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Pearl Therapeutics Announces Positive Results from Phase 1 Trial of PT003, a Bronchodilator Combination Therapeutic for Chronic Obstructive Pulmonary Disease, and Initiation of Phase 2b Trial

-- PT003 Demonstrated To Be Safe and Well Tolerated by Healthy Volunteers in Phase 1 Trial --

REDWOOD CITY, CALIF., March 29, 2010 – Pearl Therapeutics Inc., a company developing clinically differentiated combination therapies for the treatment of highly prevalent chronic respiratory diseases, today announced positive results from a Phase 1 safety and pharmacokinetics study of PT003, its lead combination therapeutic for the treatment of chronic obstructive pulmonary disease (COPD). Based on these results, and previously announced positive results from Phase 2a studies of PT003's individual components, the company has advanced PT003 into a Phase 2b trial.

PT003 is an inhaled combination bronchodilator product comprised of glycopyrrolate, a long-acting muscarinic antagonist (LAMA), and formoterol, a well-known, established, long-acting β_2 -agonist (LABA), delivered via a hydrofluoroalkane metered dose inhaler (HFA-MDI). 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.

"COPD is a progressive lung disease affecting millions of patients, representing an important unmet clinical need. Pearl's technology has the potential to satisfy the medical community's need for long-acting bronchodilator combination products that allow bronchodilators of different pharmacological classes to be combined, thereby improving patient outcomes, medication delivery and adherence," said Gary T. Ferguson, M.D., pulmonologist and director of the Pulmonary Research Institute of Southeast Michigan. "The Phase 2b study of Pearl's bronchodilator combination product is intended to evaluate the potential clinical benefits of combining known active drugs to achieve maximum bronchodilation."

"Phase 2a monotherapy trials of our glycopyrrolate HFA-MDI (PT001) and our formoterol HFA-MDI (PT005) demonstrated that we could safely and effectively deliver highly potent therapeutics to COPD patients with our innovative proprietary particle platform. Based on these successes, we are advancing our unique LAMA-LABA combination product into a mid-stage trial to optimize treatment of COPD patients via maximum bronchodilation," said Perry Karsen, president and chief executive officer of Pearl Therapeutics. "The initiation of the PT003 Phase 2b trial is an important milestone in our clinical

program to develop combinations of drugs that previously could not be formulated together in a consistent and robust MDI form."

PT003 Phase 1 and 2b Study Details

The randomized, double-blind, single-dose, crossover Phase 1 study assessed the safety and pharmacokinetics of the monotherapies PT001and PT005 delivered alone and concurrently and the combination therapy PT003 administered in 16 healthy volunteers. Results showed that all of the formulations were well tolerated. Evaluation of pharmacokinetics showed that Pearl's porous particle platform delivers reproducible, predictable and therapeutically relevant concentrations of all of the active agents studied.

The Phase 2b dose-ranging study will compare twice-daily dosing of PT003 against placebo, glycopyrrolate HFA-MDI (PT001), formoterol HFA-MDI (PT005), Spiriva[®] HandiHaler[®] (tiotropium bromide inhalation powder) and Foradil[®] Aerolizer[®] (formoterol fumarate inhalation powder) in patients with COPD. The study will aid in the identification of the optimal dose of PT003 for evaluation in a Phase 3 trial based on efficacy and safety parameters. The study is currently enrolling patients. For information about enrollment opportunities, please visit. <u>www.clinicaltrials.gov</u>.

About Pearl's Proprietary Porous Particle Technology and HFA-MDI Products

Pearl has overcome fundamental chemistry, manufacturing and control (CMC) issues associated with MDIs via its proprietary porous particle technology. These particles have allowed the formulation of both formoterol and glycopyrrolate in the MDI format, with highly stable, robust and aerodynamically efficient drug delivery. Pearl has developed a broad portfolio of high-performance combination and monotherapy MDI products, including PT003, PT001 and PT005, utilizing this formulation platform, without the need for complex drug delivery devices or manufacturing processes.

Pearl also is developing 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.

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 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 products that focus on the development of combination products in order to optimize the treatment of COPD.

About Pearl Therapeutics

Pearl Therapeutics is developing combination therapies for the treatment of highly prevalent respiratory diseases, including chronic obstructive pulmonary disease (COPD) and asthma. Leveraging its proprietary particle technology, formulation expertise and unparalleled 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 Clarus Ventures, New Leaf Ventures and 5AM Ventures. For more information, please visit us at http://www.pearltherapeutics.com.

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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