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Pearl Therapeutics to Present Complete PT003 Results from Phase 2b COPD Study in a Late-Breaker Session at the American Thoracic Society Annual Meeting

REDWOOD CITY, CALIF.,” April 29, 2011 – Pearl Therapeutics Inc. announced today that complete results from the Company’s Phase 2b study of [PT003](#) in patients with moderate-to-very severe COPD will be presented during a late-breaker poster session at the upcoming annual meeting of the American Thoracic Society (ATS). PT003 (GFF-MDI) is a proprietary, fixed-dose combination of glycopyrrolate, a long-acting muscarinic antagonist (LAMA), and formoterol, an established, long-acting beta-2 agonist (LABA) delivered via a pressurized hydrofluoroalkane metered dose inhaler (HFA MDI). It 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.

“Our presentation at this year’s ATS represents a particularly important step in the progression of Pearl’s bronchodilator franchise,” said [Chuck Bramlage](#), Pearl Therapeutics’ chief executive officer. “Not only is it an opportunity to present our strong clinical evidence to peers, but from a business perspective, it speaks to the speed and fiscal efficiency with which Pearl has expedited the clinical development of our lead bronchodilator combination and its individual components. In fewer than four years since initial financing, Pearl has completed the significant Phase 2b study being highlighted at ATS, as well as other key clinical and non-clinical studies. This is a testimonial to the Pearl team and its novel co-suspension platform. We expect this momentum will continue as we advance PT003 and its components, into a series of four additional Phase 2b studies, and make plans for Phase 3 trials in parallel.”

The ATS annual meeting is taking place May 13-18 in the Colorado Convention Center in Denver, CO. Information regarding the ATS presentations is below and full abstracts will be available through the American Journal of Respiratory and Critical Care Medicine journal website beginning on May 2 at <http://ajrccm.atsjournals.org>.

Presentation Date/Time: Wednesday, May 18, 2011 from 8:15am – 10:45am

Poster Title: Pearl Therapeutics’ combination LAMA/LABA 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

Abstract Number: 611

Session and Location: D30 , Room 403-404, Colorado Convention Center

In December 2010, Pearl released [top-line Phase 2b results](#) from this study, which demonstrated that PT003 provides superior bronchodilation compared to the current market leader, Spiriva, as well as to Foradil, placebo and PT003’s

individual components, Pearl's glycopyrrolate MDI (PT001; GP MDI) and formoterol MDI (PT005; FF MDI). The p-value for all comparisons was ≤ 0.0002 . Additional data on primary and secondary endpoints will be presented at ATS.

Phase 2b Study Design

This Phase 2b study randomized 118 patients to one of the following study arms: high or low dose PT003 administered twice-daily (BID), high or low dose PT001, PT005, tiotropium bromide (Spiriva[®] Handihaler[®]), formoterol fumarate (Foradil[®] Aerolizer[®]) 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. The primary endpoint in this study was an improvement in lung function as assessed by FEV₁ AUC₀₋₁₂ (forced expiratory volume in one second)*, relative to baseline at the start of treatment.

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 (GFF-MDI), 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 (GMFF MDI), 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 co-suspension 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.

** 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.*

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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