Pulmatrix Drug Candidate Receives "Qualified Infectious Disease Product" (QIDP) Designation from the FDA

The FDA designation adds five years of market exclusivity for Pulmatrix' inhaled product for treating fungal infections in the lungs of CF patients

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LEXINGTON, Mass., Jan. 17, 2017 /PRNewswire/ -- Pulmatrix, Inc. (NASDAQ: PULM), a clinical stage biopharmaceutical company developing innovative inhaled therapies to address serious pulmonary diseases, today announced that its drug candidate for treating fungal infections in the lungs of CF patients, PUR1900, has been designated as a "Qualified Infectious Disease Product" (QIDP) by the U.S. Food & Drug Administration.

Under the QIDP program, which is designed to speed the development of novel drugs against important pathogens, Pulmatrix will receive five years of additional market exclusivity for PUR1900.

In its letter to Pulmatrix, the FDA wrote: "We have reviewed your request and conclude that it meets the criteria for QIDP. Therefore we are designating your Itraconazole Inhalation Powder (PUR1900) product for inhalation use as a QIDP for….treatment of pulmonary *Aspergillus* infections in patients with cystic fibrosis."

"The new QIDP designation is a significant boost to our efforts to make this drug available as quickly as possible to cystic fibrosis (CF) patients suffering from fungal lung infections," said Pulmatrix CEO Robert Clarke, PhD. "It will give us the benefit of an expedited regulatory review. Added to our existing FDA Orphan drug designation for PUR1900, it will give us a full 12 years of market exclusivity."

Currently, many CF patients experience allergic reactions when their lungs become infected with a fungus called *Aspergillus*. Doctors now try to treat those infections with oral drugs such as itraconazole. Oral antifungals require very high doses to get enough of the drug to the lungs through the bloodstream to fight the fungus, causing severe side effects, and oral antifungals are not always effective.

Pulmatrix's goal is to solve this problem by combining itraconazole with its innovative dry powder iSPERSE™ technology. The combination of iSPERSE™ and itraconazole makes it possible for patients to

inhale the drug into their lungs, to the site of infection, where it's needed.

"By delivering the drug directly to the lungs, we should be able to fight the infection far more effectively than the oral drug can, with far fewer side effects," explained Pulmatrix's Chief Scientific Officer, David L. Hava, PhD. "That should bring great benefits to patients."

About Pulmatrix

Pulmatrix is a clinical stage biopharmaceutical company developing innovative inhaled therapies to address serious pulmonary disease using its patented iSPERSE™ technology. The Company's proprietary product pipeline is focused on advancing treatments for lung diseases, including opportunities in major pulmonary diseases through collaborations, like PUR0200, a branded generic in clinical development for chronic obstructive pulmonary disease (COPD) and PUR1900, an inhaled antifungal that could benefit severe asthmatics and patients with rare disease like cystic fibrosis. Pulmatrix's product candidates are based on iSPERSE™ , its proprietary dry powder delivery platform, which seeks to improve therapeutic delivery to the lungs by maximizing local concentrations and reducing systemic side effects to improve patient outcomes.

FORWARD-LOOKING STATEMENTS

Certain statements in this press release that are forward-looking and not statements of historical fact are forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. The Company cautions that such statements involve risks and uncertainties that may materially affect the Company's results of operations. Such forward-looking statements are based on the beliefs of management as well as assumptions made by and information currently available to management. Actual results could differ materially from those contemplated by the forward-looking statements as a result of certain factors, including but not limited to the ability to establish that potential products are efficacious or safe in preclinical or clinical trials; the ability to establish or maintain collaborations on the development of therapeutic candidates; the ability to obtain appropriate or necessary governmental approvals to market potential products; the ability to obtain future funding for developmental products and working capital and to obtain such funding on commercially reasonable terms; the Company's ability to manufacture product candidates on a commercial scale or in collaborations with third parties; changes in the size and nature of competitors; the ability to retain key executives and scientists; and the ability to secure and enforce legal rights related to the Company's products, including patent protection. A discussion of these and other factors, including risks and uncertainties with respect to the Company, is set forth in the Company's annual report on Form 10-K filed by the Company with the Securities and Exchange Commission on March 10, 2016. The Company disclaims any intention or obligation to revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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