



Mylan and Atomo Diagnostics Announce WHO Prequalification Approval for Mylan HIV Self Test

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HERTFORDSHIRE, England and PITTSBURGH and SYDNEY, July 8, 2019 /PRNewswire/ -- Global pharmaceutical company [Mylan N.V.](#) (NASDAQ: MYL) and medical device manufacturer Atomo Diagnostics today announced that the *Mylan HIV Self Test*, a handheld *in vitro* HIV rapid diagnostic test for self-testing, has received Prequalification approval by the World Health Organization (WHO PQ).

The WHO PQ process includes a rigorous evaluation of the test's technical performance and manufacturing sites. Prequalification signifies that the product meets global standards of quality, safety and performance and is a signal to global funders and Ministries of Health that the product can be procured. The *Mylan HIV Self Test* detects the presence or absence of HIV antibodies through a fingerstick. It uses one-fifth the volume of blood necessary for other tests and provides a result in just 15 minutes.

Linda-Gail Bekker, Executive Director of the Desmond Tutu HIV Foundation and a former president of the International AIDS Society, stated, "HIV self-testing can be a game-changer in helping us meet the ambitious UNAIDS 90-90-90 targets, which require that 90% of all HIV positive people know their status by 2020. Having more high-quality and user-friendly HIV self-tests on the market, like the *Mylan HIV Self Test* that has been Prequalified by the World Health Organization, will give us a powerful tool in expanding diagnosis and treatment of vulnerable and previously untested populations."

The convenience and discretion afforded by self-testing enables individuals to test in the comfort and privacy of their own home, making the test an effective way of reaching hard-to-reach populations. In September 2018, Mylan announced a partnership with Atomo Diagnostics, the manufacturer of the test, covering more than 100 countries across Africa, Asia, the Middle East, the Commonwealth of Independent States (CIS), and Latin America.

About WHO Prequalification (PQ)

WHO Prequalification (PQ) aims to ensure that diagnostics, medicines, vaccines, and immunization-related equipment and devices for high burden diseases meet global standards of quality, safety and efficacy, to optimize use of health resources and improve health outcomes.

The prequalification process consists of a transparent, scientifically sound assessment, which includes dossier review, consistency testing or performance evaluation, and site visits to manufacturers. This information, in conjunction with other procurement criteria, is used by UN and other procurement agencies, including PEPFAR and Global Fund, to make purchasing decisions regarding diagnostics, medicines and/or vaccines.

For more information, visit <https://www.who.int/topics/prequalification/en/>.

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](#). We routinely post information that may be important to investors on our website at [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 creating integrated rapid diagnostic test (RDT) platforms for blood-based testing. The recipient of multiple international awards for innovation, Atomo's all-in-one *AtomoRapid™* handheld devices make it easy to test and screen for a range of infectious diseases and chronic conditions. Unlike standard, multi-component rapid test kits, *AtomoRapid™* platforms integrate features and functionality, including built-in sterile safety lancets, calibrated blood collection systems, and unique buffer delivery mechanisms.

As well as commercialising products in its own brand, Atomo provides OEM product development services to specialist diagnostic companies worldwide.

To find out more, visit: <http://atomodiagnostics.com/>



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