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Pulmatrix and Mylan Enter Into ex-U.S. Development Agreement for PUR0200

LEXINGTON, Mass. and HERTFORDSHIRE, England and PITTSBURGH, June 16, 2015 /PRNewswire/ -- Pulmatrix, a clinical stage biopharmaceutical company developing innovative inhaled therapies for serious pulmonary diseases, today announced that it has entered into an ex-U.S. development agreement with Mylan N.V. (Nasdaq: MYL), one of the world's leading global pharmaceutical companies. The agreement is for PUR0200, a clinical stage bronchodilator therapy being studied for chronic obstructive pulmonary disease (COPD) and the first small molecule formulation from the company's novel iSPERSE™ inhaled dry powder technology. PUR0200 is under development as a once-daily therapy in a capsule-based dry powder inhaler (DPI).

PUR0200 contains a long-acting muscarinic agent (LAMA) being studied for the treatment of COPD and current clinical development is focused on pharmacokinetic bioequivalence in Europe. According to IMS Health, global sales of LAMA monotherapies for COPD are approximately $5 billion for the 12 months ending Dec. 31, 2014 with $1.5 billion in sales outside the U.S. Continued development work under the agreement will initiate in 2015.

Robert Clarke, CEO of Pulmatrix, said: "Our agreement with Mylan for the development of PUR0200 is a major step for Pulmatrix and the continued development of our iSPERSE technology. At the current stage of development of PUR0200 and goals of the program, Mylan is the ideal partner to bring this product forward for COPD patients."

Mylan President Rajiv Malik said: "Mylan is excited to partner with Pulmatrix on this potential generic LAMA DPI opportunity. This collaboration demonstrates our continued commitment to building our global respiratory pipeline, a key strategic growth driver for the company."

Under the terms of the agreement, Pulmatrix will lead the development work and pharmacokinetic clinical study with collaborative support from Mylan. Mylan has retained an option for PUR0200 ex-U.S. based on successful completion of the clinical study. Financial terms of the agreement are confidential.

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 rare diseases, including PUR1900, a, inhaled anti-fungal for patients with cystic fibrosis (CF) as well as PUR1500, an inhaled product for the treatment of idiopathic pulmonary fibrosis. In addition, Pulmatrix is pursuing opportunities in major pulmonary diseases through collaboration with partners. This includes PUR0200, a branded generic in clinical development for chronic obstructive pulmonary disease (COPD), and other potential first-in-class treatments. 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.

Pulmatrix 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. Pulmatrix cautions that such statements involve risks and uncertainties that may materially affect Pulmatrix'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 obtain appropriate or necessary governmental approvals to market potential products; the ability to obtain future funding for developmental products and working capital; and the ability to secure and enforce legal rights related to the companies' products, including patent protection. A discussion of these and other factors, including risks and uncertainties with respect to Pulmatrix, is set forth in the registration statement on Form S-4 filed by Pulmatrix on April 15, 2015, as amended. Pulmatrix 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.

About Mylan
Mylan is a global pharmaceutical company committed to setting new standards in healthcare. Working together around the world to provide 7 billion people access to high quality medicine, we innovate to satisfy unmet needs; make reliability and service excellence a habit; do what's right, not what's easy; and impact the future through passionate global leadership. We offer a growing portfolio of around 1,400 generic pharmaceuticals and several brand medications. In addition, we offer a wide range of antiretroviral therapies, upon which approximately 40% of HIV/AIDS patients in developing countries depend. We also

operate one of the largest active pharmaceutical ingredient manufacturers and currently market products in about 145 countries and territories. Our workforce of approximately 30,000 people is dedicated to creating better health for a better world, one person at a time. Learn more at mylan.com

This press release includes statements that constitute "forward-looking statements," including with regard to sales of products; product development, studies and potential; product markets; and the company's strategy, future growth and performance. These statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Because such statements inherently involve risks and uncertainties, actual future results may differ materially from those expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to: the impacts of competition; changes in economic and financial conditions of the company's business; strategies by competitors or other third parties to delay or prevent product introductions; risks inherent in product development and legal and regulatory processes; risks associated with international operations; changes in third party relationships; uncertainties and matters beyond the control of management; and the other risks detailed in the company's filings with the Securities and Exchange Commission. The company undertakes no obligation to update these statements for revisions or changes after the date of this release.

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/pulmatrix-and-mylan-enter-into-ex-us-development-agreement-for-pur0200-300099588.html

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