



PDL BioPharma Reports Results From Phase 3 Trial of Terlipressin In Type 1 Hepatorenal Syndrome

FREMONT, Calif., Aug. 3 /PRNewswire-FirstCall/ -- PDL BioPharma, Inc. (PDL) (Nasdaq: PDLI) today announced that a double-blind, placebo-controlled, Phase 3 clinical study of terlipressin, a vasoactive peptide, did not meet its primary endpoint in the treatment of type 1 hepatorenal syndrome (HRS), a life-threatening complication of advanced liver disease characterized by rapidly progressive kidney failure. In this study, the primary endpoint was treatment success, defined as the percentage of patients alive at Day 14 who demonstrated reversal of type 1 HRS, based upon two measurements of serum creatinine levels less than or equal to 1.5 mg/dL without dialysis or recurrence of disease. The data showed a positive trend toward treatment success, but did not reach statistical significance.

"We are disappointed that the trial of terlipressin did not meet its primary endpoint, as there is a substantial unmet need in HRS," said Steven Benner, M.D., Chief Medical Officer, PDL. "We will work with Orphan Therapeutics to further analyze the study results."

PDL obtained U.S. commercial rights to terlipressin following its acquisition of ESP Pharma in March 2005. The original agreement between ESP Pharma and Orphan Therapeutics was established in June 2004.

Peter Teuber, Ph.D., President of privately-held Orphan Therapeutics, said, "We applaud the investigator community for their support and participation in this important clinical trial for a disease that has a serious unmet medical need. Although the primary endpoint showed only a trend towards improvement, I am encouraged by other results and look forward to reviewing the data with the Food and Drug Administration."

This Phase 3 study, conducted by Orphan Therapeutics, was the first randomized, double-blind, placebo-controlled clinical trial of terlipressin in type 1 HRS in the United States. The study, which evaluated the safety and the potential effect of terlipressin on kidney function and survival in patients with type 1 HRS, enrolled 112 patients at 30 liver disease centers in the United States and five centers outside the United States. Patients were randomized to receive terlipressin or placebo every six hours until a reversal of HRS was seen or for up to 14 days.

About PDL BioPharma

PDL BioPharma, Inc. is a biopharmaceutical company focused on discovering, developing and commercializing innovative therapies for severe or life-threatening illnesses. The company currently markets and sells a portfolio of leading products in the acute-care hospital setting in the United States and Canada and generates royalties through licensing agreements with top-tier biotechnology and pharmaceutical companies based on its pioneering antibody humanization technology. Currently, PDL's diverse late-stage product pipeline includes six investigational compounds in Phase 2 or Phase 3 clinical development for hepatorenal syndrome, inflammation and autoimmune diseases, cardiovascular disorders and cancer. The company's research platform is focused on the discovery and development of antibodies for the treatment of cancer and autoimmune diseases. For more information, please see PDL's website at www.pdl.com.

Forward-looking Statements

The information in this press release should be considered accurate only as of the date of the release. PDL has no intention of updating and specifically disclaims any duty to update the information in this press release for any reason, except as required by law, even as new information becomes available or other events occur in the future. This press release may contain "forward-looking statements" that are based on current expectations and assumptions that are subject to risks and uncertainties. The actual results may differ materially from those in the forward-looking statements because of various factors, risks and uncertainties, including in particular the outcome of further analysis and discussions with the FDA. For further information regarding factors, risks and uncertainties that may cause such differences, please refer to the filings PDL has made with the Securities and Exchange Commission, including the "Risk Factors" sections of PDL's Quarterly and Annual Reports, copies of which may be obtained at the "Investors" section on PDL's website at www.pdl.com. All forward-looking statements in this press release are qualified in their entirety by this cautionary statement.

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