

LINK Medical partners with Sedana Medical for its international phase III study of inhaled sedation with isoflurane and AnaConDa for children in intensive care units

STOCKHOLM, Sweden, December 06, 2019

LINK Medical, the Northern European clinical research organization (CRO), today announced that it will carry out a pivotal phase III clinical trial on behalf of Sedana Medical, the Swedish medical technology and pharmaceutical company. The international study will assess the efficacy and safety of Sedana Medical's drug candidate IsoConDa (isoflurane) administered via Sedana Medical's AnaConDa inhalation device for inhaled sedation of critically ill children. This inhaled sedation therapy has the potential to provide an effective and safe alternative to the current standard of care.

"We are excited to be entering a strategic partnership with Sedana Medical," said Ola Gudmundsen, CEO at LINK Medical. "Our expertise in the management of complex international trials will allow us to efficiently deliver robust clinical data for this anesthetic study."

"LINK Medical is well positioned to conduct our planned pediatric study that will begin recruitment in September 2020. LINK has an international network of talented medical professionals with expertise in anesthesiology, patient recruitment and the management of multi-center studies and we are very pleased to partner with LINK." said Christer Ahlberg, CEO of Sedana Medical.

Critically ill children requiring sedation are currently administered with midazolam

intravenously. This drug can cause serious adverse effects including withdrawal, low blood pressure and prolonged sedation after discontinuation. The phase III clinical trial being carried out by LINK Medical will compare the therapeutic effects of IsoConDa (isoflurane) administered via Sedana Medical's AnaConDa device against the use of intravenous midazolam in the anesthesia of critically ill children. The study will involve 160 patients in four European countries, and the primary endpoint will be the percentage of time of adequately maintained sedation target depth.

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- Ola Gudmundsen

About LINK Medical

LINK Medical is a full-service contract research organization (CRO) providing product development services for the pharmaceutical and medical device industries across Northern Europe. We offer a well-integrated local presence in the Nordics, UK and Germany.

Reaching from early phase development to post-marketing, we have over 180 employees providing expert guidance across every aspect of a project - all from ONE source. Our promise is to improve and accelerate your product development through transformative methods, active communication and optimal solutions. As a strategic partner, we provide expert competence and technology to enable evidence-based decision-making that supports the delivery of superior clinical outcomes.

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