



## **Pulmatrix Presents Top Line Clinical Data Showing Inhaled Drug Candidate, PUR118, Demonstrated Anti-Inflammatory Efficacy In Phase 1b Trial with COPD Patients**

*Clinical Results from Lead Product Candidate Created from Pulmatrix's Proprietary iSPERSE™ Inhaled Therapeutics Platform*

*Three Presentations at European Respiratory Society Highlight Data Related to PUR118*

Lexington, MA – September 4, 2012 – [Pulmatrix](#), Inc., a clinical stage biotechnology company creating novel inhaled therapeutics, today announced top line results from a clinical study showing that the novel inhaled therapeutic, PUR118, demonstrated anti-inflammatory efficacy and was well-tolerated in two Phase 1b studies in patients with chronic obstructive pulmonary disease (COPD). These results, that showed PUR118's beneficial impact on biomarkers of airway inflammation and mucus clearance, are the first clinical efficacy results from PUR118 which is the company's lead iCALM™ inhaled therapeutic candidate created from the iSPERSE™ dry powder delivery platform. Design aspects of these clinical trials, along with supporting and related preclinical data, were presented at the European Respiratory Society (ERS) Annual Congress on Monday, September 3, 2012, in Vienna, Austria.

"These clinical data clearly validate the potential for PUR118 to control COPD patients' symptoms and significantly improve their lung function, while also showing PUR118 to be well tolerated," said John Hanrahan, MD, MPH, Chief Medical Officer and Senior Vice President at Pulmatrix. "Based on the strength of these initial efficacy signals, we intend to now move forward into a Phase 2 trial of PUR118 in COPD patients, accelerating this clinical program with a goal of more rapidly bringing this unique treatment approach to patients with inflammatory airway conditions and the physicians who care for them."

The presentations at ERS highlight PUR118's potential to offer a new inhaled approach for control of airway inflammation in COPD and other respiratory conditions. PUR118 clinical and preclinical data highlights include:

- A Phase 1b clinical trial that showed PUR118 was well tolerated in both healthy volunteers and patients with COPD;
- Exploratory endpoints in the Phase 1b clinical study that assess biomarkers of inflammation and mucus clearance support a favorable impact of PUR118 treatment on both airway inflammation and mucociliary airway clearance velocity;
- Phase 1b clinical data demonstrated reduction in the levels of the same critical airway inflammatory signaling molecules/biomarkers evident in preclinical models, and confirmed preclinical data on the ability of PUR118 and iCALM therapies to reduce airway neutrophilic inflammation, as reported in previous studies and those presented at ERS;

- Preclinical data from PUR118 and related iCALM studies presented at ERS demonstrated robust and consistent airway anti-inflammatory impact in animal models of a number of chronic diseases. Highlights from these preclinical studies included:
  - PUR118 reduced tobacco smoke induced chemokine and cytokine protein levels associated with neutrophilic inflammation in mouse BAL samples, suggesting that its anti-inflammatory efficacy is comparable to other clinical stage targets (p38 / PDE4) with demonstrated clinical efficacy;
  - PUR118 reduces TLR-induced chemokine and cytokine secretion and gene expression in macrophages, suggesting that the *in vivo* activity of PUR118 and other iCALM therapeutics is at least partially mediated through activity on macrophages.
- PUR118 was clinically evaluated in an innovative Phase 1 clinical study, and the design and implementation of the Phase 1 study were jointly presented by Pulmatrix and Quotient Clinical in a poster at ERS.

### **About the Phase 1 Trial Design for PUR118**

The clinical development program for PUR118 comprises a Phase 1 trial structured into a four-part, dose-ranging clinical study protocol, first in healthy normal volunteers and then patients with COPD. Part 1 of this clinical study was a randomized, placebo controlled, single ascending dose, 4-way crossover tolerability/safety study in 12 healthy male and female subjects aged 18 to 65. Part 2 was a randomized, double-blind (2 active, 1 placebo), placebo-controlled, multiple-dose group, 14 day dose escalation design in 24 healthy male and female subjects age 18 to 65. Part 3 was an open-label, parallel group design in 36 male and female subjects aged 45 to 70 years, with mild (GOLD stage 1-2), stable COPD. Part 4 was an open-label, single dose, 4 way crossover design in male and female ex-smoking subjects age 45-70, with mild (GOLD stage 0-2), stable COPD. In each part of this four-part Phase 1 trial, tolerability and safety of PUR118 was assessed at each dose level. Additionally, the effect of PUR118 on mucociliary airway clearance velocity over the 2 hours after dosing was evaluated along with exploratory and relevant biomarkers for efficacy.

### **About PUR118**

PUR118 is the lead iCALM product candidate from Pulmatrix's proprietary iSPERSE dry powder delivery platform. PUR118's novel mechanism of action as an iCALM therapeutic is designed to harness the body's natural defenses to prevent and treat chronic respiratory diseases and respiratory infections in diseases such as chronic obstructive pulmonary disease (COPD) and cystic fibrosis. Clinical and preclinical data with PUR118 have demonstrated the ability to treat and prevent disease, in both viral and bacterial diseases, as well as reduced inflammation in the lung. PUR118 is in human clinical efficacy studies for COPD and cystic fibrosis.

### **About Pulmatrix**

[Pulmatrix](#), Inc. is a [clinical stage](#) biotechnology company developing and commercializing a novel inhaled dry powder drug platform to create a new generation of inhaled therapeutics. The platform, called iSPERSE™ (inhaled small particles easily respirable and emitted), enables drugs to be delivered in

inhaled dry powders with unique properties for high drug loading and highly efficient dispersibility and delivery to the airways. iSPERSE can create dry powder formulations with virtually any drug substance, including small molecules, biologics and multi-drug combinations, as well as the company's proprietary iCALM™ (inhaled Cationic Airway Lining Modulators) inhaled therapies. The Company is pursuing both proprietary and partnered applications for iCALM and iSPERSE. For additional information about Pulmatrix, please visit [www.pulmatrix.com](http://www.pulmatrix.com).

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