November 1, 2013

Mylan Confirms First-to-File Patent Challenge Relating to Uloric®

-Expects to be eligible for 180 days of marketing exclusivity-

PITTSBURGH, Nov. 1, 2013 /PRNewswire/ -- Mylan Inc. (Nasdaq: MYL) today confirmed that its U.S.-based subsidiary Mylan Pharmaceuticals Inc. has been sued by Teijin Limited, Teijin Pharma Limited and Takeda Pharmaceuticals U.S.A., Inc., in connection with the filing of an Abbreviated New Drug Application (ANDA) with the U.S. Food and Drug Administration (FDA) for Febuxostat Tablets, 40 mg and 80 mg. This product is the generic version of Uloric®, which is indicated for the chronic management of hyperuricemia in patients with gout. It is not recommended for the treatment of asymptomatic hyperuricemia.

Mylan believes it is one of the first companies to have filed a substantially complete ANDA containing a Paragraph IV certification for this product and expects to be eligible for 180 days of marketing exclusivity upon final FDA approval. The plaintiffs have filed a lawsuit against Mylan in the United States District Court for the District of Delaware.

For the 12 months ending June 30, 2013, Uloric had U.S. sales of approximately $260.7 million, according to IMS Health.

Currently, Mylan has 179 ANDAs pending FDA approval representing $84.6 billion in annual sales, according to IMS Health. Forty of these pending ANDAs are potential first-to-file opportunities, representing $24.1 billion in annual brand sales, for the 12 months ending June 30, 2013, according to IMS Health.

This press release includes statements that constitute "forward-looking statements," including with regard to the expected first-to-file status and pending litigation. 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: the use of legal, regulatory and legislative strategies by competitors or other third parties to delay or prevent product introductions; risks inherent in legal and regulatory processes; and the other risks detailed in the company's filings with the Securities and Exchange Commission. The company undertakes no obligation to update these statements for revisions or changes after the date of this release.

Mylan is a global pharmaceutical company committed to setting new standards in health care. 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 1,200 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 approximately 140 countries and territories. Our workforce of more than 20,000 people is dedicated to improving the customer experience and increasing pharmaceutical access to consumers around the world. But don't take our word for it. See for yourself. See inside. mylan.com

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