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Mylan Confirms First-to-File Patent Challenge Relating to BREVIBLOC®

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

PITTSBURGH, Nov. 25, 2014 /PRNewswire/ -- Mylan Inc. (Nasdaq: MYL) today confirmed that it and several subsidiaries have been sued by Baxter International, Inc., Baxter Healthcare Corporation and Baxter Healthcare S.A., (collectively, "Baxter") in connection with the filing of an Abbreviated New Drug Application (ANDA) with the U.S. Food and Drug Administration (FDA) for Esmolol HCl in Sodium Chloride Injection, 10mg/ml (250 ml) and 20 mg/ml (100 ml). This product is the generic version of BREVIBLOC®, which is indicated for supraventricular tachycardia or noncompensatory sinus tachycardia, and intraoperative and postoperative tachycardia and/or hypertension.

Mylan believes that its subsidiary Agila is the first company 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 receiving final FDA approval. Baxter filed lawsuits against the Mylan companies in the United States District Court for the District of New Jersey and the Northern District of West Virginia.

For the 12 months ending Sept. 30, 2014, BREVIBLOC had U.S. sales of approximately $49 million, according to IMS Health.

Currently, Mylan has 287 ANDAs pending FDA approval representing $111.6 billion in annual sales, according to IMS Health. Forty-four of these pending ANDAs are potential first-to-file opportunities, representing $29.5 billion in annual brand sales, for the 12 months ending June 30, 2014, according to IMS Health.

This press release includes statements that constitute "forward-looking statements," including with regard to the expected first-to-file status, pending litigation, and marketing of products. 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, legislative or other 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 1,300 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. Learn more at mylan.com.

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