Press Release
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Neola Medical Reports Positive Safety Results from First Clinical Pilot Study and Advances Towards Next Phase of Clinical Development

Neola Medical today announces final results from its clinical pilot study, confirming a favorable safety profile of Neola® across the studied patient population, including very low birth weight preterm born babies. The results provide important insights that support the development of Neola® and advance the next phase of clinical and regulatory activities.

The clinical pilot study confirms that Neola® is safe and well tolerated across the studied patient population, including very low birth weight preterm born babies, representing an important milestone in the clinical development program.

“We are encouraged by the results confirming the favourable safety profile of Neola®,” says CEO Hanna Sjöström. “Importantly, the study has provided valuable insights into how the technology performs in a clinical setting, helping to define the optimization of the device. We now have a clear understanding of where Neola® can deliver the greatest clinical value, particularly in the detection of life-threatening lung complications in preterm born babies. We are sharpening our product offering by introducing lung collapse detection as a key capability, providing continuous monitoring with decision support for timely intervention.”

The study provided important insights into signal behavior in a clinical environment, which is expected in early-stage development of novel monitoring technologies. These findings have been addressed through refinement of signal processing and optimization of the device and its clinical application. Furthermore, Neola Medical is now focusing on high-value clinical use cases, such as the detection of significant pulmonary complications, including life-threatening lung collapse (pneumothorax), where the technology is expected to provide the greatest clinical benefit.

To support the continued regulatory pathway in the United States, Neola Medical plans to engage with the U.S. Food and Drug Administration (FDA) to align on the clinical and regulatory strategy. Subject to regulatory feedback, the company intends to initiate a clinical study in preterm born babies in the U.S. by mid 2027.

Background
Neola Medical’s first clinical pilot study was conducted at the neonatal intensive care unit at Södra Älvsborgs Sjukhus in Borås, Sweden. The study evaluated the safety and performance of Neola® in continuous lung monitoring in preterm born babies. A total of 10 babies were included, with gestational age from 28 weeks and a weight between 1000–3000 grams.

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About Neola Medical
Neola Medical AB (publ) develops an innovative medical technology device for non-invasive, continuous lung monitoring and real-time alerts of potentially life-threatening lung collapse in preterm born babies. By enabling instant detection, the technology aims to support earlier intervention, improve clinical decision-making, enhance long-term outcomes, and ultimately contribute to saving lives. The patented, cutting-edge technology was developed at Lund University in Sweden and is based on near-infrared light measurements in the lungs. Neola Medical builds on Sweden's longstanding legacy of medical technology innovation and contributions to global health care. Neola Medical was founded in 2016 and is listed on NASDAQ First North Growth Market (ticker: NEOLA). Read more at www.neolamedical.com. The company's Certified Adviser is FNCA Sweden AB.

Attachments
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