July 15, 2013

Mylan Confirms First-to-File Patent Challenge Relating to Vimpat(R)

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

PITTSBURGH, July 15, 2013 /PRNewswire/ -- Mylan Inc. (Nasdaq: MYL) today confirmed that the company has been sued by UCB, Inc., UCB Pharma GMBH, Research Corporation Technologies, Inc. and Harris FRC Corporation in connection with the filing of an Abbreviated New Drug Application (ANDA) with the U.S. Food and Drug Administration (FDA) for Lacosamide Tablets, 50 mg, 100 mg, 150 mg and 200 mg. This product is the generic version of Vimpat®, which is approved as an adjunctive therapy to treat partial-onset seizures of people diagnosed with epilepsy aged 17 years and older.

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 and several other ANDA filers in the United States District Court for the District of Delaware.

For the 12 months ending March 31, 2013, Vimpat® had U.S. sales of approximately $338 million, according to IMS Health.

Currently, Mylan has 173 ANDAs pending FDA approval representing $82.9 billion in annual sales, according to IMS Health. Thirty-five of these pending ANDAs are potential first-to-file opportunities, representing $22.6 billion in annual brand sales, for the 12 months ending Dec. 31, 2012, 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 approximately 1,100 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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