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FDA ACCEPTS FINAL SECTION OF NDA FILING FOR LUCASSIN®
-- Priority Review Granted --

Lebanon, NJ, and Clinton, NJ, June 12, 2009 – Orphan Therapeutics, LLC and Ikaria Holdings, Inc. announced today that the U.S. Food and Drug Administration (FDA) has accepted the final section of the New Drug Application (NDA) filing seeking marketing approval for LUCASSIN® (terlipressin for injection) for the treatment of hepatorenal syndrome (HRS) Type 1. The filing was completed on May 4, 2009, and LUCASSIN has been granted Priority Review as well as Orphan Drug status and Fast Track designation.

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.

In September 2008, Ikaria acquired the North American rights to LUCASSIN, including responsibility for manufacturing, distribution, marketing, sales, customer service and post-market development. Those rights will be transferred to Ikaria following marketing approval.

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. Terlipressin was recently 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 U.S.

About Orphan Therapeutics, LLC

Orphan Therapeutics, LLC, is a privately held drug development company dedicated to developing treatments for rare and serious diseases. It was founded in 2003 with the initial purpose to develop and seek U.S. FDA approval for its first product, LUCASSIN® (terlipressin), for the treatment of hepatorenal syndrome (HRS) Type 1.

About Ikaria Holdings, Inc.

Ikaria Holdings, Inc. is a biotherapeutics company whose acute care products and therapies address the significant unmet needs of critically ill patients. The company's lead product, INOmax[®] (nitric oxide) for inhalation, is the only FDA-approved drug for the treatment of hypoxic respiratory failure in term and near-term newborns, and also is marketed in Canada, Europe, Latin America and Australia. INOmax is approved for marketing in Japan and Mexico. Ikaria is engaged in new and ongoing clinical development of INOmax, carbon monoxide for inhalation and hydrogen sulfide. Ikaria also acquired the North American rights to terlipressin, which currently is under review by the FDA for the treatment of hepatorenal syndrome Type 1. Ikaria is headquartered in Clinton, NJ, with research facilities in Seattle, WA and Madison, WI, and a manufacturing facility in Port Allen, LA. For more information, please visit www.ikaria.com.

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