IKARIA® COMMENCES GLOBAL REGISTRATION TRIAL FOR BIOABSORBABLE CARDIAC MATRIX
- PRESERVATION I Investigates Novel Device for Cardiac Remodeling and Congestive Heart Failure -

Hampton, NJ – January 3, 2012 – Ikaria, Inc., a critical care company focused on developing and commercializing innovative therapies for critically ill patients in the hospital and ICU settings, today announced that it has commenced its global development program, the PRESERVATION I clinical trial, for its Bioabsorbable Cardiac Matrix (BCM). The CE Mark registration trial has commenced in Australia, and will be followed in Europe. The trial also is expected to commence in other countries, including Israel.

PRESERVATION stands for A Placebo Controlled, Multicenter, Randomized, Double-Blind Trial to Evaluate the Safety and Effectiveness of IK-5001 for the Prevention of Remodeling of the Ventricle and Congestive Heart Failure After Acute Myocardial Infarction.

BCM, also known as IK-5001, is being investigated to prevent ventricular remodeling and subsequent congestive heart failure (CHF) following acute myocardial infarction (AMI). Ventricular remodeling is the structural alteration of the damaged heart muscle that occurs following an acute heart attack. Once this damage occurs, the weakened heart muscle forces the rest of the heart to compensate. Under this extra workload, the heart muscle dilates, the walls of the heart thin, and the heart further remodels, thereby causing another cycle of dilation and overcompensation. The extra workload to the heart causes further structural damage and can lead to congestive heart failure.

BCM, an aqueous mixture of sodium alginate and calcium gluconate, will be delivered in a bolus injection via the coronary artery during catheterization and flows into the damaged heart muscle, where it forms a flexible scaffold, or "matrix," that provides physical support of the heart muscle during recovery and repair. Once the heart tissue heals, BCM gradually dissipates and is excreted through the kidneys.

"Due to the novel self-assembling and self-disassembling nature of BCM, as well as the fact that it provides structural support to the heart without any metabolic affect on the body, we believe the medical device pathway is the most appropriate regulatory approval pathway," stated Douglas Greene, MD, Executive Vice President of Research & Development of Ikaria.

PRESERVATION I is a placebo-controlled, multi-center, randomized double-blind clinical trial involving approximately 300 patients which evaluates the safety and effectiveness of BCM when administered to patients who had successful percutaneous coronary intervention (PCI) following acute ST-segment elevation myocardial infarction (STEMI).

It is estimated that of the more than approximately 690,000 patients throughout Europe, Australia and Israel who are hospitalized for AMI, approximately 40% experience the more serious STEMI. According to published estimates, approximately 30% to 40% of patients with AMI later suffer from CHF. Moreover, the cost of re-hospitalization and other long-term treatments for CHF can be significant. For example, the American Heart Association estimates that in 2008 the direct and indirect cost of CHF was $20 billion to $30 billion, of which approximately half was related to AMI.

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The major endpoints for the PRESERVATION I trial are: 1) Left ventricular end diastolic volume index (anatomic measurement of left ventricular end diastolic volume index will be assessed through echocardiogram); 2) a validated, disease-specific, self-administered, questionnaire to quantify symptoms, function, and the quality-of-life of subjects, and; 3) an exercise tolerance test to measure the response to treatment in subjects with moderate to severe heart disease.

The trial aims to recruit patients across 45 sites. Approximately 50 Australian patients will be recruited at 11 clinical trial sites.

Ikaria acquired the exclusive worldwide license to develop and commercialize BCM from BioLineRx Ltd. in 2009. More information on the PRESERVATION I trial can be found at www.clinicaltrials.gov.

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 pursuing a number of new indications for inhaled nitric oxide. Ikaria's late-stage pipeline is also comprised of LUCASSIN® (terlipressin), a potential treatment for hepatorenal syndrome Type 1; 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.

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