



## Mylan Extends Commitment to Fight HIV/AIDS by Partnering with Atomo Diagnostics to Expand Access to HIV Self-Testing in Low- and Middle-Income Countries

September 24, 2018

HERTFORDSHIRE, England and PITTSBURGH and SYDNEY, Sept. 24, 2018 /PRNewswire/ -- Global pharmaceutical company [Mylan N.V.](#) (NASDAQ: MYL) and medical device company Atomo Diagnostics today announced a strategic partnership to commercialize CE-Marked *in vitro* HIV rapid diagnostic tests for self-testing in low- and middle-income countries. The tests will allow individuals to confidently screen themselves in the privacy of their own homes with a device engineered for simplicity and accuracy. The tests are designed to detect the presence or absence of HIV antibodies in a single drop of blood obtained from a fingertip. Results are delivered in just 15 minutes, which is essential for access to early treatment and care.

A third of the 36.7 million people living with HIV are not aware of their status. While HIV testing rates have improved, many countries still face obstacles in expanding access to testing, such as patients being hard-to-reach or socially isolated due to stigma and discrimination. Deploying point-of-care self-tests in community-based settings that deliver prompt and accurate results is vital to increasing the proportion of people who know their HIV status. The sooner an individual is tested, the sooner counseling can be offered and prevention options or treatment can be initiated, which is critical to halting further transmission of the virus.

Mylan CEO Heather Bresch commented, "Today's announcement is another great example of our work to support the HIV/AIDS community, especially those living in low- and middle-income countries. I am proud of Mylan's efforts to fight HIV/AIDS around the world, which is part of our long-standing commitment to increase access to treatment to address some of the world's most significant public health issues. Today, 40% of all people living with HIV who are receiving treatment depend on antiretrovirals that we produce. But our work is far from over, with too many new infections each year and too many people not receiving the care they need. Our partnership with Atomo to supply HIV rapid diagnostic tests for self-testing is an important step in our collective goal of preventing HIV infections and expanding treatment."

Founder and CEO of Atomo Diagnostics John Kelly said, "We are delighted that our innovative HIV self-tests have been chosen by Mylan, the global health leader in HIV treatment and the largest supplier of ARVs. This strategic partnership will mean that the products designed by Atomo can be introduced to more than 100 countries, so that millions of people will have access to award-winning rapid tests. We believe that Mylan is the ideal partner to ensure that our HIV self-test products have maximum impact in the fight against HIV/AIDS."

While in some countries, like the U.S. and in Europe, HIV self-tests are readily available in pharmacies, HIV testing in low- and middle-income countries remains dependent on the diagnostic test being conducted in formal settings by trained professionals. Scaling up self-testing globally requires a simple and reliable product. Atomo is partnering with Mylan to supply all-in-one test devices that offer improved functionality and ease-of-use compared to current multi-component rapid diagnostic tests.

Atomo products are highly accurate. In laboratory and in-field evaluations, Atomo diagnostic tests demonstrated an aggregated 99.6% for sensitivity and specificity. Atomo HIV self-test products are CE-marked and are being evaluated by the World Health Organization for prequalification.

Under the terms of the agreement, Mylan has exclusive rights to commercialize the products in more than 100 countries in Africa, Asia, the Middle East, the Commonwealth of Independent States (CIS) and Latin America. Mylan plans to launch the *Mylan HIV Self-Test* in global markets in early 2019.

### **Mylan's Commitment to the HIV/AIDS Patient Community**

Mylan is the world's largest supplier by volume of HIV/AIDS therapies. More than 40% of the 20 million patients on treatment worldwide depend on a Mylan product every day. For more than a decade, Mylan has been a leader in providing access to quality, dependable and affordable ARVs in 100 countries around the world. This includes introducing in 2009 the first generic one-tablet-once-a-day combination for developing countries – only three years after the originator product launched in the U.S. Since that time, Mylan has been the first to market with nearly half of the new products tentatively approved by the FDA under PEPFAR. Mylan was also the first generic drug maker to develop a heat-stable version of a drug critical for second-line regimens and has consistently developed innovative pediatric formulations for children in developing countries. Mylan has long been a supporter of the patient community through the sponsorship of free community HIV/AIDS testing and clinical research. Learn more about Mylan's work with infectious disease [here](#). Watch [this video](#) to learn more about Mylan's commitment to people living with HIV/AIDS.

*This press release includes statements that constitute "forward-looking statements", including with regard to Mylan planning to launch the Mylan HIV Self-Test in global markets in early 2019. 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: success of clinical trials and our or our partners' ability to execute on new product opportunities; any regulatory, legal or other impediments to our or our partners' ability to bring products to market; other risks inherent in product development; the scope, timing, and outcome of any ongoing legal proceedings, including government investigations, and the impact of any such proceedings on our or our partners' businesses; actions and decisions of healthcare and pharmaceutical regulators, and changes in healthcare and pharmaceutical laws and regulations, in the United States and abroad; the impact of competition; strategies by competitors or other third parties to delay or prevent product introductions; the effect of any changes in our or our partners' customer and supplier relationships and customer purchasing patterns; any other changes in third-party relationships; changes in the economic and financial conditions of the businesses of Mylan or its partners; uncertainties and matters beyond the control of management; and the other risks detailed in Mylan's filings with the Securities and Exchange Commission. Mylan undertakes no obligation to update these statements for revisions or*

changes after the date of this release.

### **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 more than 7,500 marketed products around the world, including antiretroviral therapies on which more than 40% of people being treated for HIV/AIDS globally depend. We market our products in more than 165 countries and territories. We are one of the world's largest producers of active pharmaceutical ingredients. Every member of our approximately 35,000-strong workforce is dedicated to creating better health for a better world, one person at a time. Learn more at [Mylan.com](http://Mylan.com). We routinely post information that may be important to investors on our website at [investor.mylan.com](http://investor.mylan.com).

### **About Atomo Diagnostics**

Atomo Diagnostics is a world leader in medical device design and development, based in Sydney, Australia. The company specialises in pioneering rapid diagnostic test (RDT) solutions for use with capillary blood samples.

The recipient of multiple international awards for innovation, *AtomoRapid™* device platforms put the end user first and make it easy to test and screen for a range of infectious diseases and chronic conditions. Unlike standard, multi-component rapid test kits, Atomo's all-in-one platforms integrate features and functionality, incorporating a sterile safety lancet, calibrated blood collection system, and unique buffer delivery mechanism.

Atomo provides OEM product development services to specialist diagnostic companies worldwide, as well as commercialising products in its own brand. To find out more, visit <http://atomodiagnosics.com/oem/>



[View original content to download multimedia: http://www.prnewswire.com/news-releases/mylan-extends-commitment-to-fight-hiv-aids-by-partnering-with-atomo-diagnostics-to-expand-access-to-hiv-self-testing-in-low-and-middle-income-countries-300717198.html](http://www.prnewswire.com/news-releases/mylan-extends-commitment-to-fight-hiv-aids-by-partnering-with-atomo-diagnostics-to-expand-access-to-hiv-self-testing-in-low-and-middle-income-countries-300717198.html)

SOURCE Mylan N.V.

Mylan: Christine Waller (Media), 724.514.1968, Email: [communications@mylan.com](mailto:communications@mylan.com); Melissa Trombetta (Investors), 724.514.1813, Email: [InvestorRelations@mylan.com](mailto:InvestorRelations@mylan.com); Atomo Diagnostics: John Kelly, +61 (0)2 9099 4750, Email: [john.kelly@atomodiagnosics.com](mailto:john.kelly@atomodiagnosics.com)