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Mylan Challenges FDA Ruling on Exclusivity Relating to Celecoxib

Mylan Seeks to Confirm Shared 180-Day Exclusivity

PITTSBURGH, April 25, 2014 /PRNewswire/ -- Mylan Inc. (Nasdaq: MYL) today announced that it has filed suit against the U.S. Food and Drug Administration (FDA), challenging the agency's decision regarding generic drug marketing exclusivity on Celecoxib Capsules, the generic version of Pfizer's Celebrex®.

FDA issued a decision holding that eligibility for 180 days of exclusivity is only available to an applicant who first filed a PIV certification to an original patent and who then also made a timely PIV certification to a reissued patent, despite an earlier appellate court decision that held the original patent invalid, and a subsequent decision holding the reissued patent invalid.

Mylan believes that the FDA has seriously erred in its decision in this case, and maintains that it is in a position to receive final approval on May 30, upon expiration of Celebrex's remaining patents. Other companies, including Teva, have settled for a December 2014 launch date, and will be unable to launch on May 30.

Mylan CEO Heather Bresch commented: "We believe the FDA has made an unprecedented error in this case which clearly caught all industry participants off guard, as evidenced by some who have already settled with Pfizer for December 2014 launch dates, which is post patent expiry. Mylan seeks an order compelling FDA to grant final approval of Mylan's ANDA on May 30, 2014."

This press release includes statements that may constitute "forward-looking statements," including with regard to pending litigation. 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, risks inherent in legal and regulatory matters 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. But don't take our word for it. See for yourself. See inside. mylan.com

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