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### **IKARIA'S INOFLO (NITRIC OXIDE) FOR INHALATION TO BE OFFICIALLY APPROVED IN JAPAN**

*Represents approval of first pharmaceutical nitric oxide product in Japan to help critically ill newborns who suffer from hypoxic respiratory failure*

**Clinton, NJ, June 18, 2008**– Ikaria Holdings, Inc., through its subsidiary INO Therapeutics LLC, announced today that Japan's Ministry of Health, Labor, and Welfare's Council on Drugs and Food Sanitation (CDFS) has recommended approval of INOflo (nitric oxide) for inhalation. INOflo (brandname INOmax® in the United States) will be indicated for the treatment of newborns who suffer from hypoxic respiratory failure (HRF), a potentially life-threatening condition that keeps babies' lungs from delivering enough oxygen to their bodies. INOflo is expected to be officially approved by Japan's Ministry of Health, Labor and Welfare (MHLW) in July 2008.

INOflo, which has been designated an orphan drug in Japan, was recommended for approval by Japan's First Committee on Drugs in May of this year. However, because INOflo represents a new mechanism of action not previously approved in Japan, it was reviewed again by the CDFS Department on Drugs. INOflo is the first pharmaceutical gas approved in Japan, a designation it also has received in the United States, Europe, Canada, Australia, Singapore and several countries in Latin America.

Daniel Tasse, President & CEO of Ikaria, remarked, "As we broaden the reach of INOmax to new continents, we are expanding our ability to advance critical care around the globe. We look forward to bringing this important therapy in neonatal critical care to Japan."

## **About INOmax**

INOmax<sup>®</sup>, in conjunction with ventilatory support and other appropriate agents, is used for the treatment of term and near-term (>34 weeks) neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension.

INOmax is designed to help critically ill newborns breathe more effectively by dilating the blood vessels of the lungs, which improves oxygen uptake and maximizes oxygen supply to the tissues of the body. INOmax therapy has been shown reduce the need for a highly invasive surgical procedure known as extracorporeal membrane oxygenation, or ECMO. During ECMO, an infant's blood is mechanically oxygenated by connecting the baby to a heart-lung machine.

INOmax should not be used in the treatment of neonates known to be dependent on right-to-left shunting of blood. Abrupt discontinuation of INOmax may lead to a worsening condition. Methemoglobinemia is a dose-dependent side effect of inhaled nitric oxide therapy. Nitrogen dioxide (NO<sub>2</sub>) forms rapidly in gas mixtures containing nitric oxide and oxygen thus may cause airway inflammation and damage. Methemoglobin, NO<sub>2</sub>, and FiO<sub>2</sub> should be monitored during nitric oxide administration.

For more information on INOmax, please visit [www.inomax.com](http://www.inomax.com).

## **About Icaria Holdings, Inc.**

Icaria Holdings, Inc. is a fully integrated biotherapeutics company focused on the development and commercialization of innovative pharmaceutical and biological products and drug/device combinations for the critically ill in the hospital and ICU setting. The company's product, INOmax<sup>®</sup> (nitric oxide) for inhalation, is an FDA-approved drug for the treatment of hypoxic respiratory failure in term and near-term newborns. The drug also is approved by regulatory authorities and used in Canada, Europe, Australia and Latin America. In addition to the ongoing clinical development as well as the marketing and selling of its INOmax product, Icaria is engaged in a number of Phase 2 trials with Covox<sup>®</sup> (carbon monoxide) for inhalation and Phase 1 trials with hydrogen sulfide (H<sub>2</sub>S) for various critical care indications. Icaria has a staff of approximately 360 people and is headquartered in Clinton, NJ, with research facilities in Seattle, WA and Madison, WI and manufacturing in Port Allen, LA. For more information on Icaria, please visit [www.icaria.com](http://www.icaria.com).

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