

## **Pulmatrix and Quotient announce completion of innovative COPD proof-of-concept clinical program**

### **Presentation at ERS 2012 international conference**

**September 4, 2012** – Pulmatrix, a clinical stage biotechnology company creating novel inhaled therapeutics, and Quotient Clinical, a leading provider of specialist early stage drug development services, today announced the completion of an early clinical program to achieve proof-of-concept data in COPD patients for PUR118, Pulmatrix's lead iCALM™ (inhaled dry powder cationic airway lining modulator) therapeutic. The design and preliminary results from this program were presented at the European Respiratory Society (ERS) 2012 conference in Vienna, Austria.

The clinical program was based upon a single, innovative and flexible clinical design to enable timeline acceleration from clinical entry into initial safety and tolerability evaluation in healthy volunteers, through to pharmacodynamic/efficacy data in mild-moderate COPD patients (GOLD Stages 0 – 2). Positive proof-of-concept data was achieved in less than nine months, compared to conventional timelines that can typically stretch to more than two years.

Mark Egerton, Managing Director, Quotient Clinical said: "Our work with Pulmatrix has evolved into a landmark case study to illustrate how early development processes and timelines can be expedited. This single, four part protocol seamlessly integrated healthy volunteer and COPD patient investigations by building in flexibility, enabling the project team to rapidly respond to emerging safety and PD data. In addition, an adaptive biomarker strategy encompassing a range of anti-inflammatory, respiratory and imaging biomarkers was utilized. We are now using this as a model for designing early exploratory and development programs."

"This innovative, flexible, and adaptive clinical design implemented by Quotient allowed dose-ranging safety and efficacy data to be compiled and understood in a timeframe that was markedly faster than is typical of early-phase clinical drug development. This permitted the potential of our lead iCALM drug candidate, PUR118, to be appreciated much earlier and in greater depth than a conventional path could accommodate," said John Hanrahan, MD MPH, Chief Medical Officer and Senior Vice President at Pulmatrix.

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### **About Quotient Clinical**

Quotient Clinical, part of Quotient Bioresearch, "Quotient", has over 20 years' experience delivering high quality data to provide innovative early drug development solutions to pharmaceutical and biotechnology clients worldwide, including 17 of the top 20 pharmaceutical companies. Our expertise in Exploratory Clinical Pharmacology, Drug Product Optimisation, and <sup>14</sup>C Enabled Drug Development, underpinned by our unique Translational Pharmaceutics™ and Synthesis-to-Clinic™ delivery platforms, adds significant value to client development programs.

For further information, visit [www.quotientbioresearch.com/clinical](http://www.quotientbioresearch.com/clinical) or email [clinical@quotientbioresearch.com](mailto:clinical@quotientbioresearch.com)

### **About Quotient Bioresearch**

Quotient Bioresearch is a leading provider of early stage and specialist drug development services to life science clients worldwide. We provide tailored solutions for pharmaceutical, biotechnology and agrochemical clients, using state-of-the-art technologies underpinned by unparalleled medical, chemical and biological expertise. Our consultative, science-driven approach ensures the highest quality service to support and accelerate new product development. Our extensive range of capabilities spans Chemistry and Metabolism, Bioanalytical Sciences, and Clinical. These can be provided independently or integrated into bespoke work programmes.

For additional information or to discuss your specific needs, contact us on [info@quotientbioresearch.com](mailto:info@quotientbioresearch.com) or visit [www.quotientbioresearch.com](http://www.quotientbioresearch.com)

### **About Pulmatrix**

[Pulmatrix](http://www.pulmatrix.com), 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. Pulmatrix's lead iCALM drug candidate, PUR118, is in human clinical efficacy studies in chronic obstructive pulmonary disease (COPD) and cystic fibrosis. 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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