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Pearl Therapeutics Completes Phase 2b Study of Glycopyrrolate, Defines Dose-Response Curve and Identifies Optimal Dose of PT001

REDWOOD CITY, CALIF. – September 13, 2012 – Pearl Therapeutics Inc. today announced the completion of a randomized, double-blind Phase 2b dose-ranging study in which six doses of the long-acting muscarinic antagonist (LAMA), glycopyrrolate (GP) ranging from 18 micrograms to 600 nanograms BID were delivered via metered-dose inhaler (GP MDI; PT001) to patients with moderate-to-severe COPD. In this study (NCT01566773) and the previously conducted dose-ranging GP MDI studies, a total of nine descending doses (a 240-fold range) of GP have been evaluated. The results, which Pearl plans to present at appropriate medical meetings in 2013, identify doses that are believed to be the lowest effective and optimal doses of GP MDI. Further, they support progression in combination with BID formoterol fumarate (FF MDI, PT005), the LABA component of Pearl's fixed dose bronchodilator combination PT003 (GFF MDI) towards a Phase 3 program.

"By taking full advantage of the flexibility of our porous-particle-based co-suspension MDI formulation platform, we were able to assess doses of GP MDI as low as 600 nanograms, allowing us to characterize fully the dose-response curve of GP MDI. To our knowledge, this is the first time that doses of a LAMA MDI this low have been able to be studied," commented Colin Reisner, chief medical officer and executive vice president of clinical development for Pearl Therapeutics. "These GP MDI dose-ranging results strengthen our confidence in dose selection of this potent bronchodilator and demonstrate our commitment to satisfying the most stringent regulatory expectations."

"The identification of an optimal BID dose of GP MDI complements Pearl's earlier clinical findings in which the optimal BID dose of FF MDI was determined," added Chuck Bramlage, chief executive officer for Pearl Therapeutics. "We have made exceptional progress over a relatively short period of time – completing nine studies in four years – developing and testing an array of monotherapy MDIs as well as fixed dose combination MDIs to ensure that the most appropriate dose and dosing regimen were selected in advance of pivotal trials. With the upcoming completion of this comprehensive Phase 2 program, we are preparing to transition rapidly to Phase 3 to valuate safety and efficacy of PT003 in COPD patients."

Pearl's tenth study (NCT01587079) is ongoing, and is designed to quantify the additive benefit of low doses of GP in fixed-dose combination with FF. Results of this trial are expected to provide preliminary evidence for the U.S. regulatory requirement known as the "combination rule," which requires sponsors to demonstrate that each component of a fixed dose combination makes a contribution to the clinical activity of the combination product, and that the combination product is superior to each component alone. This study is expected to conclude in the third quarter of 2012, with data also being submitted for presentation at appropriate medical meetings in 2013.

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 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 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.

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