PRESS RELEASE

AGA's INO Therapeutics receives US FDA approval for treatment for critically ill newborns

A new treatment that will help critically ill newborn infants breathe more effectively and reduce their need for an invasive surgical procedure has been approved by the US Food and Drug Administration.

INO Therapeutics, Inc., a subsidiary of AGA, announced today that it has received approval for its new product, INOmax® (nitric oxide) for inhalation.

INOmax®, the first and only pulmonary vasodilator, is indicated for the treatment of full-term and near-term newborn infants (more than 34 weeks gestation) with hypoxic respiratory failure and is used in conjunction with ventilatory support and other appropriate agents. INOmax® dilates the blood vessels of the lungs so they can carry more oxygen, and reduces the need for a highly invasive surgical procedure called ECMO (extracorporeal membrane oxygenation) in infants who have clinical or echocardiographic evidence of pulmonary hypertension.

"We are delighted that INO Therapeutics finally is able to bring this valuable treatment to critically ill babies," said Lars Källsäter, general manager of AGA Healthcare. "INOmax® has been used in clinical studies for more than six years, and this approval will help to ensure that ultimately, this therapy will become available to every newborn baby who needs it."
INOmax® will be launched as soon as the logistics of the complete therapy are in place, which is expected in the first quarter of 2000. In order to ensure safe and effective delivery of the product, INO Therapeutics plans to provide it as part of a system, consisting of the drug, delivery device, equipment maintenance and service, and round-the-clock support for health care professionals.
INO Therapeutics, Inc., with its expertise in critical care, is the core of the global inhaled nitric oxide strategic business unit of the AGA Healthcare division of AGA AB, Sweden. The company is headquartered in Clinton, New Jersey, USA.

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