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## IKARIA'S INOFLO (NITRIC OXIDE) FOR INHALATION APPROVED IN JAPAN

*Ikaria to Market and Distribute INOflo via Partnership with Air Water Incorporated and Sumitomo Seika Chemicals*

**Clinton, NJ, July 21, 2008**– Ikaria Holdings, Inc., through its subsidiary INO Therapeutics LLC, announced today that Japan's Ministry of Health, Labor and Welfare (MHLW) has approved INOflo® (nitric oxide) for inhalation for improvement of hypoxic respiratory failure (HRF) with concurrent pulmonary hypertension in neonates. INOflo (brand name INOmax® in the United States) has been shown to improve oxygenation and reduce the need for ECMO, a highly invasive cardiopulmonary bypass procedure.

INOflo is the first pharmaceutical gas approved in Japan and has been designated as an orphan drug by Japan's MHLW, granting a statutory exclusivity period of 10 years, during which time generic versions of INOflo will not be approved.

INOflo will be imported and distributed through a partnership with Air Water Incorporated and Sumitomo Seika Chemicals.

Daniel Tassé, President & CEO of Ikaria®, remarked, "Approval of INOflo in Japan is a significant milestone for Ikaria and a further validation of the benefits of our therapy. Currently, INOmax remains the only pharmaceutical vasodilator approved for the treatment of persistent pulmonary hypertension in newborns and is used in thousands of neonates with hypoxic respiratory failure each year."

Mr. Tassé continued, "Our partnership with Air Water Incorporated and Sumitomo Seika Chemicals will enable us to quickly bring INOflo to the Japanese market. Boasting one of the most highly regarded healthcare systems in the world, Japan will provide Ikaria with an important avenue for incremental growth and a significant foothold as we continue to expand our portfolio of critical care products outside the USA."

## **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 to 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, and therefore may cause airway inflammation and damage. Methemoglobin, NO<sub>2</sub>, and FiO<sub>2</sub> should be monitored during nitric oxide administration.

INOflo<sup>®</sup> is a registered trademark in Japan, in the name of AGA Aktiegolag.

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

## **About Ikaria Holdings, Inc.**

Ikaria 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, Ikaria 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. Ikaria has a staff of approximately 380 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 Ikaria, please visit [www.ikaria.com](http://www.ikaria.com).

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