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Mylan Signs Agreement with Gilead to Accelerate Access to Hepatitis C Treatments, Sovaldi® (Sofosbuvir) and Single Tablet Regimen of Ledipasvir/Sofosbuvir, in Developing Countries

PITTSBURGH and HYDERABAD, India, Sept. 15, 2014 /PRNewswire/ -- Mylan Inc. (Nasdaq: MYL) today announced that its subsidiary Mylan Laboratories Limited has entered into an agreement with Gilead Sciences, Inc. under which Mylan has been licensed the non-exclusive rights to manufacture and distribute sofosbuvir and the investigational single tablet regimen of ledipasvir/sofosbuvir in 91 developing countries. Sofosbuvir is marketed by Gilead under the brand name Sovaldi®.



The countries within the agreement account for more than 100 million people living with hepatitis C globally representing 54% of the total global infected population.¹

Mylan CEO Heather Bresch said, "Hepatitis C is a growing public health problem in developing countries, with Central and East Asia and North Africa among the regions most affected by this disease.² Unfortunately, patients in these regions often lack access to critical and effective treatments. This agreement with Gilead will allow Mylan to provide early access to a more affordable version of Sovaldi, helping to meet the unmet medical needs of the millions of patients in developing countries who do not currently have access to this life-saving medicine."

Under the licensing agreement, Mylan will receive a technology transfer enabling the company to manufacture low-cost versions of the medicines for developing markets.

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). The FDA and the European Medicines Agency are currently reviewing Gilead's applications for a single tablet regimen of ledipasvir/sofosbuvir; it is an investigational agent and its safety and efficacy have not been established.

This press release includes statements that constitute "forward-looking statements," including with regard to 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 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

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

² World Health Organization. "Hepatitis C - Key Facts." <http://www.who.int/mediacentre/factsheets/fs164/en/>. Accessed on Sept. 4, 2014.

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