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**Pearl Therapeutics Announces Successful Completion of Phase 2b Safety  
and Efficacy Studies of COPD Combination, PT003**

*- Pearl on track to commence Phase 3 program in 2012 -*

**REDWOOD CITY, CALIF.** – January 6, 2012 – Pearl Therapeutics Inc. today announced the completion of two Phase 2b clinical studies of [PT003](#), the Company’s investigational inhaled combination bronchodilator product for the treatment of patients with moderate-to-severe COPD. The first of these two trials (NCT01349803) was a 237-subject cardiovascular safety study designed to measure the change in mean heart rate following twice-daily (BID) chronic administration of the combination PT003, and its components PT001 and PT005. The second (NCT01349816) was a 185-patient, randomized, double-blind dose-confirmation study of different doses of PT003 compared with its components. PT003, PT001 and PT005 were shown to be safe, effective and well tolerated, with no meaningful changes in heart rate or other cardiovascular safety parameters relative to baseline as measured by Holter monitor over two weeks. Pearl plans to present results of these trials at appropriate medical meetings in 2012.

“We were able to conduct these two studies, as well as the previously announced Phase 2b dose-ranging studies of PT001 and PT005 in approximately six months, which is a testament to both the skill and commitment of our clinical team, and the efficacy and safety profiles of our combination bronchodilator observed to date,” said [Chuck Bramlage](#), chief executive officer for Pearl Therapeutics. “With this operational excellence, along with the continued safety and efficacy of our bronchodilator combination, we are confident in our plan to advance PT003, PT001 and PT005 into the rigor of late-stage clinical scrutiny.”

These two clinical trials are part of the Company’s five-study Phase 2b program that included three previously completed, randomized, double-blind trials: one dose-ranging trial each of PT005 and PT001, plus a placebo- and active-controlled study of PT003 compared with its components and marketed bronchodilators, Foradil® Aerolizer® and Spiriva® HandiHaler®. Approximately 700 patients with moderate-to-severe COPD have taken part in Pearl’s Phase 2b clinical program to date.

“The totality of findings from our clinical program to date, which includes five Phase 2b studies, two Phase 1/2a studies and one Phase 1 study, present a strong foundation on which we plan to build a comprehensive Phase 3 program to support regulatory approval of PT003,” added [Dr. Colin Reisner](#), chief medical officer and executive vice president of clinical development for Pearl Therapeutics, “I believe the world-class team of pulmonary drug development specialists that we have assembled, and our proven ability to conduct well-controlled and highly informative trials will provide the regulatory support needed to make our bronchodilator product family available for the very large patient population which suffers from the debilitating effects of COPD.”

## 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](http://www.pearltherapeutics.com).

Editor's Notes:

- 1) *Spiriva® HandiHaler® (tiotropium bromide inhalation powder) is a registered trademark of Boehringer Ingelheim Pharmaceuticals.*
- 2) *Foradil® is a registered trademark of Astellas Pharma; and Aerolizer® is a registered trademark of Novartis AG.*

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