January 26, 2015

Mylan Expands Hepatitis C Licensing Agreement with Gilead to Include Investigational Pan-Genotypic Agent

PITTSBURGH and HYDERABAD, India, Jan. 26, 2015 /PRNewswire/ -- Mylan Inc. (Nasdaq: MYL) today announced that its subsidiary Mylan Laboratories Limited is expanding its hepatitis C licensing agreement with Gilead Sciences, Inc. to include the non-exclusive rights to manufacture and distribute the investigational NS5A inhibitor GS-5816 and single tablet regimen of sofosbuvir(Sovaldi®)/GS-5816, once approved, in 91 developing countries. The single tablet regimen is being evaluated in Phase 3 clinical studies for the treatment of all six genotypes of hepatitis C.

If approved by regulatory authorities, the sofosbuvir/GS-5816 regimen would become the first all-oral single tablet regimen for all hepatitis C genotypes. A pan-genotypic therapeutic option is particularly important for developing countries, where genotype testing is often unreliable or not readily available.

Mylan President Rajiv Malik said, "We are proud to partner with Gilead, once again, in our joint effort to quickly expand access to high quality, affordable medications to the more than 100 million people living with hepatitis C in developing countries.[1] The potential to offer the sofosbuvir/GS-5816 regimen is particularly exciting, as it is an innovative compound that is being studied to treat all hepatitis C genotypes - a medical advancement that could significantly increase access to treatment."

This agreement is in addition to the licensing and technology transfer agreement that Mylan entered into with Gilead in September 2014, which grants Mylan the non-exclusive rights to manufacture and distribute sofosbuvir and ledipasvir/sofosbuvir in 91 developing countries. Mylan also partners with Gilead on expanding access to high quality, affordable antiretrovirals for the treatment of HIV/AIDS in India and other developing countries.

About GS-5816

The single tablet regimen of sofosbuvir/GS-5816 is an investigational agent and its safety and efficacy have not been established. Phase 3 studies evaluating the combination of GS-5816 and sofosbuvir are currently underway, with data anticipated in the second half of 2015.

About Sofosbuvir

Sofosbuvir was approved under the trade name Sovaldi® by the U.S. Food and Drug Administration (FDA) in December 2013 based on clinical studies that showed sofosbuvir, in combination with other agents, achieved very high cure rates with a course of treatment as short as 12 weeks depending on viral genotype. Sofosbuvir also was approved by the European Commission in January 2014 and is a recommended treatment option in the World Health Organization's first hepatitis C treatment guidelines (released in April 2014).

Private Securities Litigation Reform Act of 1995 -- A Caution Concerning Forward-Looking Statements

This press release includes statements that constitute "forward-looking statements," including with regard to product approvals and sales, 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 legal and regulatory processes; risks associated with international operations; 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 25,000 people is dedicated to improving the customer experience and increasing pharmaceutical access to consumers around the world. Learn more at mylan.com.

[1] World Health Organization. "Guidelines for the screening, care and treatment of persons with hepatitis C infection." April 2014.

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