



## **PRESS RELEASE**

### **AGA HEALTHCARE'S INO THERAPEUTICS RECEIVES US FDA APPROVABLE NOTICE FOR TREATMENT FOR CRITICALLY ILL NEWBORNS**

A new treatment for critically ill newborn infants to help them breathe more effectively and reduce their need for an invasive surgical procedure has received “approvable” status from the US Food and Drug Administration. INO Therapeutics, Inc., a subsidiary of the AGA Healthcare division of AGA AB, announced today that it has received notification from the FDA that its new product, INOmax<sup>TM</sup> (nitric oxide) for inhalation, is approvable. The company cannot promote or sell INOmax until the FDA has approved the drug, a process that is dependent on INO Therapeutics submitting final product labeling. The therapy would be used by physicians in the United States for newborns suffering from hypoxic respiratory failure.

INOmax, the first and only pulmonary vasodilator, is being reviewed by the FDA for the treatment of full-term and near-term newborn infants (more than 34 weeks gestation) with hypoxic respiratory failure. The product dilates the blood vessels of the lungs so they can carry more oxygen.

“We are hopeful that we will be able to bring this valuable treatment to critically ill babies,” said Lars Källsäter, President and General Manager of AGA Healthcare. “In clinical studies, INOmax has been shown to help increase the amount of oxygen in the blood of these compromised infants, and to reduce the need to subject these infants to a highly invasive surgical procedure called ECMO (extracorporeal membrane oxygenation) that is associated with many risks.”

If INOmax receives FDA clearance it 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, including INOmax, an INOvent 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 INO strategic business unit of the AGA Healthcare division at AGA AB of Sweden. The company is headquartered in Clinton, New Jersey, USA.

AGA Healthcare is a division of the AGA group with a turnover of more than SEK 2000 million and activities in 28 countries in Europe and the Americas.

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