



## IKARIA® BEGINS ENROLLMENT OF PIVOTAL TRIAL FOR LUCASSIN®

**Clinton, NJ, November 30, 2010** – Ikaria, Inc. announced that it has enrolled the first patients in its pivotal Phase III trial for LUCASSIN® (terlipressin). The multi-center, randomized, placebo-controlled, double-blind trial is known as the REVERSE Trial.

LUCASSIN is being developed for the treatment of hepatorenal syndrome (HRS) Type 1, an orphan-designated condition for which there currently are no approved drugs in the United States. HRS Type 1 is the development of kidney failure in patients with late-stage 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 REVERSE Trial will compare terlipressin in combination with albumin to placebo with albumin, and will have a primary endpoint of HRS reversal, which is defined as two serum creatinine values of less than or equal to 1.5 mg/dL taken at least 48 hours apart, without any intervening hemodialysis, transplant or elevation of creatinine above a pre-specified level. Transplant-free survival and overall survival are among the secondary endpoints of the trial.

“The start of the REVERSE trial marks Ikaria’s intent to provide the data necessary to fulfill the regulatory requirement to seek U.S. marketing approval to bring an approved treatment option to the patients with HRS Type 1,” commented Douglas Greene, MD, Executive Vice President, Research & Development, Ikaria.

In November 2009, Orphan Therapeutics received a complete response to its marketing application from the U.S. Food & Drug Administration (FDA), citing the need for an additional clinical trial. Ikaria acquired ownership of the LUCASSIN in North America and Australia from Orphan Therapeutics in March 2010.

LUCASSIN is a synthetic vasopressin analogue that acts via the vasopressin V1a 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. Terlipressin 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.

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

Ikaria, Inc. is a biotherapeutics company focused on developing and commercializing innovative therapeutics and interventions designed to address the significant unmet needs of critically ill patients. The company’s lead product is INOtherapy®, an all-inclusive offering of drug product, services and technologies. INOMAX® (nitric oxide) for inhalation, the drug included in the

INOtherapy offering, is the only FDA-approved drug for the treatment of hypoxic respiratory failure associated with pulmonary hypertension in term and near-term infants. INOtherapy also is marketed in Puerto Rico, Canada, Australia, Mexico and Japan. Icaria acquired the North American and Australian rights to LUCASSIN® (terlipressin), a potential treatment for hepatorenal syndrome Type 1, as well as the exclusive worldwide license to IK-5001, a potential treatment for preventing cardiac remodeling and subsequent congestive heart failure following acute myocardial infarction. The company also has a number of investigational compounds in development. Icaria is headquartered in Clinton, NJ, with research facilities in Seattle, WA and Madison, WI, and a manufacturing facility in Port Allen, LA. Please visit [www.ikaria.com](http://www.ikaria.com).

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