Mylan Initiates Voluntary Nationwide Recall of Select Lots of Injectable Products Due to the Presence of Particulate Matter

April 23, 2015

POTTERS BAR, England, and PITTSBURGH – April 23, 2015 – Mylan N.V. (Nasdaq: MYL) today announced that its U.S.-based Mylan Institutional business is conducting a voluntary nationwide recall to the hospital/user level of select lots of the following injectable products due to the presence of visible foreign particulate matter observed during testing of retention samples.

NDC Number	Product Name and Strength	Size	Lot Number	Expiration Date
67457-464-20	Gemcitabine for Injection, USP 200mg	10 mL	7801396	08/2016
67457-464-20	Gemcitabine for Injection, USP 200mg	10 mL	7801401	08/2016
0069-3857-10	Gemcitabine for Injection, USP 200mg	10 mL	7801089	07/2015
67457-463-02	Gemcitabine for Injection, USP 2 g	100 mL	7801222	03/2016
67457-462-01	Gemcitabine for Injection, USP 1 g	50 mL	7801273	05/2016
67457-493-46	Carboplatin Injection 10mg/mL	100 mL	7801312	06/2015
0069-0146-02	Methotrexate Injection, USP 25mg/mL	2 mL (5 x 2mL)	7801082	07/2015
0069-0152-02	Cytarabine Injection 20mg/mL	5 mL (10 x 5mL)	7801050	05/2015

Administration of a sterile injectable that has foreign particulates has the potential of severe health consequences. Intrathecal administration could result in a life threatening adverse event or result in permanent impairment of a body function. Intravenous administration has the potential to damage and/or obstruct blood vessels which could induce emboli, particularly in the lungs. If a right to left cardiac shunt is present, the particulate may lead to arterial emboli and result in stroke, myocardial infarction, respiratory failure, and loss of renal and hepatic function or tissue necrosis. Other adverse effects associated with intravenous injection of particulate matter include local inflammation, phlebitis, allergic response and/or embolization in the body and infection. Intra-arterial administration could result in damage to blood vessels in the distal extremities or organs. Intramuscular administration could result in foreign-body inflammatory response, with local pain, swelling and possible long term granuloma formation. To date, Mylan has not received any reports of adverse events related to this recall.

Gemcitabine for Injection, USP 200mg is an intravenously administered product indicated for the treatment of ovarian cancer, breast cancer, non-small cell lung cancer and pancreatic cancer. These lots were distributed in the U.S. between Feb. 18, 2014, and Dec. 19, 2014, and were manufactured and packaged by Agila Onco Therapies Limited, a Mylan company. Lot 7801089 is packaged with a Pfizer Injectable label.

Carboplatin Injection 10mg/mL is an intravenously administered product indicated for the treatment of advanced ovarian carcinoma. The lot was distributed in the U.S. between Aug. 11, 2014, and Oct. 7, 2014, and was packaged by Agila Onco Therapies Limited, a Mylan company, with a Mylan Institutional label.

Methotrexate Injection, USP 25mg/mL can be administered intramuscularly, intravenously, intra-arterially, or intrathecally and is indicated for certain neoplastic diseases, severe psoriasis and adult rheumatoid arthritis. The lot was distributed in the U.S. between Jan. 16, 2014, and March 25, 2014, and was packaged by Agila Onco Therapies Limited, a Mylan company, with a Pfizer Injectables label.

Cytarabine Injection can be administered intravenously or intrathecally and in combination with other approved anti-cancer drugs is indicated for remission induction in acute non-lymphocytic leukemia of adults and pediatric patients. The lot was distributed in the U.S. between May 02, 2014, and July 24, 2014, and was manufactured and packaged by Agila Onco Therapies Limited, a Mylan company located in Bangalore, India and is packaged with a Pfizer Injectables label.

Mylan is notifying its distributors and customers by letter and is arranging for return of all recalled products. Distributors, retailers, hospitals, clinics, and physicians that have these products which are being recalled should stop use and return to place of purchase.

Consumers with questions regarding this recall can contact Mylan Customer Relations at 800.796.9526 or customer.service@mylan.com, Monday through Friday from 8 a.m. – 5 p.m. EST. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to using these drug products.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

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 around 1,400 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 about 145 countries and territories. Our workforce of approximately 30,000 people is dedicated to creating better health for a better world, one person at a time. Learn more at mylan.com.