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Mylan and Zyomyx Enter into Exclusive Distribution Agreement for Innovative Point-of-Care CD4 Diagnostic Test, Enhancing Mylan's Leadership Position in HIV Care

PITTSBURGH and FREMONT, Calif., June 30, 2013 /PRNewswire/ -- Mylan Inc. (Nasdaq: MYL) today announced that it has entered into an exclusive agreement with Zyomyx, Inc. for the rights to distribute Zyomyx's proprietary point-of-care (POC) CD4 T-cell count test in the developing world. CD4 count testing is a critical diagnostic component in treating HIV/AIDS, as medical professionals refer to a patient's CD4 count to determine when to begin and/or alter HIV treatment. As part of the agreement, Mylan also has made a strategic equity investment in Zyomyx.

The Zyomyx POC CD4 test is currently in final stages of development and expected to launch in the near-term, pending applicable regulatory approvals. Mylan expects to distribute the portable, easy-to-use, low-cost test in the developing world alongside its broad portfolio of high quality, affordable generic antiretroviral (ARV) drugs in order to improve access to and guide HIV/AIDS treatment in resource-limited settings.

To complement the exclusive agreement with Zyomyx, Mylan also announced that it has signed a Global Access Commitment with the Bill & Melinda Gates Foundation, an investor in Zyomyx. Mylan has committed to ensuring that the Zyomyx POC CD4 technology can be made available and accessible at a reasonable price in high burden HIV countries. Increasing access to affordable and effective health interventions for those in need is a priority for the foundation.

Mylan CEO Heather Bresch commented, "Mylan's mission is to set new standards in health care and provide the world's 7 billion people access to high quality medicine. We expect that this distribution agreement with Zyomyx and our collaboration with the Bill & Melinda Gates Foundation will be a true game changer in improving access to treatment of HIV in the developing world by enabling rapid, low-cost testing of patients in any location, however remote, thereby ensuring immediate enrollment on treatment. Further, this distribution agreement and investment represents Mylan's entry into diagnostics as we strive to meet the evolving needs of our customers and patients. It will transform Mylan from a leading provider of HIV treatments to a leading provider of HIV health care solutions, which will continue to differentiate Mylan in this important area."

Rajiv Malik, Mylan's president, added, "Zyomyx's CD4 test is a revolutionary technology that couldn't come at a better time. The World Health Organization's revised antiretroviral treatment guidelines increase the number of people living with HIV and eligible for treatment to close to 26 million, and pregnant women are now advised to start treatment as soon as they test positive. The more quickly patients can receive CD4 testing, the more quickly they can access life-saving medicine. Mylan's investment in Zyomyx is just one step in our efforts to support the goal of universal access to HIV/AIDS treatment."

Trevor Mundel, president of Global Health at the Bill & Melinda Gates Foundation, said, "HIV patients in the developing world have long faced considerable challenges accessing CD4 testing due to the poor availability of testing in rural areas, the challenges of travel to testing sites and the cost of the tests. Mylan's investment in Zyomyx and collaboration with the foundation will potentially greatly enhance access to testing and treatment in the developing world."

The Zyomyx CD4 count test, the first product developed using Zyomyx's breakthrough diagnostic platform, is easy-to-use and the fastest yet, providing results in less than 10 minutes with minimal training. The test is portable and disposable — small enough to fit into a back-pack and requiring no grounded electricity — making it ideal for use in developing markets and rural settings. Importantly, the test is highly accurate and has proven to be equivalent in accuracy to flow cytometry, the current gold standard in CD4 count testing.

Peter Wagner, president and CEO of Zyomyx, said, "As a diagnostics company, we are excited about the potential impact of this agreement with Mylan, a pharmaceutical company that has access to nearly every HIV/AIDS treatment clinic in Africa through its impressive distribution network. Together, we will be able to ensure that people living with HIV/AIDS in the highest burden countries receive both the testing and lifesaving treatment they need."

Mylan has been a leading global player in the HIV/AIDS arena for more than a decade and a leader in bringing to market innovations that enhance access to treatment, for instance producing fixed dose combinations, which provide a reduced pill burden and once-a-day dosage, and patient-convenient "combo" packs. Mylan also developed multiple FDA/WHO-approved heat-stable ARV products, which can be distributed and used in warm climates where refrigeration infrastructure is not widely available. In addition, Mylan has been a global leader in producing ARV formulations for pediatric use. Today, Mylan supplies high quality ARVs to more than 120 countries around the world and nearly 40% of HIV/AIDS patients receiving treatment in developing countries depend on one of the company's ARV products.

Under the terms of the distribution and supply agreement, Zyomyx will supply the POC CD4 test to Mylan, and Mylan will pay development and commercial milestones and a share of profits to Zyomyx for the exclusive rights to distribute the POC CD4 test in Africa; Asia (excluding Japan and South Korea but including (without limitation) Russia, Central Asia and the Middle East); CEE; CIS; South America and Central America (including Mexico); and the Caribbean Islands. Further, simultaneous with the execution of the distribution and supply agreement, Mylan made a strategic equity investment in Zyomyx and entered into an agreement with the Bill & Melinda Gates Foundation to provide improved and affordable CD4 testing access to patients in high burden HIV countries. All other terms of the agreements are confidential.

This press release includes statements that constitute "forward-looking statements," including with regard to the distribution and supply agreement. 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 of competition; failure to achieve anticipated sales; changes in economic and financial conditions of the company's business; uncertainties and matters beyond the control of management; and the other risks detailed in the company's periodic 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.

About Zyomyx

Zyomyx, Inc., a privately held diagnostics company based in Fremont, California, is an innovator in the development and commercialization of proprietary diagnostic platforms. The Zyomyx product development infrastructure and suite of proprietary assay and surface technologies are ideally suited for the development of affordable, disposable point-of-care diagnostic products, designed to increase access to testing. Zyomyx's immediate focus is an advanced but simple and inexpensive CD4 T-cell point-of-care test that will be launched globally and is configured to meet the needs of developing countries. For more information, visit <http://www.zyomyx.com>.

About Mylan

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 approximately 1,100 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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