



<b>Contacts:</b>	Noreen McKiernan Pearl Therapeutics (650) 305-2609 nmckiernan@pearltherapeutics.com	Aline Schimmel Scienta Communications (312) 238-8957 aschimmel@scientapr.com
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### **Pearl Therapeutics Announces Positive Results for Phase 2b Dose-Ranging Study of Formoterol MDI**

*- Generates Comprehensive Evidence to Select FF Dose for Future Phase 3 LAMA/LABA combination (PT003) Program -*

**REDWOOD CITY, CALIF.**, August 30, 2011 – Pearl Therapeutics Inc. today announced positive results from a randomized, double-blind, Phase 2b, dose-ranging study of its formoterol fumarate metered dose inhaler (FF MDI; PT005), a long-acting beta-2 agonist (LABA) compared to placebo and Foradil® Aerolizer® in patients with moderate-to-severe COPD. All doses of FF MDI tested produced highly statistically significant improvements in lung function (FEV1 AUC 0-12) compared to placebo ( $p < 0.0001$ ). Dose ordering (incremental increase in efficacy with increasing doses) was observed across the three FF MDI doses evaluated, and the two lower doses tested were comparable to 12 mcg Foradil, the currently approved dose. This study marks the fourth in a series of detailed clinical evaluations of FF by Pearl in its novel MDI formulation platform, and significantly expands the safety and efficacy database of FF MDI. Detailed results of this study will be presented at a future conference.

“Successful completion of this study is an important milestone in the development of [PT003](#), Pearl’s combination of FF with glycopyrrolate, a long acting muscarinic antagonist (LAMA). The dose ordering and consistent response observed in this study confirm the robustness of Pearl’s breakthrough formulation platform, and strengthen the value of FF MDI as the LABA arm of the PT003 program,” commented [Colin Reisner](#), Pearl’s chief medical officer and executive vice president of clinical development. “The totality of data from this and previous studies provides Pearl with the confidence to select a dose of FF MDI to progress into PT003 Phase 3 studies.”

[Chuck Bramlage](#), Pearl’s chief executive officer added, “This study was completed in only three months, demonstrating the drive of the Pearl development organization, enthusiasm of Pearl’s clinical investigators, and our overall commitment to capital efficiency while generating high quality clinical data. In the next few months, we look forward to presenting results from the remaining three studies in our ongoing Phase 2b program, which is funded by our 2010 Series C financing. We intend to meet with the FDA in the first half of 2012, in preparation for PT003 registrational studies targeted to start in late 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. 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](http://www.pearltherapeutics.com).

*Editor's note: Foradil<sup>®</sup> is a registered trademark of Astellas Pharma; and Aerolizer<sup>®</sup> is a registered trademark of Novartis AG.*

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