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

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REDWOOD CITY, Calif., Jan. 6, 2012 /PRNewswire/ -- Pearl Therapeutics Inc. today announced the completion of two Phase 2b clinical studies of PT003 [1], 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 [2], 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
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SOURCE [3]

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Links:
[1] http://www.pearltherapeutics.com/PT003
[2] http://pearltherapeutics.com/management-team#chuck
[3] http://www.bio-medicine.org/medicine-technology-1/Pearl-Therapeutics-Announc

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