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Mylan Launches Generic Precedex™ Injection Another Key Product Approval

PITTSBURGH, Aug. 19, 2014 /PRNewswire/ -- Mylan Inc. (Nasdaq: MYL) announced that its business Mylan Institutional has launched Dexmedetomidine Hydrochloride Injection, 100 mcg (base)/mL, packaged in 200 mcg (base)/2 mL Single-dose Vials, which is therapeutically equivalent to Hospira's Precedex™. Mylan yesterday received final approval from the U.S. Food and Drug Administration (FDA) for its Abbreviated New Drug Application (ANDA) for this product, which is indicated for the sedation of non-intubated patients prior to and/or during surgical and other procedures, and began shipping immediately.



Mylan CEO Heather Bresch commented: "Mylan's launch of a therapeutically equivalent version of Precedex Injection, another of a number of key approvals that had been pending with FDA, represents an important addition to Mylan's injectables portfolio and growing line of products in the anesthesia and pain management category. As we continue to bring a high quality, reliable supply of injectable products to the U.S. market, Mylan looks forward to delivering on its promise of providing quality medicine and service excellence in the increasingly important institutional space."

Dexmedetomidine Hydrochloride Injection, 100 mcg (base)/mL, packaged in 200 mcg (base)/2 mL Single-dose Vials, had U.S. sales of approximately \$156.2 million for the 12 months ending June 30, 2014, according to IMS Health.

Currently, Mylan has 295 ANDAs pending FDA approval representing \$105.8 billion in annual sales, according to IMS Health. Forty-three of these pending ANDAs are potential first-to-file opportunities, representing \$25.0 billion in annual brand sales, for the 12 months ending December 31, 2013, according to IMS Health.

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

This press release includes statements that constitute "forward-looking statements," including with regard to sales of products. 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: strategies by competitors or other third parties to delay or prevent product introductions; risks inherent in legal and regulatory processes; 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.

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