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Mylan Launches Generic Cerebyx® Injection

HERTFORDSHIRE, England and PITTSBURGH, Dec. 29, 2016 /PRNewswire/ -- Mylan N.V. (NASDAQ, TASE: MYL), today announced the U.S. launch of Fosphenytoin Sodium Injection USP, 75 mg/mL, (50 mg PE*/mL), packaged in 100 mg PE*/2 mL, and 500 mg PE*/10 mL single-use vials, a generic version of Pfizer's Cerebyx® Injection. Mylan received final approval from the U.S. Food and Drug Administration (FDA) for its Abbreviated New Drug Application (ANDA) for this product, for the treatment of certain types of severe seizures. (1)



Fosphenytoin Sodium Injection USP, 75 mg/mL, (50 mg PE*/mL), packaged in 100 mg PE*/2 mL, and 500 mg PE*/10 mL single-use vials had U.S. sales of approximately \$36.3 million for the 12 months ending October 31, 2016, according to IMS Health.

The product is part of Mylan's growing global portfolio of more than 450 injectable products, which includes liquid, lyophilized and dry-powder formulations delivered in a range of mechanisms including ampoules, vials, ready-to-use bags and pre-filled syringes. Mylan's global network of nine injectable facilities produces hundreds of millions of doses each year.

Currently, Mylan has more than 240 ANDAs pending FDA approval representing approximately \$95.6 billion in annual brand sales, according to IMS Health. Forty-one of these pending ANDAs are potential first-to-file opportunities, representing \$32.5 billion in annual brand sales, for the 12 months ending June 30, 2016, according to IMS Health.

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 2,700 generic and branded pharmaceuticals, including antiretroviral therapies on which approximately 50% of people being treated for HIV/AIDS worldwide depend. We market our products in more than 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 35,000-strong workforce is dedicated to creating better health for a better world, one person at a time. Learn more at mylan.com.

PE* = Phenytoin Sodium Equivalents

(1) Cardiovascular risk is associated with rapid infusion rates. The rate of intravenous Cerebyx® administration should not exceed 150 mg phenytoin sodium equivalents (PE) per minute because of the risk of severe hypotension and cardiac arrhythmias. Careful cardiac monitoring is needed during and after administering intravenous Cerebyx®. Although the risk of cardiovascular toxicity increases with infusion rates above the recommended infusion rate, these events have also been reported at or below the recommended infusion rate. Reduction in rate of administration or discontinuation of dosing may be needed

This press release includes statements that constitute "forward-looking statements," including with regard to the Company's injectables portfolio. 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 or its partners' ability to develop, manufacture, and commercialize products; any regulatory, legal, or other impediments to Mylan's or its partners' ability to

bring products to market; 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.

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