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Pearl Therapeutics' Phase 2b Results Show a 50% Improvement in Lung Function with PT003 Compared to Spiriva® and Foradil® in Patients with COPD

- Additional Details of Primary and Secondary Endpoints Presented at American Thoracic Society -

REDWOOD CITY, CALIF., May 18, 2011 – Pearl Therapeutics Inc. presented detailed efficacy and safety results today from the Company's phase 2b study of PT003 (GFF MDI) in patients with moderate-to-very severe COPD during a late-breaker poster session at the annual meeting of the American Thoracic Society (ATS). PT003 is a proprietary fixed-dose combination of glycopyrrolate (GP), a long-acting muscarinic antagonist (LAMA), and formoterol fumarate (FF), an established, long-acting beta-2 agonist (LABA) delivered via a pressurized hydrofluoroalkane metered dose inhaler (HFA MDI). In addition to details of Pearl's Phase 2b primary endpoint, today's poster highlights findings from secondary endpoints that reinforce the superiority of PT003 over both of its individual components as well as market-leading active comparators in patients with moderate-to-very severe COPD. Top-line results from the primary endpoint of this study were disclosed in December 2010.

The study's primary endpoint was improvement in lung function after one week of dosing, as assessed by FEV_1* $AUC_{0\text{-}12}$ relative to baseline at the start of treatment. Treatment with PT003 resulted in a statistically significant improvement in mean FEV_1 $AUC_{0\text{-}12}$ of 47% (or 93 mL) over Foradil® and 49% (or 95 mL) over Spiriva® after one week of dosing ($p<0.0001$ for both comparisons).

"These results demonstrate an overwhelmingly superior outcome and an even larger degree of bronchodilation than our internal benchmark of 70 mL, providing what we believe to be a clinically meaningful benefit," noted Colin Reisner, MD, FCCP, FAAAAI, chief medical officer, and executive vice president of clinical development and medical affairs at Pearl Therapeutics. "While current COPD medications offer some relief, a significant need still exists for many patients. I am especially optimistic that PT003 has the potential of fulfilling this unmet need for COPD patients at all stages of severity."

Expanding the benefits beyond its primary endpoint, PT003 also demonstrated a statistically significant improvement in peak FEV_1 on day one, with further benefit observed on day seven relative to all comparators and placebo. Treatment with PT003 yielded an improvement in peak FEV_1 levels of 42% (or 64 mL) over Foradil and 74% (or 92 mL) over Spiriva as measured on day one; and an improvement of 37% (or 89 mL) over Foradil and 75% (or 141 mL) over Spiriva when measured on day seven ($p<0.03$ for all comparisons). Furthermore, PT003 demonstrated a faster onset of action than did Spiriva on day one (75% higher probability of onset at any time point during the first 2 hours following administration, $p\leq0.0003$).

PT003 also demonstrated a significant improvement in morning trough FEV_1, which is a measure of lung function in patients before they receive their first dose of medication in the morning. This is a particularly relevant measurement for COPD patients who often report that their symptoms are most severe in the morning and cause them to struggle with morning activities. In this Phase 2b study, following one week of study medication, morning trough FEV_1 levels in the PT003 arm were improved by 48% (or 68 mL) over Foradil and 52% (or 73 mL) over Spiriva ($p<0.014$ for both measures).

"The overall improvement in lung function, including the fast onset of action with higher peak improvements in FEV_1 and morning trough FEV_1 is a strong indicator of how PT003's twice-a-day dosing can benefit patients' disease management," continued Dr. Reisner. "To assess the full clinical potential of PT003, and ensure that we have the strongest possible regulatory package, we plan to initiate four additional Phase 2b studies in the next few weeks. These studies will further characterize the dose response of PT003 and its components, and will include extensive safety assessments."

"The substantial improvement shown by PT003 in the primary and secondary endpoints relative to both its components and current market leaders is impressive, and we believe demonstrates its clinical and commercial potential," added Chuck Bramlage, Pearl's chief executive officer. "However, given the competitive nature of the COPD market, we felt it was essential that PT003 clearly demonstrate superiority to marketed products before pursuing additional clinical work. With an improvement in mean FEV_1 AUC_{0-12} of more than 70 mL over Spiriva and Foradil, we have exceeded the superiority hurdle that we set for PT003. We have therefore made the decision to advance PT003 into the next stage of Phase 2b development, with a targeted initiation of Phase 3 trials in the second half of 2012."

The ATS annual meeting is being held from May 13-18 in the Colorado Convention Center in Denver, CO. A reproduction of the poster, titled "Novel Combination of Glycopyrrolate and Formoterol MDI (GFF-MDI) Provides Superior Bronchodilation Compared to its Components Administered Alone, Tiotropium DPI, and Formoterol DPI in a Randomized, Double-Blind, Placebo-Controlled Phase 2b Study in Patients with COPD," may be retrieved on the Publications page of the Pearl website.

PT003 Dose Selection and Phase 2b Study Design

As part of a previously conducted dose-ranging study, Pearl determined that a BID administration 9.6 µg formoterol (FF) MDI provided equivalent bronchodilation to Foradil. In another study, multiple doses of glycopyrrolate (GP) were tested against the currently marketed LAMA, Spiriva, and the results supported the progression of 36 µg and 72 µg BID. Thus, in this Phase 2b trial, two formulations of PT003 were studied, each containing 9.6 µg FF plus one of two doses of GP: 36 µg or 72 µg. In addition, to investigate the effective dose range of FF MDI, a 7.2 µg BID dose was also tested.

One hundred eighteen patients were randomized in the Phase 2b study to receive four of the following eight treatments in a cross-over study: 36 µg GP/9.6 µg FF (PT003), 72 µg GP/9.6 µg FF (PT003), 36 µg GP (PT001), 7.2 µg FF (PT005) , 9.6µg FF (PT005), Spiriva, Foradil and placebo. Placebo, PT003, PT001 and PT005 were administered BID via HFA MDI for one week while Spiriva and Foradil were administered according to their approved label: 18 µg once daily (via Handihaler® inhaler) and 12 µg BID (via Aerolizer® inhaler), respectively, each for one week.

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. Pearl is developing inhaled combination products designed to optimize the treatment of COPD.

About Pearl Therapeutics

Pearl Therapeutics is a privately held company developing 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.

** FEV_1 (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.*

Editor's note: Spiriva® HandiHaler® (tiotropium bromide inhalation powder) is a registered trademark of Boehringer Ingelheim Pharmaceuticals; Foradil® is a registered trademark of Astellas Pharma; and Aerolizer® is a registered trademark of Novartis AG.

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