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Sedana Medical receives go-ahead for pediatric study

- Milestone on the road to market exclusivity

Sedana Medical AB (publ) (SEDANA: FN Stockholm) today announces the company has been approved for its planned pediatric study from the Pediatric Committee of EMA, European Medicines Agency, (PDCO).

A complete Marketing Authorization Application (MAA) for drugs in EU must include a PDCO agreed and approved study plan for children, a so-called PIP (Pediatric Investigation Plan).

"It is incredibly satisfying that PDCO has now approved our planned pediatric study, our PIP. An approved study plan on children is one of the prerequisites for a European market approval for our therapy, so this is really a milestone," says Christer Ahlberg, CEO of Sedana Medical.

The study includes 160 children aged 3 to 17 years. Sedation will last for 12-48 hours with either midazolam or isoflurane using AnaConDa. The first patient is planned to be recruited in April 2020 and preliminary duration of the clinical trial is 18 months. It is only the plan that must be approved in connection with the application for MAA. The outcome of the study is not a requirement for obtaining an authorization for use in adults, so the timetable for approval of IsoConDa is not affected by this decision.

Other important documents in the application for a European marketing authorization are a preclinical evaluation and a pharmaceutical / technical compilation. This type of documentation is currently being compiled in parallel with the ongoing registration-based clinical Phase III study aimed at getting IsoConDa (isoflurane) approved for inhalation sedation in intensive care in Europe.

"Since the filed registration documentation will now be complete, that is, also covers children, an approval will mean that Sedana Medical will receive ten years of market exclusivity in Europe for the use of isoflurane in sedation in intensive care," says Peter Sackey, medical director of Sedana Medical.

During this period no competitor will have the opportunity to sell or market isoflurane for this purpose without having themselves undergone the same procedure as Sedana Medical.

Sedana Medical's 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.

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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, Great Britain and Spain as well as external distributors in the rest of Europe, Canada, Australia, Japan and South Korea. The company headquarters are based in Stockholm, Sweden with R&D operations in Ireland.