventilated for more than 24 hours, a target group that globally amounts to between two and four million patients per year. In total, the Company consider this to be a market of SEK 10-20 billion per year, of which Europe accounts for about SEK 6 billion.

For additional information, please contact:

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Sedana Medical is listed on Nasdaq First North in Stockholm
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This information is such that Sedana Medical AB (publ) is obliged to disclose pursuant to the EU Market Abuse Regulation. The information was released for public disclosure, through the agency of the contact persons above, on 26 July 2018 at 16:45 (CET).

Sedana Medical AB (publ) has developed and sells the medical device AnaConDa, for the administration of volatile anaesthetics to mechanically ventilated patients. A major clinical registration study is currently ongoing to obtain market approval in Europe for inhalation sedation in intensive care units with the pharmaceutical IsoConDa® (isoflurane)
Sedana Medical has direct sales in the Nordic countries, Germany, France and Spain as well as external distributors in the rest of Europe, Canada, Australia and South Korea. The company headquarters are based in Stockholm, Sweden with R&D operations in Ireland.