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Mylan Launches Generic Reclast® Injection

HERTFORDSHIRE, England and PITTSBURGH, June 2, 2017 /PRNewswire/ -- Mylan N.V. (NASDAQ, TASE: MYL) today announced the U.S. launch of Zoledronic Acid Injection, 5 mg/100 mL Single Dose Vial, a generic version of Novartis' Reclast® Injection. Mylan 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 treatment of Paget's disease of bone in men and women.



Zoledronic Acid Injection, 5 mg/100 mL Single Dose Vial, had U.S. sales of approximately \$22.1 million for the 12 months ending March 31, 2017, according to QuintilesIMS Health.

Currently, Mylan has 234 ANDAs pending FDA approval representing approximately \$104 billion in annual brand sales, according to QuintilesIMS Health. Forty-four of these pending ANDAs are potential first-to-file opportunities, representing \$42.3 billion in annual brand sales, for the 12 months ending December 31, 2016, according to QuintilesIMS Health. Currently, one out of every 13 prescriptions filled in the U.S. - brand-name or generic - is a Mylan product.

Mylan has one of the largest injectable portfolios in the industry, with more than 100 products available to patients in the U.S. across a broad array of therapeutic categories. Mylan's global injectables manufacturing capacity has grown from 11 million units in 2012 to 500 million units today.

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 approximately 7,500 marketed products around the world, including antiretroviral therapies on which approximately 50% of people being treated for HIV/AIDS in the developing world depend. We market our products in more than 165 countries and territories. 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 <u>mylan.com</u>.

To view the original version on PR Newswire, visit:<u>http://www.prnewswire.com/news-releases/mylan-launches-generic-reclast-injection-300467691.html</u>

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