



INHALED NITRIC OXIDE DATA PRESENTED AT EUROPEAN ACADEMY OF PEDIATRICS MEETING

Clinton, NJ, October 25, 2008– Ikaria Holdings, Inc. today announced that results from its Phase III clinical trial - INOT27, nitric oxide for inhalation for the treatment of bronchopulmonary disease (BPD) in premature babies – were presented at the European Academy of Pediatrics in Nice, France. The pre-specified primary endpoint, survival without BPD, did not meet statistical significance, with the INOT27 treatment group achieving a 65.3% success rate compared to a 65.5% success rate for the control group ($p=0.73$).

BPD most commonly occurs in pre-term (less than 30 weeks of gestational age) infants with birth weights less than 1,500 g. BPD is even more pronounced in very pre-term infants (less than 26 weeks of gestational age) with birth weights less than 1,000 g. and who have been treated for respiratory distress syndrome.

“These results were quite unexpected based on prior evidence indicating the efficacy of inhaled nitric oxide in the prevention of BPD in pre-term infants,” stated lead researcher Jean-Christophe Mercier, MD, MSci, Professor of Pediatrics, University of Paris - Denis Diderot Medical School and Associate Professor, Division of Pediatric and Neonatal Intensive Care, Hôpital Robert Debré, Paris. “Although the study was well designed, a lower dose was administered to higher birth weight infants than in previous studies which -- combined with certain risk-factors of the patient population -- may have contributed to these results. We hope that further research will demonstrate the potential of nitric oxide to improve outcomes for pre-term infants.”

The multi-center, double-blind, controlled Phase III clinical trial, examined 800, pre-term infants ranging in gestational age from 24 weeks to 28 weeks, 6 days. All patients required the use of surfactant within 24 hours of birth or the use of CPAP, or continuous positive airway pressure, to maintain an oxygen saturation value of greater than or equal to 85 percent. Upon informed consent of the parent or guardian, patients were assigned either to five parts per million (ppm) of inhaled nitric oxide for seven to 21 days or to five ppm of nitrogen gas for seven to 21 days. Patient response was measured at 36 weeks. The rate of serious and fatal adverse events was comparable between treatment groups. Long-term follow-up is ongoing.

“In the studies conducted by our group, the use of inhaled nitric oxide resulted in a statistically significant improvement in both the short- and long-term pulmonary outcome for pre-term infants at high risk for BPD,” commented Roberta A. Ballard, MD, Professor of Pediatrics, University of California, San Francisco, and Emeritus Professor of Pediatrics and Obstetrics and Gynecology, University of Pennsylvania. “However, those studies administered a higher dose of nitric oxide to premature infants with an established higher risk of BPD. I believe the risk-dose equation may

have contributed to the results of this trial, and anticipate that additional studies will provide clarification.” Dr. Ballard has published more than 60 papers in peer-review journals, and is active in the research to prevent BPD in premature infants with respiratory problems.

Ikaria Holdings, Inc. currently is analyzing the data and conducting additional research to better understand the results and determine opportunities for future research into the use of nitric oxide in different doses or specific patient sub-groups for the treatment of BPD in premature infants. Nitric oxide for inhalation should not be used routinely as a preventive treatment in pre-term infants for the prevention of BPD.

About Ikaria Holdings, Inc.

Ikaria Holdings, Inc. is a fully integrated biotherapeutics company focused on the development and commercialization of innovative pharmaceuticals, biologic messengers and drug-device combinations for hospitalized, critically ill patients. The company’s lead product, INOmax® (nitric oxide) for inhalation, is the only FDA-approved drug for the treatment of hypoxic respiratory failure in term and near-term newborns, and also is marketed in Canada, Europe, Australia and Latin America. INOmax recently was approved for marketing in Japan. Ikaria is engaged in new and ongoing clinical development of INOmax, Covox® (carbon monoxide) for inhalation and hydrogen sulfide. Ikaria is headquartered in Clinton, NJ, with research facilities in Seattle, WA and Madison, WI, and a manufacturing facility in Port Allen, LA. For more information, please visit www.ikaria.com.

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