

Neola Medical Signs Agreement with Leading U.S. Hospital for Pivotal Clinical Study on Preterm Born Babies Following IRB Approval

Neola Medical AB today announces it has signed an agreement with a prominent neonatal intensive care unit (NICU) in the U.S., located at Children’s Regional Hospital at Cooper in Camden, New Jersey, USA, to enable the initiation of the pivotal clinical study on preterm born babies with its medical device for continuous lung monitoring, Neola®. The agreement follows the Institutional Review Board (IRB) approval at Children’s Regional Hospital at Cooper, a key regulatory milestone. As one of Neola Medical’s strategically important study sites, Cooper’s NICU plays a central role in building the clinical evidence base required to support the planned FDA application for market authorization.

“I am looking forward to evaluating the innovative non-invasive Neola® lung monitoring device at Children’s Regional Hospital at Cooper NICU with the potential and hope of improving the care of the newborn,” says Vineet Bhandari, MD, DM, FAAP, principal investigator and division head of Neonatology at Children’s Regional Hospital at Cooper and professor at Cooper Medical School of Rowan University.

The IRB approval represents a key regulatory milestone, confirming that the study complies with the requirements for patient safety and clinical ethics. The signed agreement enables the initiation of a clinical study at the neonatal intensive care unit at Children’s Regional Hospital at Cooper.

“The IRB approval at Children’s Regional Hospital at Cooper and the signed agreement to initiate the pivotal clinical study, mark an important milestone in advancing the clinical validation of our medical device, Neola®, in the U.S. We are especially honored to work with Dr. Vineet Bhandari, one of the world’s most prominent key opinion leaders in neonatology. His clinical leadership at Cooper’s NICU adds significant weight to this strategically important study site, which will play a central role in building the clinical evidence base for our planned FDA application and long-term market expansion,” says Hanna Sjöström, CEO at Neola Medical.

About Cooper University Health Care

Cooper University Health Care is one of the leading academic medical centers in the U.S., renowned for its expertise in neonatal and pediatric care. It is affiliated with Cooper Medical School of Rowan University. Headquartered in Camden, New Jersey, Cooper has revenues of more than \$2.4 billion and more than 11,000 team members. Cooper treats patients from all 50 states and 35 countries, and more than 2.4 million patients visit Cooper’s facilities annually. Visit www.CooperHealth.org to learn more.

About Children’s Regional Hospital at Cooper

Children’s Regional Hospital at Cooper houses a Level III Neonatal Intensive Care Unit (NICU) with 35 beds, providing comprehensive care for full-term and premature infants with various medical and surgical conditions related to premature birth, respiratory, neurologic or immunologic disorders.

For further information, contact:

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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 complications 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 a spectroscopic method that measures changes in lung volume and oxygen gas concentration. 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

[Neola Medical Signs Agreement with Leading U.S. Hospital for Pivotal Clinical Study on Preterm Born Babies Following IRB Approval](#)