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Mylan Announces CE Mark for MyT4™ Point-of-Care CD4 Diagnostic Test

PITTSBURGH, Jan. 9, 2014 /PRNewswire/ -- Mylan, Inc. (Nasdaq: MYL) today announced that Zyomyx's MyT4™ point-of-care CD4 diagnostic test has received the CE Certificate of Conformity in the European Union, an important step toward launching this innovative test and expanding access to affordable, accessible and reliable diagnostics for people living with HIV globally. As a result, the MyT4™ CD4 test can now bear the CE Mark, which demonstrates that the MyT4™ CD4 test complies with stringent requirements related to the quality, safety, and performance of in vitro medical devices found in the applicable EU laws. Mylan and Zyomyx, the manufacturer of MyT4™, announced in July 2013 their exclusive distribution agreement for the test in developing countries.

Mylan CEO Heather Bresch commented, "Mylan is proud to continue its commitment to setting new standards in health care by collaborating with Zyomyx on their MyT4™ test. The CE Mark for the MyT4™ test testifies to the exacting quality, safety and performance of this important diagnostic tool and we look forward to begin distributing it in the coming months."

According to the Joint United Nations Programme on HIV/AIDS, more than 28 million people living with HIV are in need of antiretroviral therapy treatment. Measuring a person's CD4 count provides an indication of the virus' impact on their immune system, and is a critical tool in staging and monitoring HIV patients. Significant barriers to routine CD4 measurement exist in developing countries, primarily because diagnostic equipment is available only in centralized laboratory facilities. The durable construction and rapid time-to-result of the MyT4™ test allow for its use in decentralized settings, such as rural communities, mitigating barriers posed by the limited availability of existing diagnostic devices.

This press release includes statements that constitute "forward-looking statements," including with regard to regulatory matters. 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 impact and effects of legal or regulatory proceedings; 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.

Mylan is a global pharmaceutical company committed to setting new standards in health care. 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 more than 1,300 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 approximately 140 countries and territories. Our workforce of more than 20,000 people is dedicated to improving the customer experience and increasing pharmaceutical access to consumers around the world. But don't take our word for it. See for yourself. See inside. mylan.com

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