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

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

PITTSBURGH, Feb. 9, 2015 /PRNewswire/ -- Mylan Inc. (Nasdaq: MYL) today confirmed that it and its subsidiary Mylan Pharmaceuticals have been sued by Bayer Healthcare LLC, Bayer Healthcare Pharmaceuticals Inc., and Onyx Pharmaceuticals Inc., in connection with the filing of an Abbreviated New Drug Application (ANDA) with the U.S. Food and Drug Administration (FDA) for Sorafenib Tablets, 200 mg. This product is the generic version of NEXAVAR®, which is indicated for the treatment of certain types of cancers including unresectable hepatocellular carcinoma and advanced renal cell carcinoma.

Mylan believes that it 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. The plaintiffs filed suit against the Mylan companies in the United States District Court in the District of Delaware.

For the 12 months ending Dec. 31, 2014, NEXAVAR had U.S. sales of approximately $48 million, according to IMS Health.

Currently, Mylan has 283 ANDAs pending FDA approval representing $107.1 billion in annual sales, according to IMS Health. Forty-three of these pending ANDAs are potential first-to-file opportunities, representing $27.2 billion in annual brand sales, for the 12 months ending June 30, 2014, according to IMS Health.

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 25,000 people is dedicated to improving the customer experience and increasing pharmaceutical access to consumers around the world. Learn more at mylan.com.

Private Securities Litigation Reform Act of 1995 — A Caution Concerning Forward-Looking Statements

This press release includes statements that constitute "forward-looking statements," including with regard to product approvals, 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 impacts of competition; changes in economic and financial conditions of the company's business; strategies by competitors or other third parties to delay or prevent product introductions; risks inherent in legal and regulatory processes; uncertainties and other matters beyond the control of management; 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.