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### **IKARIA® RECEIVES FDA ORPHAN DRUG DESIGNATION FOR INHALED CARBON MONOXIDE FOR DELAYED GRAFT FUNCTION IN SOLID ORGAN TRANSPLANTS**

**Clinton, NJ, July 28, 2008** – Ikaria Holdings, Inc., a fully integrated critical care biotherapeutics company, announced today that the U.S. Food and Drug Administration (FDA) has granted orphan drug designation for inhaled carbon monoxide for use in the reduction of the incidence and severity of delayed graft function (DGF) in patients undergoing solid organ transplantation.

Ralf Roskamp, M.D., Executive Vice President of Research and Development for Ikaria, commented, "The designation of orphan drug status is a significant step that will greatly facilitate the development of inhaled carbon monoxide as a potential treatment for DGF in solid organ transplants. Pre-clinical data has demonstrated that the compound may possess anti-inflammatory, cytoprotective and anti-apoptotic properties that could potentially improve ischemic-reperfusion mediated malfunction in transplanted organs and allow for an important advance in solid organ transplantation. We look forward to advancing our research of inhaled carbon monoxide as part of our overall goal of delivering new therapies for the underserved critical care market."

Ikaria is currently conducting a single-blind, placebo controlled, dose-escalating Phase 2 study of inhaled carbon monoxide in patients receiving renal transplants. The primary endpoint of the study is to evaluate the safety and tolerability of increasing carbon monoxide dose levels when administered as an inhaled gas to kidney transplant patients over the course of one hour in an acute hospital setting. The study was initiated in August 2007 and is currently enrolling patients.

Delayed graft function following kidney transplantation represents an unmet medical need with considerable health burdens. DGF occurs when the kidney does not function sufficiently after transplantation, often requiring dialysis to support the patient. The underlying cause of DGF is ischemia-reperfusion injury, which occurs when blood flow is returned to damaged tissue, leading

to an inflammatory response that could result in poor organ function. In the United States, approximately 28,000 patients received a solid organ transplant in 2007.

Orphan drug designation provides an accelerated FDA review process, tax advantages and a seven-year period of market exclusivity in the US upon product approval.

**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 400 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.ikaria.com](http://www.ikaria.com).

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