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Mylan Confirms First-to-File Patent Challenge Relating to Pristiq® Tablets

-Paragraph IV Litigation Underway-

PITTSBURGH, June 28, 2012 /PRNewswire/ -- Mylan Inc. (Nasdaq: MYL) today confirmed that the company has been sued by Pfizer Inc., Wyeth LLC, Wyeth Pharmaceuticals Inc., and PF Prism C.V. in connection with the filing of an Abbreviated New Drug Application (ANDA) with the U.S. Food and Drug Administration (FDA) for Desvenlafaxine Succinate Extended-release Tablets, 50 mg and 100 mg. This product is the generic version of Pfizer's Pristiq® Tablets, which are indicated for the treatment of major depressive disorder (MDD) in adults.(1)

Mylan believes it is one of the first companies to have filed a substantially complete ANDA containing a Paragraph IV certification for both strengths and expects to share 180 days of marketing exclusivity upon final FDA approval. The plaintiffs filed the lawsuit in the U.S. District Court for District of Delaware.

For the 12 months ending March 31, 2012, Pristiq Tablets had total sales of approximately $559.4 million, according to IMS Health.

Currently, Mylan has 169 ANDAs pending FDA approval representing $83.9 billion in annual sales, according to IMS Health. Thirty-seven of these pending ANDAs are potential first-to-file opportunities, representing $25.6 billion in annual brand sales, for the 12 months ending Dec. 31, 2011, 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 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 1,100 generic pharmaceuticals and several brand medications. In addition, we offer a wide range of antiretroviral therapies, upon which approximately one-third 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 150 countries and territories. Our workforce of more than 18,000 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

(1) Desvenlafaxine is not indicated for use in pediatric patients. Adolescents and young adults taking antidepressants for major depressive disorder are at an increased risk of suicidal thinking and behavior. Patients of all ages who are started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior. People who are hypersensitive to desvenlafaxine or venlafaxine hydrochloride should not take the drug, nor should people taking monoamine oxidase inhibitors (MAOIs) due to severe, potentially life-threatening, interactions. Other severe reactions have occurred when used in combination with drugs that affect the central nervous system. Desvenlafaxine may cause or make some conditions worse. Consult your healthcare provider for further information.

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