

Press release April 10, 2018

Sedana Medical AB (publ) updates the schedule for the IsoConDa study.

Sedana Medical AB ("Sedana Medical or the Company") announces that the schedule for patient recruitment in the ongoing Phase 3 IsoConDa study is likely to be extended.

Performing clinical studies in the intensive care unit is challenging as most patients are in a critical condition and are often unconscious when included in the study. The guidelines for how to recruit these patients are strictly followed but leave some room for interpretation. In connection with an inspection of the study, a local authority has criticized certain aspects of the approach for the inclusion of some unconscious patients who were unable to give their own consent before inclusion in the study. Overall this issue could affect approximately 1/3 of the patients included to date. The company now has 4 weeks to answer these findings. As a result there is a risk that the pace of patient recruitment will be reduced and that the study will take longer than planned. The company has initiated a comprehensive action plan to address the current situation. As a result the Company has decided to no longer communicate a time when the IsoConDa study is expected to be completed. From the next quarter, the company will instead report the number of randomized patients already included in the study.

For additional information, please contact:

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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 10 April 2018 at 22.30 PM (CET).

Sedana Medical AB (publ) has developed and sells the medical device AnaConDa, for the administration of volatile anaesthetics to mechanically ventilated patients.

Sedana Medical has direct sales in the Nordic countries, Germany, France and Spain as well as external distributors in the rest of Europe, Middle East, Canada, Australia and South Korea. The company headquarters are based in Stockholm, Sweden with R&D operations in Ireland.