ORPHAN THERAPEUTICS ANNOUNCES INITIATION OF ROLLING NDA SUBMISSION FOR LUCASSIN® (terlipressin) FOR THE TREATMENT OF HEPATORENAL SYNDROME TYPE 1

May 28, 2008 (Lebanon, NJ) – Orphan Therapeutics today announced that it has begun submission of the rolling LUCASSIN® (terlipressin) New Drug Application (NDA) for the treatment of hepatorenal syndrome (HRS) type 1 in patients with late-stage liver cirrhosis. LUCASSIN® had previously been granted orphan status and fast track designation for this indication by the U.S. Food and Drug Administration (FDA). Currently no drug is approved in the U.S. to treat HRS type 1, a rare and life-threatening condition in late-stage liver disease.

The LUCASSIN® rolling NDA submission is based on the results from OT-0401,[1] a randomized, double-blind, multi-center, placebo-controlled Phase III study in 112 patients with HRS type 1 conducted by Orphan Therapeutics, and is independently supported by TAHRS,[2] a second randomized, multi-center, controlled study in 46 patients coordinated by the University of Barcelona. Orphan Therapeutics holds exclusive rights to the TAHRS data for the NDA submission.

"We are pleased to report that, coinciding with the start of our rolling NDA for LUCASSIN®, the two HRS studies, OT-0401 and TAHRS, have been published in the May 2008 issue of *Gastroenterology*," said Peter Teuber, president of Orphan Therapeutics. "I would like to thank all authors, investigators and members of the LUCASSIN® team for their contributions to these two landmark trials, which together represent the largest number of HRS patients studied in a randomized and controlled study design to-date."

The rolling submission process enables companies that have been granted fast track designation to submit sections of the NDA to the FDA as they become available. The FDA grants fast track status to drug candidates that treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. Terlipressin received orphan drug designation in October 2004 and fast track status in April 2005 for treatment of HRS type 1.

ABOUT HEPATORENAL SYNDROME (HRS)

Hepatorenal syndrome (HRS) is the progressive development of renal dysfunction in patients with late stage liver cirrhosis without any other causes of renal failure. It is likely caused by a very low blood flow through the kidneys, and two types have been described. HRS type 1 is characterized by rapid renal failure with a high mortality rate that exceeds 80% within three months. HRS type 2 represents a less aggressive form with longer survival.

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[1] Sanyal 2008: Sanyal AJ, Boyer TD, Garcia-Tsao G, Regenstein F, Rossaro L, Appenrodt B, Blei A, Gülberg V, Sigal S, Teuber P and the Terlipressin Study Group. A randomized, prospective, double-blind, placebo controlled trial of terlipressin for type 1 hepatorenal syndrome. *Gastroenterology*. 2008;134:1360-1368.

[2] Martín-Llahí 2008: Martín-Llahí M, Pépin M-N, Guevara M, Díaz, F, Torre A, Monescillo A, et al. Terlipressin and albumin vs albumin in patients with cirrhosis and hepatorenal syndrome: a randomized study. *Gastroenterology*. 2008;134:1352-1359

The only potentially curative treatment for HRS and its underlying end-stage liver disease is liver transplantation, provided that the patient is a suitable candidate for transplantation and survives until a transplant is available. However, many patients may not receive a new liver, further supporting the need for alternate therapy options.

ABOUT LUCASSIN® (terlipressin)

LUCASSIN® (terlipressin) is a synthetic vasopressin analogue that acts via the vasopressin V_1 receptor as a systemic vasoconstrictor, resulting in an increase in effective arterial volume and improved renal blood flow in patients with HRS. Terlipressin is not approved by the FDA for use in the U.S. Outside the U.S., terlipressin has been available for over two decades. It has been a standard of care in Europe for esophageal variceal hemorrhage in patients with liver cirrhosis, and was recently approved in France, Ireland and South Korea for the treatment of patients with HRS type 1.

ABOUT ORPHAN THERAPEUTICS

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. For more information contact Stephen Zoegall, Ph.D., at Berry & Company Public Relations (212 253-8881; szoegall@berrypr.com) or visit http://www.orphantherapeutics.com/.