FOR IMMEDIATE RELEASE

Orphan Therapeutics Announces Rolling NDA Submission for LUCASSIN™ (terlipressin) to Treat Type 1 Hepatorenal Syndome

Company Reacquires North American Marketing Rights From PDL BioPharma

Lebanon, NJ (December 18, 2006) – Orphan Therapeutics announced today plans to initiate a rolling submission in the second quarter of 2007 for a New Drug Application (NDA) with the FDA to commercialize LUCASSIN™ (terlipressin), its drug candidate for treating type 1 hepatorenal syndrome (HRS). HRS is a life-threatening condition characterized by rapid kidney failure in patients with end-stage liver cirrhosis, for which there is currently no drug treatment available. Patients with type 1 HRS have an average survival rate of two to four weeks.

The rolling submission process enables companies that have been granted fast track designation by the FDA to submit sections of the NDA to the agency 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 fast track status in April 2005 for type 1 HRS, and orphan drug designation in October 2004.

“We are very pleased with the agreement between Orphan Therapeutics and the FDA’s Division of Cardiovascular and Renal Products to initiate a rolling NDA, with the clinical section to be submitted first,” said Peter Teuber, PhD, President of Orphan Therapeutics. “This decision is the result of a very constructive Pre-NDA meeting with FDA officials last month,” he added.

Orphan Therapeutics also announced that it has agreed to acquire full commercialization rights for terlipressin in North America from PDL BioPharma, its previous marketing partner. By mutual agreement Orphan Therapeutics has assumed marketing rights, and the partnership between the two companies has formally been terminated.

ABOUT ORPHAN THERAPEUTICS:
Founded in 2003, Orphan Therapeutics, LLC is a privately-held, specialty pharmaceutical company dedicated to developing and commercializing treatments for rare but serious diseases. Its initial purpose is to develop and seek FDA approval for LUCASSIN™ (intravenous terlipressin) for the treatment of hepatorenal syndrome (HRS) type 1 in the United States.

For more information, contact:

Peter Teuber, PhD
Orphan Therapeutics
908-849-4805

Paul Hendley
Berry & Company
212-253-8881
phendley@berrypr.com