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Pearl Therapeutics' PT003 Combination Therapy for COPD Demonstrates Superior Bronchodilation Compared to Spiriva® and Foradil® in Randomized Phase 2b Study

REDWOOD CITY, CALIF., December 1, 2010 – Pearl Therapeutics Inc. today announced that their lead combination bronchodilator, PT003, met the primary efficacy endpoint in a recently completed Phase 2b clinical trial in patients with moderate to very severe chronic obstructive pulmonary disease (COPD). These top-line results show that PT003 provides superior bronchodilation compared to the current market leader, tiotropium bromide (Spiriva® Handihaler®), as well as to formoterol fumarate (Foradil® Aerolizer®), placebo and the individual components of PT003 ($p \leq 0.0002$ for all comparisons). In addition PT003 was shown to be safe and well tolerated.

PT003 is an inhaled combination bronchodilator product comprised of glycopyrrolate, a long-acting muscarinic antagonist (LAMA), and formoterol, a long-acting beta-2-agonist (LABA), delivered via a hydrofluoroalkane metered dose inhaler (MDI). In this Phase 2b study, two doses of PT003 were compared to Spiriva, Foradil, placebo, glycopyrrolate MDI (PT001), and formoterol MDI (PT005). The primary assessment for this study was change in lung function following one week of dosing, as assessed by FEV_1 $AUC_{0\text{-}12}$ (forced expiratory volume in one second)*, relative to baseline at the start of treatment. Both doses of PT003 were superior to Spiriva ($p<0.0001$), Foradil ($p \leq 0.0002$), placebo ($p<0.0001$), PT001 ($p<0.0001$), and PT005 ($p<0.0001$).

In addition to FEV_1 AUC, which assesses overall improvement in lung function over the duration of treatment, Pearl measured peak FEV_1 on days one and seven, which measures the maximum improvement in lung function observed during the assessment period. Both doses of PT003 were superior to Spiriva and Foradil on day one ($p<0.03$), with further benefit observed on day seven ($p< 0.002$).

"In order to assess the incremental benefit of PT003 over current treatments we included Spiriva and Foradil, two widely used products for the management of patients with COPD as active comparators. The impressive results generated by PT003 validate our combination approach and the strength of our porous particle technology," said Dr. Colin Reisner, chief medical officer and EVP of clinical development of Pearl Therapeutics. "The improvement in lung function demonstrated by PT003 in this trial is encouraging and supports the potential of this product in the treatment of patients with COPD."

Pearl plans to advance PT003 into additional Phase 2b clinical studies in the first half of 2011. Complete data from this Phase 2b study will be presented in 2011 at an appropriate scientific conference.

PT003 Phase 2b Study Design

The Phase 2b dose-ranging study compared twice-daily (BID) dosing of PT003 against its monotherapy components, PT001 and PT005, as well as Spiriva, Foradil and placebo in 118 patients with moderate to very severe COPD. Placebo, PT003, PT001 and PT005 were administered BID for one week while Spiriva and Foradil were administered according to their approved label: 18 µg (via Handihaler® inhaler) once daily, and 12 µg (via Aerolizer® inhaler) BID, respectively, each for one week.

About PT003

PT003 is an inhaled combination bronchodilator product comprised of glycopyrrolate (PT001), a long-acting muscarinic antagonist (LAMA), and formoterol (PT005), an established, long-acting beta-2-agonist (LABA), delivered via a hydrofluoroalkane metered dose inhaler (HFA-MDI). Pearl's proprietary porous particle technology allows the formulation of both formoterol and glycopyrrolate in the MDI format, with highly stable, robust and aerodynamically efficient drug delivery. PT003 is the first and only dual long-acting rapid bronchodilator LAMA-LABA combination product in development in an HFA-MDI formulation, the most widely used inhalation drug delivery format.

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 and results in symptoms such as shortness of breath that worsens with exercise and chronic cough. 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.

For more information on COPD, please visit the Therapeutic Areas page on the Pearl website.

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 (COPD) and asthma. Leveraging its proprietary particle technology, as well as formulation and 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 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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