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Mylan Launches Generic Vidaza® Injection

HERTFORDSHIRE, England and PITTSBURGH, June 2, 2016 /PRNewswire/ -- Mylan N.V. (NASDAQ, TASE: MYL) today announced the U.S. launch of Azacitidine for Injection, 100 mg/vial, which is a generic version of Celgene's Vidaza® Injection, 100 mg/vial. Mylan received final approval from the U.S. Food and Drug Administration (FDA) for its Abbreviated New Drug Application (ANDA) for this product. Azacitidine for Injection is a nucleoside metabolic inhibitor indicated for the treatment of the five French-American-British (FAB) subtypes of myelodysplastic syndrome, a blood cell disorder that can occur as a result of cancer treatments or can progress to leukemia.

Azacitidine for Injection, 100 mg/vial, had U.S. sales of approximately $236.3 million for the 12 months ending March 31, 2016, according to IMS Health.

Mylan's launch of this product adds to the company's portfolio of more than 150 injectable products available to patients in the U.S. across a broad array of therapeutic categories. Azacitidine for Injection is also a part of a growing U.S. portfolio of more than 20 oncology medications that includes treatments for breast, lung, colorectal, ovarian and hematologic cancers.

Currently, Mylan has 254 ANDAs pending FDA approval representing $108.3 billion in annual brand sales, according to IMS Health. Forty-three of these pending ANDAs are potential first-to-file opportunities, representing $37.2 billion in annual brand sales, for the 12 months ending December 31, 2015, according to IMS Health.

This press release includes statements that constitute "forward-looking statements," including with regard to the statement that Mylan's launch of this product adds to the company's growing portfolio of more than 150 injectable products available to patients in the U.S. across a broad array of therapeutic categories and is part of a growing U.S. portfolio of more than 20 oncology medications. 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 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; 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.

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 approximately 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 nearly 35,000-strong workforce is dedicated to creating better health for a better world, one person at a time. Learn more at mylan.com.

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