Press Release
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Neola Medical prepares for pivotal clinical study on preterm born babies in the USA

Neola Medical AB is advancing to the clinical validation phase with its medical device for continuous lung monitoring, Neola®. In preparation for a pivotal clinical study on preterm born babies in the USA, scheduled for 2025, Neola Medical will launch a clinical pilot study at a Swedish hospital. The pivotal clinical study, along with the successful Human Factors study results and the recently obtained CB certificate, will be instrumental in supporting Neola Medical's forthcoming FDA application for market approval in the USA.

“Exciting months lay ahead, as we advance into the clinical validation phase and gear up for the pivotal clinical study on preterm born babies in the USA. This study will be a cornerstone in our journey toward securing FDA market approval.”, says CEO Hanna Sjöström.

Neola Medical takes significant steps toward market approval in the USA. The company's lung monitoring device has achieved critical milestones that meet key regulatory requirements for FDA approval. The successful Human Factors Validation study conducted in the USA, along with the recently acquired CB certification, underscores the product’s safe design and essential performance. As a result, Neola Medical is transitioning from the technical verification phase to the clinical validation phase, initiating clinical studies.

The company is now in detailed planning for a pivotal clinical study on preterm born babies in the USA, scheduled to begin in 2025. In preparation for this, Neola Medical will conduct a clinical pilot study on preterm born babies at a neonatal intensive care unit in Sweden. The clinical protocol for the Swedish study has been finalized, and the company is currently in contract negotiations with a Swedish hospital.

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About Neola Medical
Neola Medical AB (publ) develops revolutionizing medical technology device for non-invasive continuous lung monitoring and real-time alerts of life-threatening lung complications of preterm born infants. Immediate detection of complications provides the possibility of early treatment, improved health care and healthier lives for preterm born infants. The patented cutting-edge technology is developed at Lund University in Sweden and based on a spectroscopic method that measures lung volume changes and oxygen gas concentration. Neola Medical is building on a historic Swedish legacy of medical technology innovation and invaluable contributions to global health care. The company 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.

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Attachments
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