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Pearl Therapeutics Reports Positive Phase 2b Results of PT001 in patients with COPD

- Results Confirm Glycopyrrolate Twice-Daily Dosing -

REDWOOD CITY, CALIF. – December 7, 2011 – Pearl Therapeutics Inc. today announced positive top-line results from a randomized, double-blind, Phase 2b, dose-ranging study of glycopyrrolate, a long-acting muscarinic agonist (LAMA) delivered twice a day (BID) via metered-dose inhaler (GP MDI; PT001) in patients with moderate-to-severe COPD. Four doses of GP MDI were compared to placebo and Atrovent® HFA Inhalation Aerosol, a short-acting muscarinic antagonist given four times a day (QID). All doses of GP MDI tested produced statistically significant improvements in lung function (FEV1 AUC 0-12)[1] compared to placebo ($p<0.0001$). Further, doses of PT001 were identified that were non-inferior to Atrovent HFA. PT001 was well tolerated and no safety concerns were identified. This study complements Pearl's previous assessment of PT001's clinical profile relative to well established marketed muscarinic antagonists[2], and provides additional dose ranging data for glycopyrrolate component of Pearl's LAMA/LABA combination product, PT003. Detailed results of this Phase 2b study of PT001 will be presented at a future conference.

Dr. Colin Reisner, chief medical officer and executive vice president of clinical development for Pearl Therapeutics commented, "This Phase 2b study provides important information about the safety and efficacy of GP MDI, the LAMA component of PT003, our lead combination bronchodilator candidate for the treatment of COPD. Further, the activity profile of GP MDI in this study is consistent with that observed in two previously reported studies and supports the BID dosing that we believe will provide the best symptom relief for patients with moderate-to-severe COPD."

"A significant part of the very large COPD market is driven by the use of BID LABAs and inhaled corticosteroids. However, a rapid-acting, BID LAMA to complement these options is not yet available," said Chuck Bramlage, chief executive officer for Pearl Therapeutics. "We believe GP MDI has the clinical profile to fill this treatment gap and become a best-in-class LAMA monotherapy. In addition, GP MDI is a key component of our combination bronchodilator PT003, which, pending the successful completion of our remaining Phase 2b studies, we expect to advance into Phase 3 trials in 2012."

About COPD

Chronic obstructive pulmonary disease (COPD) is a preventable and treatable lung disease that is the fourth leading cause of death in the United States. Each year 12 million Americans are diagnosed with COPD and an additional 12 million Americans may have COPD but remain undiagnosed. Research shows that many do not get optimal treatment.

Bronchodilator medications are central to symptom management and are prescribed on an as-needed or regular basis to prevent or reduce symptoms. Long-acting inhaled bronchodilators have been shown to be most effective and convenient. Combining bronchodilators of different pharmacological classes, as recommended by The Global Initiative for Chronic Obstructive Lung Diseases (GOLD), 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.

About Pearl Therapeutics

Pearl Therapeutics is a privately held company developing inhaled combination therapies for the treatment of highly prevalent respiratory diseases, including chronic obstructive pulmonary disease and asthma. Pearl is rapidly advancing a pipeline of products including PT003, an inhaled, fixed-dose combination bronchodilator product comprised of a long-acting muscarinic antagonist (LAMA) and a long-acting beta-2 agonist (LABA) delivered via a metered dose inhaler (HFA MDI); and PT010, a triple-combination product that combines the LAMA and LABA components of PT003 with an inhaled corticosteroid (ICS) for twice-daily administration from an HFA MDI for the treatment of severe COPD. Both PT003 and PT010 are developed with Pearl's proprietary porous particle cosuspension technology, which allows the formulation of multiple products in the MDI format, with highly stable, robust and aerodynamically efficient drug delivery. Founded in 2006, Pearl Therapeutics is privately held and backed by 5AM Ventures, Clarus Ventures, New Leaf Ventures and Vatera Healthcare. For more information, please visit www.pearltherapeutics.com.

[1] *FEV1 (forced expiratory volumes in one second) is a common measurement of lung function in patients with asthma, cystic fibrosis, and COPD and is typically used to predict the severity of pulmonary disease. AUC (area under the curve) is a measure of therapeutic benefit over a period of time.*

[2] *Previously, Pearl has reported a comparative assessment of PT001 relative to Spiriva®, a long-acting, once-a-day, muscarinic antagonist. See announcements dated May 18, 2010 and January 6, 2010 for more information.*

Editor's note: Atrovent® HFA (Ipratropium Bromide) and Spiriva® HandiHaler® (tiotropium bromide inhalation powder) are registered trademarks of Boehringer Ingelheim Pharmaceuticals.

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