Mylan is Expanding its Voluntary Nationwide Recall of Select Lots of Injectable Products Due to the Presence of Particulate Matter

June 8, 2015

HERTFORDSHIRE, ENGLAND, AND PITTSBURGH – June 8, 2015 – Mylan N.V. (Nasdaq: MYL) today announced that its U.S.-based Mylan Institutional business is expanding its 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.

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.

NDC Number	Product Name and Strength	Package Size	Lot Number	Expiration Date
0069-3857-10	Gemcitabine for Injection, USP 200 mg	10 mL	7801084	07/2015
0069-3857-10	Gemcitabine for Injection, USP 200 mg	10 mL	7801110	08/2015
67457-463-02	Gemcitabine for Injection, USP 2 g	100 mL	7801221	03/2016
67457-464-20	Gemcitabine for Injection, USP 200 mg	10 mL	7801398	08/2016
67457-464-20	Gemcitabine for Injection, USP 200 mg	10 mL	7801406	08/2016
67457-464-20	Gemcitabine for Injection, USP 200 mg	10 mL	7801427	09/2016
67457-462-01	Gemcitabine for Injection, USP 1 g	50 mL	7801284	05/2016
67457-467-99	Methotrexate Injection, USP 50 mg/2 mL (25 mg/mL)	5 x 2 mL	7801421	09/2016

Gemcitabine for Injection, USP 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 January 8, 2014, and February 10, 2015, and were manufactured and packaged by Agila Onco Therapies Limited, a Mylan company. Lot 7801084 and 7801110 are packaged with a Pfizer Injectable label.

Methotrexate Injection, USP 25 mg/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 December 8, 2014, and December 19, 2014, and was packaged by Agila Onco Therapies Limited, a Mylan company.

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.