



## LUCASSIN® APPROVED IN AUSTRALIA

**Hampton, NJ and Melbourne – April 23, 2012** – Ikaria, Inc., a critical care company focused on developing and commercializing innovative therapies for critically ill patients, announced today the approval of LUCASSIN® (terlipressin) by the Therapeutic Goods Administration (TGA) of Australia. LUCASSIN is approved for the treatment of Hepatorenal Syndrome Type 1 (HRS 1) in patients who are actively being considered for a liver transplant.

HRS Type 1 is the development of kidney failure in patients with advanced liver cirrhosis in the absence of any other cause. It is characterized by rapid onset of renal failure with a high mortality rate that exceeds 80% within three months. The only cure is a liver transplant.

LUCASSIN is a synthetic vasopressin analogue that acts via the vasopressin V1 receptor as a systemic vasoconstrictor, mainly in the splanchnic (abdominal) circulation, which appears to increase effective arterial volume and improves renal blood flow, thereby improving renal function in patients with HRS.

“We are delighted that the TGA has made LUCASSIN available to patients with HRS 1 in Australia,” stated Daniel Tassé, Chairman and CEO of Ikaria. “Our commitment to advancing the care of critically ill patients today has taken one step further with the approval of this clinically important therapy.”

Terlipressin also is approved in France, Ireland, Spain and South Korea for the treatment of patients with HRS Type 1. Terlipressin is not approved by the FDA for use in the United States. A Pivotal, Phase III clinical trial, known as the REVERSE trial, evaluating the efficacy and safety of LUCASSIN in HRS 1 patients is ongoing in the United States and Canada. LUCASSIN has received orphan drug designation status for HRS 1 in the United States and Australia.

LUCASSIN will be marketed through Ikaria Australia Pty Ltd which was established in 2009. “We’re pleased to be able to offer clinicians with the first and only approved medical therapy for the treatment of HRS 1,” said Dr. Lorna Meldrum, General Manager of Ikaria Australia Pty Ltd.

Ikaria acquired ownership of the LUCASSIN in North America and Australia from Orphan Therapeutics in March 2010.

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

Ikaria, Inc. is a critical care company focused on developing and commercializing innovative therapies designed to address the significant needs of critically ill patients (in the hospital and ICU settings). The company's lead product is INOMAX® (nitric oxide) for inhalation, the only FDA-approved drug for the treatment of hypoxic respiratory failure associated with pulmonary hypertension in term and near-term infants. It is offered through the INOMAX therapy package, an all-inclusive offering of drug product, drug-delivery system, on-site training and 24/7/365 technical assistance and support. The INOMAX therapy package also is marketed in Puerto Rico, Canada, Australia, Mexico and Japan. The company is investigating additional indications for INOMAX in bronchopulmonary dysplasia, and for inhaled nitric oxide with the INOpulse® DS drug-delivery system as a drug-device combination product in pulmonary arterial hypertension (PAH) and chronic obstructive pulmonary disease (COPD). Ikaria's late-stage pipeline is also comprised of LUCASSIN® (terlipressin), a potential treatment for Hepatorenal Syndrome Type 1, which is currently approved and marketed in Australia; as well as Bioabsorbable Cardiac Matrix (BCM), a potential treatment for preventing cardiac remodeling and subsequent congestive heart failure following acute myocardial infarction. Ikaria is headquartered in Hampton, NJ, with a research facility in Madison, WI, and manufacturing facilities in Port Allen, LA and Madison, WI. Please visit [www.ikaria.com](http://www.ikaria.com).

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