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Pearl Therapeutics Announces Positive Results from Phase 2a Trial of Formoterol Inhalation Aerosol in Chronic Obstructive Pulmonary Disease

-- Company's First Clinical Trial in COPD; Demonstrates Safety and Efficacy of Formoterol Fumarate Delivered by Pearl's Proprietary High-Performance Metered Dose Inhaler (MDI) Product --

REDWOOD CITY, CALIF., January 4, 2010 – Pearl Therapeutics Inc., a company developing high-quality combination therapies for the treatment of highly prevalent chronic respiratory diseases, today announced positive results from its first clinical trial in patients with chronic obstructive pulmonary disease (COPD). Results from a Phase 2a dose-ranging study of PT005, the company's formoterol fumarate hydrofluoroalkane metered dose inhaler (HFA-MDI) formulation, showed that it was well tolerated with bronchodilator efficacy and safety outcomes comparable to the active control drug Foradil[®] Aerolizer[®] (formoterol from a capsule-based, unit dose, dry powder inhaler). Pearl plans to present results from the Phase 2a study of PT005 at a future medical conference.

Formoterol fumarate is a well-known, established, long-acting β_2 -agonist (LABA) bronchodilator that is indicated for the management of asthma and COPD and administered twice daily. It exhibits rapid onset and an excellent response. One of the most potent inhaled drugs with doses in the single-digit microgram range, formoterol fumarate has been difficult to formulate in an MDI, the most widely used inhalation drug delivery format. Pearl has overcome fundamental chemistry, manufacturing and control (CMC) issues associated with MDIs via proprietary porous particles that result in highly stable, robust and aerodynamically efficient formulations. Pearl has developed a broad portfolio of high-performance combination and monotherapy MDI products utilizing this formulation platform, without the need for complex devices or manufacturing processes.

"The safety, efficacy and drug delivery performance results of PT005 relative to the Foradil Aerolizer support the further evaluation of PT005, and validate the capability of our HFA-MDI platform in the delivery of highly potent inhaled products," said Perry Karsen, president and chief executive officer of Pearl Therapeutics. "With our innovative proprietary particle platform, we have significantly improved upon the MDI format to provide highly efficient, stable and consistent pulmonary formulations that are expected to improve patient outcomes."

The Phase 2a study also identified the optimal dose of formoterol to be used in Pearl's combination therapy program. Pearl is currently advancing PT005 aggressively in combination with PT001, its glycopyrrolate inhalation aerosol, a long-acting muscarinic antagonist (LAMA) bronchodilator, as the first and only dual long-acting rapid bronchodilator combination product in an HFA-MDI delivery format. Pearl's LAMA-LABA combination product, PT003, is being evaluated for the treatment of patients with COPD.

"The clinical results of Pearl's LABA bronchodilator in an MDI format in patients with COPD, a highly debilitating and fatal disease, are promising and support further clinical development of Pearl's MDI technology," said Gary T. Ferguson, M.D., pulmonologist and director of the Pulmonary Research Institute of Southeast Michigan. "I believe Pearl's MDI products could offer patients several advantages over existing COPD therapies because of their ability to better deliver the active drug into the lungs, where it is needed for therapeutic benefit."

About COPD

Chronic obstructive pulmonary disease (COPD) is a preventable and treatable disease with significant extrapulmonary effects that may contribute to the severity in individual patients. Its pulmonary component is characterized by airflow limitation that is not fully reversible. The airflow limitation is usually progressive and associated with an abnormal inflammatory response of the lung to noxious particles or gases. While other major causes of death have been decreasing, COPD mortality has continued to rise and is now the fourth leading cause of death in the United States. Each year 12 million Americans are diagnosed with COPD, and research shows that many do not get optimal treatment. An additional 12 million Americans may have COPD and remain undiagnosed. Worldwide, cigarette smoking is the most common risk factor for COPD, and smoking cessation is the only intervention that has been shown to modify the course of the disease.

Bronchodilator medications are central to symptom management in COPD and are prescribed on an as-needed or regular basis to prevent or reduce symptoms. Long-acting inhaled bronchodilators have been shown to be more effective and convenient. Combining bronchodilators of different pharmacological classes has been shown to improve efficacy and may decrease the risk of side effects compared to increasing the dose of a single bronchodilator. As the course of COPD progresses, regular treatment with inhaled glucocorticosteroids may be added to bronchodilator treatment. Pearl is developing a suite of inhaled products that focuses on the development of combination products in order to optimize the treatment of COPD.

Pearl Therapeutics

Pearl Therapeutics is developing combination therapies for the treatment of highly prevalent respiratory diseases, including chronic obstructive pulmonary disease (COPD) and asthma. Leveraging its proprietary particle technology, formulation expertise and unparalleled product development experience, Pearl is rapidly advancing a pipeline of products that offer patients and healthcare professionals therapies that better meet their needs and improve upon the safety and efficacy of existing respiratory therapeutics. Founded in 2006, Pearl Therapeutics is privately held and backed by Clarus Ventures, New Leaf Ventures and 5AM Ventures. For more information, please visit us at http://www.pearltherapeutics.com.