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Mylan Launches Generic Harvoni® (Ledipasvir/Sofosbuvir) Under the Brand Name MyHep LVIR™ in India

HERTFORDSHIRE, England and BANGALORE, India and PITTSBURGH, Jan. 7, 2016 /PRNewswire/ -- Mylan N.V. (NASDAQ, TASE: MYL) today announced that its subsidiary, Mylan Pharmaceuticals Private Limited, has launched generic Harvoni® (Ledipasvir 90 mg/Sofosbuvir 400 mg) tablets under the brand name MyHep LVIR™Â in India.



There are approximately 12 million people who are chronically infected with Hepatitis C in India and most do not know they are infected. The Ledipasvir/Sofosbuvir combination is indicated for the treatment of Hepatitis C infection and offers a simplified Hepatitis C treatment regimen that eliminates the need for interferon and ribavirin. The product also is a single-tablet regimen and requires a therapy course of just 12 weeks. Harvoni® has exhibited high cure rates and a tolerable side effect profile across a range of patient populations.

Mylan President Rajiv Malik said, "Mylan recognizes the urgent need to expand access to high quality, affordable Hepatitis C treatment options in India, where roughly 12 million people are infected with the virus. MyHep LVIR™ is an important addition to our growing Hepato Care segment in India that gives us the opportunity to offer patients the potential to be cured through a transformative and simplified single tablet, once-daily treatment regimen. Moreover, consistent with our commitment to create better health for a better world, we are introducing various educational initiatives in India to raise awareness of the disease and its treatment options."

The launch of MyHep LVIR™ follows the successful launch of generic Sofosbuvir in India under the brand name MyHep™ in April 2015. In September 2014, Mylan entered into a licensing and technology transfer agreement with Gilead granting Mylan the non-exclusive rights to manufacture and distribute generic Sofosbuvir and Ledipasvir/Sofosbuvir tablets in 101 developing countries, including India.

Mylan also entered into an agreement with Gilead in February 2015 as the exclusive distributor of Gilead's branded Sovaldi® (Sofosbuvir 400 mg) and Harvoni® tablets in India. Mylan launched Sovaldi® in India in May 2015. Â

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

MyHep LVIR™ is an important addition to Mylan's growing Hepato Care segment in India that gives Mylan the opportunity to offer patients the potential to be cured through a transformative and simplified single tablet, once-daily treatment regimen; and that consistent with Mylan's commitment to create better health for a better world, it is introducing various educational initiatives in India to raise awareness of the disease and its treatment options. 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: any changes in or difficulties with Mylan's ability to develop, manufacture, and commercialize Hepato Care products; the impact of competition and the use of legal, regulatory and legislative strategies by competitors or other third parties to delay or prevent our introduction of new products; changes in economic and financial conditions; changes in third party relationships; actions and decisions of healthcare and pharmaceutical regulators, and changes in healthcare and pharmaceutical laws and regulations, in the United States and abroad; risks associated with international operations; other 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 1,400 generic and branded pharmaceuticals, including antiretroviral therapies on which nearly 50% of people being treated for HIV/AIDS in the developing world depend. We market our products in approximately 165 countries and territories. Our global R&D and manufacturing platform includes more than 50 facilities, and we are one of the world's largest producers of active pharmaceutical ingredients. Every member of our more than 30,000-strong workforce is dedicated to creating better health for a better world, one person at a time. Learn more at mylan.com.

1. World Health Organization. Hepatitis C Surveillance and Control. http://www.who.int/csr/disease/hepatitis/whocdscsrlyo2003/en/index4.html. Accessed on December 25, 2015.

HARVONI and SOVALDI are trademarks of Gilead Sciences, Inc.

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