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Mylan Announces Settlement Agreement for First-to-File Generic Version of TARGRETIN®

Agreement includes a no-later-than July 9, 2015 launch

PITTSBURGH, Dec. 17, 2013 /PRNewswire/ -- Mylan Inc. (Nasdaq: MYL) today announced that its subsidiary Mylan Pharmaceuticals Inc. and partner, Banner Pharmacaps Inc. (a wholly-owned subsidiary of Patheon Inc.), have entered into a settlement and license agreement with Eisai Inc. and Valeant Pharmaceuticals Luxembourg S.a.r.l that will resolve patent litigation related to Bexarotene Capsules, 75 mg. Bexarotene is the generic version of TARGRETIN®, which is indicated for the treatment of cutaneous manifestations of cutaneous T-cell lymphoma in patients who are refractory to at least one prior systemic therapy.

Pursuant to the agreement, the pending litigation will be dismissed, and Mylan and Banner will receive a license to begin selling a generic version of the product on July 9, 2015, or earlier under certain circumstances. All other terms and conditions of the settlement and license agreement are confidential, and the agreement itself is subject to review by the U.S. Department of Justice and the Federal Trade Commission.

Mylan believes that its partner, Banner, is 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 Bexarotene Capsules, 75 mg. TARGRETIN®, 75 mg, had U.S. sales of approximately $53.6 million for the 12 months ending Sept. 30, 2013, according to IMS Health.

Currently, Mylan has 178 ANDAs pending FDA approval representing $90.8 billion in annual sales, according to IMS Health. Thirty-nine of these pending ANDAs are potential first-to-file opportunities, representing $23.8 billion in annual brand sales, for the 12 months ending June 30, 2013, according to IMS Health. When including ANDAs associated with Mylan's recent acquisition of Agila, the company now has a total of 300 ANDAs pending FDA approval.

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 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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