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

*-- Long-Acting Muscarinic Antagonist (LAMA) Bronchodilator in Pearl's Proprietary High-Performance Metered Dose Inhaler (MDI) Product Shown To Be Comparable to Spiriva<sup>®</sup> in Patients with COPD --*

**REDWOOD CITY, CALIF.**, January 6, 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 a Phase 2a dose-ranging study of PT001, the company's glycopyrrolate hydrofluoroalkane metered dose inhaler (HFA-MDI) formulation. The data showed that PT001 was well tolerated and was comparable in bronchodilator efficacy and safety to the active control drug Spiriva<sup>®</sup> HandiHaler<sup>®</sup> (tiotropium bromide inhalation powder) in patients with mild to moderate chronic obstructive pulmonary disease (COPD). Pearl plans to present results from the Phase 2a study of PT001 at a future medical conference.

Glycopyrrolate is a long-acting muscarinic antagonist (LAMA) bronchodilator that is not approved by the U.S. Food and Drug Administration for administration via the inhaled route. Pearl's proprietary porous particles allow the formulation of this class of anticholinergic drugs in the MDI format, the most widely used inhalation drug delivery format. Pearl's proprietary particle platform results 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 clinical results of Pearl's LAMA bronchodilator in an MDI format are encouraging and support further clinical development of Pearl's MDI technology for the management of patients with COPD," said Charles Fogarty, M.D., PT001 clinical trial investigator and pulmonologist at Lung & Chest Medical Associates in Spartanburg, S.C. "These data, along with the results from Pearl's PT005 study, provide a strong basis for a bronchodilator combination product for the management of patients with COPD."

The Phase 2a study also identified the optimal dose of glycopyrrolate to be used in Pearl's combination therapy program. Pearl is currently advancing PT001 aggressively in combination with PT005, its formoterol fumarate inhalation aerosol, a well-known, established long acting  $\beta_2$ -agonist (LABA)

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.

"This is Pearl's second clinical trial in COPD patients demonstrating that our novel formulation of a known active drug is comparable to the marketed product in terms of safety and efficacy. These findings provide further evidence that we can successfully deliver highly potent inhaled products to patients with our innovative proprietary particle platform," said Perry Karsen, president and chief executive officer of Pearl Therapeutics. "We are encouraged by our two initial clinical trials in patients with COPD, and we anticipate that the upcoming clinical trial of our combination product will be positive as well."

### **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>.

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