Press Release Source: Protein Design Labs, Inc.

Protein Design Labs and Orphan Therapeutics Report Fast Track Designation for Terlipressin in Type 1 Hepatorenal Syndrome

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FREMONT, Calif. and LEBANON, New Jersey, April 20 /PRNewswire-FirstCall/ -- Protein Design Labs, Inc. (PDL) (Nasdaq: PDLI - News) and privately held Orphan Therapeutics, LLC today reported that the U.S. Food and Drug Administration (FDA) has granted Fast Track status to the development of terlipressin for the treatment of patients with type 1 hepatorenal syndrome (HRS).

Designation as a Fast Track product indicates that the FDA will facilitate the development and expedite the review of a new drug that is intended to treat a serious or life-threatening condition, and that demonstrates the potential to address an unmet medical need. However, Fast Track designation does not mean that the FDA will expedite approval of the product nor does it increase the likelihood of approval of the product.

PDL's wholly-owned subsidiary, ESP Pharma, Inc., has acquired from Orphan Therapeutics exclusive marketing, sales and distribution rights for terlipressin in the United States and Canada. Orphan Therapeutics holds the U.S. investigational new drug application for terlipressin and is conducting a Phase III clinical trial in the United States and Europe.

Steven Benner, M.D., Chief Medical Officer, said, "Fast Track status is a significant step in Orphan Therapeutics' efforts to develop and ultimately gain approval for terlipressin in an indication for which there is no approved therapy. We congratulate Orphan Therapeutics and look forward to their continued progress in developing this potentially life-saving therapeutic."

Peter Teuber, Ph.D., President of Orphan Therapeutics, said, "Working to address the significant unmet medical need in patients with type 1 HRS is the highest priority of our entire development team, and for all clinical experts involved in the Phase III trial around the country. The Fast Track status is a much welcomed recognition that a close and early interaction with the FDA on the development program, particularly for a small firm like ours, is critical to facilitate the development of terlipressin in patients with this life-threatening condition."

About Terlipressin

Terlipressin is a synthetic 12 amino acid peptide (1-triglycyl-8-lysine- vasopressin) derived from the natural hormone lysine-vasopressin. Due to its constrictive activity on vascular and extra-vascular smooth muscle cells (V-1 agonist), it reduces blood flow in the splanchnic area, and thereby lowers portal blood pressure. Terlipressin is currently not available in the United States, but has been marketed for more than 20 years outside the United States and is considered a standard of care for the treatment of esophageal variceal hemorrhage. More recently, it has become the most widely studied drug in hepatorenal syndrome, a rare but serious complication of liver cirrhosis for which there

is no approved treatment.

About Hepatorenal Syndrome (HRS)

HRS is the development of a functional renal failure in patients with end-stage liver disease in the absence of any other cause of renal pathology. Type 1 HRS is characterized by rapid deterioration of renal function, with a median survival time of less than two weeks, unless liver transplantation is performed. The likely pathogenic mechanism leading to HRS is a vasoconstriction of the renal circulation, secondary to a marked arterial vasodilation in the splanchnic vascular bed, leading to reduction in effective arterial blood volume with subsequent homoeostatic activation of vasoconstrictor systems. The treatment of choice is liver transplantation, if the patient is suitable for transplantation and survives until a transplant is available.

The ongoing clinical study is a double-blind, placebo-controlled Phase III trial of terlipressin in patients with type I HRS (OT-0401). In this study, patients receive terlipressin, or placebo, given intravenously as 1-2 mg every six hours. Therapy is continued until creatinine decreases to less than or equal to 1.5 mg/dl for at least 48 hours, or for a total of 14 days, unless treatment fails or the patient undergoes liver transplantation (for more information see www.clinicaltrials.gov).

About Protein Design Labs

Protein Design Labs is a fully-integrated biopharmaceutical company focused on the development and commercialization of novel therapies for treatment of inflammation and autoimmune diseases, acute cardiac conditions and cancer. As a leader in the development of humanized antibodies, PDL has licensed its patents to numerous pharmaceutical and biotechnology companies, some of which are now paying royalties on net sales of licensed products. PDL markets several biopharmaceutical products in the United States through its wholly-owned subsidiary, ESP Pharma, Inc. Further information on PDL is available at www.pdl.com or by contacting James R. Goff, Senior Director, PDL Corporate Communications, 510-574-1421 or jgoff@pdl.com.

About Orphan Therapeutics

Orphan Therapeutics, LLC is a privately held drug development company. It was founded in 2003 with the purpose of developing specialty products for rare diseases with a high unmet medical need. The initial focus is on developing and seeking FDA approval of intravenous terlipressin for the treatment of type 1 hepatorenal syndrome in the United States.

The foregoing contains forward-looking statements involving risks and uncertainties and PDL's actual results may differ materially from those in the forward-looking statements. Factors that may cause such differences are discussed in PDL's Annual Report on Form 10-K for the year ended December 31, 2004, and other filings made with the Securities and Exchange Commission. In particular, there can be no assurance that the Phase III clinical trial of terlipressin will be completed or that terlipressin will be demonstrated to be safe and effective in the treatment of type 1 hepatorenal syndrome.

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