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Mylan Announces Settlement Agreement in Litigation Relating to its Generic Silenor®

PITTSBURGH, July 17, 2012 /PRNewswire/ -- Mylan Inc. (Nasdaq: MYL) today announced that it and its subsidiary, Mylan Pharmaceuticals Inc., have entered into a settlement agreement with Somaxon Pharmaceutical, Inc. that will resolve the parties' patent litigation in connection with Mylan Pharmaceuticals' Abbreviated New Drug Application (ANDA) for Doxepin Hydrochloride Tablets, 3 mg and 6 mg, which is the generic version of Somaxon's Silenor®, indicated for the treatment of insomnia characterized by difficulty with sleep maintenance.

According to the terms of the settlement agreement, Mylan has the exclusive right to sell an authorized generic version of Silenor® in the U.S. and its territories for 180 days beginning on January 1, 2020. In certain limited circumstances, Somaxon's license to Mylan would become effective prior to January 1, 2020. Mylan's right to sell the authorized generic product could extend for as long as 360 days, and after such period Mylan will have the right to sell a generic version of Silenor® under its own ANDA. Pursuant to the agreement, the pending litigation will be dismissed. Additionally, Mylan entered into an agreement to manufacture and supply Silenor® finished product to Somaxon.

Other details of the settlement are confidential, and the agreements are subject to review by the Federal Trade Commission and the U.S. Department of Justice.

This press release includes statements that constitute "forward-looking statements," including with regard to the settlement of the litigation and sales of the product. 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: any legal or regulatory challenges to the settlement; 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 periodic 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

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