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Mylan Launches Generic Clolar® for Injection

HERTFORDSHIRE, England and PITTSBURGH, Nov. 9, 2017 /PRNewswire/ -- Mylan N.V. (NASDAQ, TASE: MYL) today announced the U.S. launch of Clofarabine Injection, 20 mg/20 mL (1 mg/mL) Single-Dose Vials, a generic version of Genzyme's Clolar®. 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 pediatric patients 1 to 21 years old with relapsed or refractory acute lymphoblastic leukemia after at least two prior regimens.

Mylan is one of the largest suppliers of cancer medicines by volume in the U.S., with a robust oncology portfolio of more than 40 products.

Clofarabine Injection, 20 mg/20 mL (1 mg/mL) Single-Dose Vials had U.S. sales of approximately \$53 million for the 12 months ending September 30, 2017, according to IQVIA.

Currently, Mylan has 219 ANDAs pending FDA approval, representing approximately \$93.5 billion in annual brand sales. Forty-five of these pending ANDAs are potential first-to-file opportunities, representing \$42.1 billion in annual brand sales, for the 12 months ending August 31, 2017, according to IQVIA. Currently, one out of every 13 prescriptions filled in the U.S. - brand-name or generic - is a Mylan product.

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 7,500 marketed products around the world, including antiretroviral therapies on which more than 40% of people being treated for HIV/AIDS globally 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 Mylan.com. We routinely post information that may be important to investors on our website at investor.mylan.com.



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