

Elevation Pharmaceuticals Presents Positive Phase 2a Results in COPD Patients at the European Respiratory Society Annual Congress

San Diego, CA – September 26, 2011 – Elevation Pharmaceuticals, Inc., a biopharmaceutical company focused on the development of new aerosol therapies for patients with respiratory diseases, announced today that it presented positive results from a Phase 2a study of EP-101 in patients with moderate to severe chronic obstructive pulmonary disease (COPD), a large and growing disease characterized by significant unmet clinical needs, at the annual meeting of the European Respiratory Society (ERS). The results demonstrated a statistically significant and well-tolerated improvement in lung function over the 24-hour time period post dosing for EP-101 versus placebo. EP-101 is a proprietary inhalation solution formulation of glycopyrrolate, a long-acting muscarinic antagonist (LAMA), delivered by an optimized, Investigational eFlow[®] Nebulizer System (PARI Pharma GmbH).

The randomized, double blind, placebo controlled, cross-over, dose-ranging study evaluated the dose response, efficacy, safety and tolerability of single doses of EP-101 in 42 patients with moderate to severe COPD. Following a single administration of one of several doses or placebo, all doses achieved a rapid onset of action (five minutes), short treatment time (two minutes), and a robust magnitude of bronchodilation compared to placebo. The bronchodilatory improvements as assessed by forced expiratory volume in one second (FEV1), a standard measure of lung function, 24 hours after dosing was dose-dependent, statistically significant ($p < 0.001$) at all doses compared to placebo, and clinically meaningful at several doses compared to placebo. Favorable efficacy trends were also seen in a number of other endpoints including sustained improvements in FEV1 over the entire 24-hour period, demonstrating the potential for once-daily dosing. Throughout the study period, EP-101 was well tolerated at all doses with a comparable safety profile to placebo.

“The positive results from this single dose Phase 2a study and the patients’ positive experience with the Investigational eFlow device support further development of EP-101 for the unmet need in COPD patients,” said Dr. Ahmet Tutuncu, Senior Vice President and Chief Medical Officer of Elevation Pharmaceuticals.

COPD patients who cannot effectively operate or benefit from a dry powder or metered dose inhaler are prescribed nebulized medicines. These patients with more severe COPD can receive a full dose with a nebulizer, regardless of disease state, because all that is required is tidal (normal) breathing. However, medicines currently available for nebulization require 2-4 doses per day and long treatment times (10-15 minutes per dose) using conventional table top jet nebulizers, often leading to poor compliance and thus clinical outcomes. Additionally, LAMAs are considered first-line therapy for moderate-to-severe COPD, but no formulation of a LAMA is available for nebulization.

EP-101 can be the first LAMA approved for a nebulizer, and it is being developed in combination with an Investigational eFlow device – a portable nebulizer providing short treatment times – significantly improving the standard of care for the large underserved subpopulation of COPD patients not adequately treated by conventional inhalers or nebulizers.

"We are very encouraged by the outcomes of this study in COPD," said Bill Gerhart, President and CEO at Elevation. "These positive results bring us closer to achieving our goal of validating a new standard of care for COPD that significantly improves patient compliance and clinical outcomes."

Based on the positive results of this Phase 2a study, Elevation drew down a \$17 million second tranche of its Series A financing and has initiated a Phase 2b study of EP-101 for which top-line results are projected to be available by the end of the first quarter of 2012. All the original participants in the Series A financing participated in the \$17 million second tranche -- Canaan Partners, Care Capital, TPG Biotech, and Mesa Verde Venture Partners.

The Phase 2b study, GOLDEN-1 (Glycopyrrolate for Obstructive Lung Disease via Electronic Nebulizer), is a randomized, double-blind, placebo-controlled, multi-center, seven arm, four-period cross-over, incomplete block, 7-day dosing study to assess the dose-response, safety, and efficacy of EP-101 in subjects with moderate to severe COPD.

The ERS annual meeting is taking place September 24-28 in the Amsterdam Convention Center in the Netherlands. Information regarding the ERS presentation is below and a full abstract [here](#).

Poster Title: Efficacy and safety of nebulized glycopyrrolate (EP-101) for administration using high efficiency nebulizer in patients with COPD. D. Singh, B. Leaker, A. Tutuncu.

Abstract Number: P869, Session: 96, Sept 25, 12:50 – 14:40, Amsterdam Convention Center

About COPD

COPD is a slow progressive disease comprising chronic bronchitis and emphysema caused largely by smoking. Despite anti-smoking campaigns, COPD is the fastest growing major disease in the U.S. and around the world. COPD is now the third leading cause of death in the U.S. and is expected to be the third leading cause in the world by 2020. The disease is largely managed with inhaled bronchodilators and corticosteroids to improve lung function and reduce the frequency of exacerbations. Longer-acting agents and combinations have proven successful for treating many COPD patients, but the sicker and older segment of the COPD population (15-20%) who require nebulizer therapy are limited to shorter-acting agents and long treatment times resulting in reduced compliance and outcomes.

About Elevation Pharmaceuticals

Elevation Pharmaceuticals is a biopharmaceutical company focused on developing new inhaled therapies for patients with respiratory disease. The Company's initial focus is on developing novel therapies for the underserved subpopulation of COPD patients not able to effectively control their disease with dry powder or metered dose inhalers. Elevation's lead drug candidate is EP-101, an inhalation solution formulation of glycopyrrolate, a long-acting muscarinic antagonist bronchodilator, in Phase 2 studies for the improved treatment of patients with severe COPD. Elevation is a privately held company headquartered in San Diego, California. For additional information, please visit www.elevationpharma.com

About eFlow® Technology and PARI Pharma

EP-101 is delivered by an investigational eFlow® Nebulizer System developed by PARI Pharma and optimized specifically for EP-101. The optimized, investigational eFlow Nebulizer System uses eFlow Technology to enable highly efficient aerosolization of medication including liquid formulations via a vibrating, perforated membrane that includes thousands of laser drilled holes. Compared to other nebulization technologies, eFlow Technology produces aerosols with a very high density of active drug, a precisely defined droplet size, and a high proportion of respirable droplets delivered in the shortest possible period of time. eFlow® Technology is not an ultrasonic nebulizer technology, and it is not a general purpose electronic aerosol generator nebulizer technology. Combined with its quiet mode of operation, small size, light weight, and battery use, eFlow Technology reduces the burden of taking daily, inhaled treatments. PARI Pharma focuses on the development of aerosol delivery devices and comprehensive inhalation drug development to advance aerosol therapies where drug and device can be optimized together. For additional information, please visit www.paripharma.com.

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