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Mylan Announces Settlement Agreement for its First-to-File Generic Version of Orapred ODT®

PITTSBURGH, Oct. 9, 2012 /PRNewswire/ -- Mylan Inc. (Nasdaq: MYL) today announced that it has entered into a settlement agreement with Shionogi Inc. and CIMA Labs Inc. that will resolve patent litigation related to Prednisolone Sodium Phosphate Orally Disintegrating Tablets (ODT), 10 mg, 15 mg and 30 mg. Prednisolone Sodium Phosphate ODT is the generic version of Shionogi's Orapred ODT®, which is indicated for the treatment of certain pulmonary diseases such as asthma. Additionally, the product is indicated for the control of certain severe or incapacitating allergic conditions, such as atopic dermatitis, and seasonal and perennial allergic rhinitis, that are intractable to adequate trials of conventional treatment.

According to the terms of the settlement, Mylan will be licensed to sell its Prednisolone Sodium Phosphate ODT product on April 1, 2014, or earlier under certain circumstances. Pursuant to the agreement, pending litigation will be dismissed. Other details of the settlement are confidential, and the agreement itself is subject to review by the U.S. Department of Justice and the Federal Trade Commission.

Mylan believes it was the first company to have filed a substantially complete abbreviated new drug application (ANDA) containing a Paragraph IV certification with the U.S. Food and Drug Administration (FDA) for Prednisolone Sodium Phosphate ODT, 10 mg, 15mg and 30 mg, and anticipates that it will be entitled to 180 days of generic market exclusivity. This product had U.S. sales of \$33.1 million for the 12 months ending June 30, 2012, according to IMS Health.

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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