



Pulmatrix Presents Data on iSPERSE for Inhaled Combination Drug Therapies, Including Triple Drug Combinations

Preclinical Data Presented at 11th US-Japan Symposium on Drug Delivery Systems

Lexington, Mass., December 19, 2011 -- [Pulmatrix](#), a clinical stage biotechnology company discovering and developing a new class of therapies for the prevention, treatment and control of respiratory diseases, today announced that its [iSPERSE™](#) inhaled drug platform demonstrated multi-drug delivery capability and superiority over conventional lactose blending for an effective therapeutic dose of the active ingredients in Advair®, salmeterol and fluticasone, as well as an additional anticholinergic bronchodilator. These preclinical data highlight the capability of iSPERSE, a proprietary salt formulation inhaled as a dry powder, to efficiently deliver consistent double- and triple-combination drug doses across a broad range of flow rates, which offers the potential of improved drug efficacy and safety for patients having both normal and lower or impaired lung function. These results were presented in a poster entitled “Pulmonary Delivery of Combination Drug Products via a Novel Dry Powder Delivery Technology” at the 11th US-Japan Symposium on Drug Delivery Systems on December 15-20, 2011, in Lahaina, Hawaii.

“iSPERSE shows tremendous promise as a superior platform for the pulmonary delivery of a broad range of therapies, including small and large drug molecules as well as multi-drug combination formulations, and therefore opens the potential for improved patient outcomes,” said Robert Langer, Professor of Chemical and Biomedical Engineering at the Massachusetts Institute of Technology, a founder of Pulmatrix and a member of Pulmatrix’s Scientific Advisory Board. “The possibility of increased drug payload and higher delivery efficiency with flow rate independence offers advantages that other dry powder platforms do not have.”

In the *in vitro* and preclinical studies, an iSPERSE fluticasone and salmeterol combination was matched to commercially available Advair Diskus®, which contains the fluticasone and salmeterol combination blended with lactose to enable pulmonary delivery. A triple iSPERSE combination of Advair components and an additional anticholinergic bronchodilator was also demonstrated. Highlights from these data include:

- iSPERSE demonstrated improved delivery efficiency over Advair Diskus, as iSPERSE was shown to deliver over 2 times more lung dose of the active pharmaceutical ingredients than Advair Diskus. This improved delivery efficiency may offer two primary benefits: reduced off-target drug exposure and oral deposition which potentially could reduce side effects such as thrush (oral candida) and other infections and reduced nominal dose (dose sparing) which lowers cost of goods.

- iSPERSE showed flow rate independent performance in terms of dose and particle size distribution which could enable iSPERSE applicability across a broad range of patient populations, expanding applications beyond patients with normal lung function to also include those having lower or impaired lung function, including pediatric, elderly, and those with compromised lung function. iSPERSE behaved flow rate independently at flow rates of 28.3 and 60.0 LPM, maintaining a similar fine particle fraction when tested via actuation from a capsule-based passive dry powder inhaler.
- The iSPERSE particle size distribution that would reach the lungs is consistent with an Advair Diskus particle size distribution (MMAD between 3.1 and 3.2 μm for iSPERSE comparable to 3.0 μm for Advair Diskus).
- iSPERSE showed excellent agreement in size distribution for both drugs (fluticasone and salmeterol) and, even with the addition of a third drug, iSPERSE was able to maintain comparable size distribution, flow rate independence and other powder properties desirable for inhaled delivery.
- Consistent delivery of dual and triple combination components was achieved, with all components of iSPERSE in both dual and triple combinations retaining expected *in vivo* activity, as demonstrated by reduced lung inflammation and airway hyper-responsiveness in a murine model of allergic asthma (ovalbumin (OVA) model).

“iSPERSE offers a dramatic advancement in dry powder inhaled drug delivery technology for both new drugs and branded generics, solving delivery problems other first and second generation dry powder technologies cannot,” said David Edwards, Professor of Biomedical Engineering at Harvard University, a founder of Pulmatrix and a member of both Pulmatrix’s Board of Directors and Scientific Advisory Board. “With combination drug capability coupled with dose reproducibility and optimal therapeutic profiles, iSPERSE can enable powerful new treatment options for a range of serious infectious and progressive respiratory diseases.”

Pulmatrix is now advancing a number of proprietary iSPERSE drug formulation candidates including small molecules, combinations and biologics in a variety of therapeutic areas, including chronic obstructive pulmonary disease (COPD), cystic fibrosis, asthma, idiopathic pulmonary fibrosis (IPF) and non-CF bronchiectasis, as well as pursuing partnerships for iSPERSE.

About iSPERSE

[iSPERSE](#) is a novel inhaled dry powder delivery platform developed by Pulmatrix for use in the delivery of drugs via inhalation for local or systemic applications. iSPERSE uses a delivery matrix containing proprietary cationic salt formulations to create a robust and flexible platform that can accommodate low or high drug loads in highly dispersible particles, yielding drug delivery capabilities not feasible with conventional dry powder technologies that rely on the use of lactose blending or low-density particles. The properties of iSPERSE have meaningful therapeutic and patient benefits, including the potential for single formulations with multiple drugs, effective inhaled drug delivery to patients with normal or impaired lung function, and the use of simple and convenient inhaler devices. iSPERSE offers the potential of a strong safety profile, as, in addition to drug and drug molecules, iSPERSE dry powders comprise exclusively generally regarded as safe (GRAS) salts and small quantities of additional, safe excipients if

needed. iSPERSE powders are made via a straightforward, proven one-step spray-drying process capable of high and consistent yields.

About Pulmatrix

[Pulmatrix](#), Inc. is a [clinical stage](#) biotechnology company discovering and developing a new class of therapies for the prevention, treatment and control of respiratory diseases. Pulmatrix's lead proprietary therapies, called inhaled cationic airway lining modulators ([iCALM™](#)), are a novel approach to prevent and treat acute exacerbations and improve lung function in patients with chronic respiratory diseases. [iCALM](#) therapies have broad potential to treat and prevent a wide range of respiratory diseases, including respiratory infections such as influenza; ventilator associated pneumonia (VAP) and respiratory syncytial virus (RSV), as well as progressive or chronic respiratory diseases such as COPD, asthma, and cystic fibrosis. For additional information about the Company, please visit <http://www.pulmatrix.com>.

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For more information, please contact:

Kathryn Morris

The Yates Network

kathryn@theyatesnetwork.com

845-635-9828